

REGULATING UNDER CONSTRAINT: THE CASE OF EU PHARMACEUTICAL POLICY

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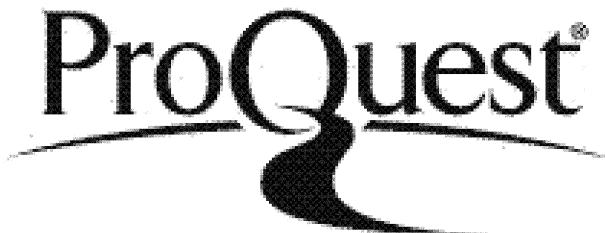


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ABSTRACT

This study is concerned with the making of regulatory policy for pharmaceuticals in the European Union. It proposes that an *ad hoc* development of Community competencies which does not amount to coherent strategy, far less a single medicines market, has resulted in a regulatory framework which favours the interests of industry. This is important on two fronts. First, it appears to run counter to contemporary research into EU regulation, which finds that consumer interests prevail over those of producers generally. Second, this pro-industry leaning seems not to be in keeping with member states' regulatory frameworks at home, which developed primarily as a means of protecting consumers' health (patients) following the *Thalidomide* tragedy. In providing support for this contention, rather than adopting an economic frame of analysis to assess – quantitatively – how the industry benefits, the study instead proposes a political perspective to understand how policy decisions have been taken.

Specifically, the study examines how supranational policy for pharmaceuticals is made with the context of a clash between the European Community's free movement of goods principles and, via the principle of subsidiarity, the right of the member states to decide their national healthcare priorities. The agenda and roles of the European Commission, the member states, consumer interests, and the industry as the sector's four primary stakeholders are scrutinised within this context. The analysis concentrates on policy level interactions, examining how the political considerations at stake over medicines have affected policy outcomes in specific instances. It is shown that the incomplete development of competencies is not just a result of the policy clash, but also because different policy impetuses (and stakeholders) have spurred different aspects of the framework. This involves the development of a multi-faceted theoretical lens in order to capture the complexities of making pharmaceutical policy at EU level.

This lens is based on the understanding that EU pharmaceutical policy is made within policy networks consisting of the four stakeholders. To gain a better grasp of the dynamics at play, these networks are tied to a regulatory policy-making framework known as the 'politics of policy'. It is a view which identifies different modes of regulatory politicking on the basis of the perceived costs and benefits the proposed intervention would bring to affected interests. Linked with wider European integration and policy-making theories, including neo-functionalism, intergovernmentalism and multi-level governance, this allows for a more complete perspective on how policy is made for the sector. Via its broader approach, therefore, the study provides insight into the complexities of making supranational policy for medicines, especially with regard to the need to balance conflicting interests within the harmonisation process.

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ABBREVIATIONS/ACRONYMS

ABPI	Association of British Pharmaceutical Industry	EAA	Europe Against AIDS
AESGP	<i>Association Européenne des Spécialités Pharmaceutiques Grand Public</i> (Association of the European Self-Medication Industry)	EAC	Europe Against Cancer
AgV	(ex) <i>Arbeitschaft der Verbraucherverbände e.V.</i> (German Consumers' Federation)	EC	European Community(ies)
BÄK	<i>Bundesausschuss der Ärzte und Krankenkassen</i> (German Federal Standing Committee of Physicians and Sickness Funds)	ECJ	European Court of Justice
BEUC	<i>Bureau Européen des Unions de Consommateurs</i> (European Consumers' Organisation)	EEA	European Economic Area
CAP	Common Agricultural Policy	EEC	European Economic Community
CCC	Consumer's Consultative Committee	EFTA	European Free Trade Area
CDER	(FDA) Center for Drug Evaluation and Research	EGA	European Generics Association
CEC	Commission of the European Communities	EMEA	European Agency for the Evaluation of Medicinal Products
CECG	Consumers in the European Community Group	EP	European Parliament
CFI	Court of First Instance	EPAR	European Public Assessment Report
CMS	Concerned Member State	EPC	European Patent Convention
CoR	Committee of the Regions	ESC	Economic & Social Committee
CP	<i>Comité Permanent des Médecins Européens</i> (Standing Committee of European Doctors)	EU	European Union
CPMP	Committee for Proprietary Medicinal Products	Euratom	European Atomic Energy Community
CPVO	Community Plant Variety Office	FDA	Food & Drug Agency
DG	Directorate-General	G10	High Level Group on Innovation and the Provision of Medicines
DGIII	(ex) Industrial Affairs DG	GATT	General Agreement on Tariffs and Trade
DGIII/E/F	(ex) Unit for Pharmaceuticals and Cosmetics	GIRP	Groupement International de la Répartition Pharmaceutique Européenne (European Association of Pharmaceutical Wholesalers)
DGIV	(ex) Competition DG	HAI	Health Action International
DGV	(ex) Employment, Industrial Relations and Social Affairs DG	ICA	Intergroup on Consumer Affairs (European Parliament)
DGV/F	(ex) Public Health Unit of DGV	ICH	International Conference on Harmonisation
DGXXIV	(ex) Consumer Policy and Consumer Health Protection DG	IGC	Intergovernmental Conference
DoH	Department of Health	INN	International Non-proprietary Name
DTC	Direct-to-Consumer Advertising	ISDB	International Society of Drug Bulletins
		MCA	Medicines Control Agency
		MoH	Ministry of Health
		NAFTA	North American Free Trade Agreement
		NCE	New Chemical Entity
		NDA	New Drug Application

NGO(s)	Non-governmental Organisation(s)
OECD	Organization of Economic Cooperation and Development
OTC	Over-the-Counter (medicines)
PDUFA	Prescription Drug User Fee Act
PhRMA	Pharmaceutical Research and Manufacturers of America
PIC	Pharmaceuticals Inspections Convention
PIRC	Public Interest Research Centre
PMA	Pharmaceutical Manufacturers of America
PPBH	Pharmaceutical Partners for Better Healthcare
PPRS	Pharmaceutical Price Regulation Scheme
R&D	Research & Development
RMOs	<i>Référence Médical Opposables</i> (French compulsory guidelines for pharmaceutical reimbursement)
RMS	Reference Member State
SEA	Single European Act
SEM	Single European Market
SLK	<i>Statens Legemiddelkontrol</i> (Norwegian Centre for Medicines Control)
SME(s)	Small-to-medium sized Enterprise(s)
SNIP	<i>Syndicat National de l'Industrie Pharmaceutique</i> (French Pharmaceutical Manufacturers' Association)
SPC	Supplementary Protection Certificate
SPCs	Summary of Product Characteristics
TCSDD	Tufts Centre for the Study of Drug Development
TEU	Treaty on European Union
TTM	Time-to-market
UK	United Kingdom
US(A)	United States of America
VAT	Value-added Tax
VFA	<i>Verband Forschender Arzneimittelhersteller</i> (German Association of Research-Based Pharmaceutical Companies)
WTO	World Trade Organisation

CHAPTER 1

NO SINGLE EUROPEAN MARKET IN PHARMACEUTICALS

Introduction

In the context of modern medicines regulation the late 1950s and early 1960s was a watershed. Under tragic circumstances the drug *Thalidomide* focused attention on the potential harm inadequately regulated medicinal products could cause. Originally released by *Chemie Grünenthal* on the West German market in 1957, and prescribed as a sleeping aid in the treatment of morning sickness for pregnant women, *Thalidomide* (*Contergan* in West Germany) was hailed as a 'break-through'. But the subsequent birth of tens of thousands of babies with congenital anomalies, as well as the affliction of many pregnant women with peripheral neuritis – a severely degenerative nerve disorder which can result in irreversible damage – saw the drug's removal from most of the major markets in 1961¹. And though the damage had been done, policy-makers set about reviewing the nature of drug registration and regulation. The result, beginning in West Germany², was a wave of new medicine laws in many countries regarding the safety evaluation of therapeutic drugs.

Having long-recognised the potential toxicity of medicinal preparations, many western countries had various regulations in place before the tragedy. These were primarily administrative, however, pertaining mainly to drug quality, advertising and promotion i.e. what claims manufacturers could make about their products. Until the early 1960s most had no independent safety and efficacy testing protocol for new drugs whatsoever. The Nordic countries and the United States were exceptions, though the latter was the only major western market to not approve *Thalidomide*.

Since the late 1950s, pharmaceutical manufacturers in the US were obliged to provide reliable and accurate information in their packaging inserts – particularly regarding any adverse effects – such that doctors and health professionals could make informed decisions on the drug's use. This was not yet the case in Europe where patients did not pay for their medicines and pressure for proof of efficacy was therefore not as strong. Moreover, the US also had a federal regulatory office for pharmaceuticals, the Food and Drug Administration (FDA), which in 1958 had been empowered by the US Congress to license manufacturers subject to their meeting certain safety standards. The *Thalidomide* disaster forced European policy-makers to look across the Atlantic to these elements of the

¹ At its peak *Thalidomide* was estimated to have been available in 46 countries and sold under 50 different tradenames (TVAC 2000).

² In 1961 the German medicines law, the *Gesetz über den Verkehr mit Arzneimitteln* (or *Arzneimittelgesetz*), was first established.

American regulatory framework. For it was on the basis of such safety and efficacy legislation that Frances Kelsey, medical officer at the FDA in charge of new drug applications, had delayed granting *Thalidomide* US market authorisation.

With the development of clinical pharmacology during the 1960s and 1970s as a result of the disaster, safety and efficacy became widespread authorisation criteria in Europe (Dukes 1985). Aware of the need to regain public confidence, most European countries also introduced stricter liability standards, though the US example of an independent body to deal with medicine applications took a little longer to become a standard model in Europe. The United Kingdom, for example, created the Committee on Safety of Drugs in 1963, to which companies were required to submit their data for assessment, but there was little government control until the 1968 Medicines Act (Orzack et al 1992) – since 1989 the Medicines Control Agency decides on all market applications. In Germany, the 1961 drug law was accompanied by the compulsory registration of all new medicines with the *Bundesgesundheitsamt* (Federal Ministry of Health) but it was only in 1967 that proof of effectiveness became an approval criteria; which was then strengthened to include approval based on clinical trial evidence in 1971. It is nevertheless as a direct consequence of the *Thalidomide* tragedy, therefore, that pharmaceuticals are today perhaps the most highly regulated of all consumer goods.

1 Pharmaceutical Policy and the Supranational Context

In Europe, the *Thalidomide* disaster also made it clear that a broader level of control was required, especially as negotiations over a six-country economic co-operation and cross-border trade regime had been concluded a year earlier³. Thus, in 1965, and towards establishing public health protection guidelines for medicines, the European Community (EC) agreed Directive 65/65/EEC on common authorisation requirements for new drugs. Guidelines for the pharmaceutical sector were likely to have been a long-term inevitability under the common market banner, but the disaster kick-started the process. Since this first piece of legislation the Community has been actively involved in the regulation of medicines⁴, and there have been numerous further regulations covering issues from guidelines on price transparency and good manufacturing practice, through to the licensing, advertising and labelling of therapeutic drugs.

Most recently and perhaps most significantly, since 26 January 1995 there has been an independent European Union (EU) institution for the regulation of pharmaceuticals. The

³ Plans for the European Economic Community (EEC) and European Atomic Energy Community (Euratom) were agreed in the 1956 Spaak Report.

⁴ For this study the terms pharmaceuticals, medicines, medicinal products and (therapeutic) drugs are employed interchangeably.

European Agency for the Evaluation of Medicinal Products (EMEA)⁵ oversees a (Community) market approval process for new drugs based on the safety and efficacy criteria laid down in 1965. But more than that, according to the European Commission press statement released at the time, the agency's establishment was "... an important part of the overall strategy of the creation for a single market for pharmaceuticals." (CEC IP 1995) The EMEA brought with it a more streamlined market approval process, lessening the time needed for new medicines to reach the market. This would facilitate their 'free movement' within the Single European Market (SEM), and represents a function which goes beyond the more limited information-dissemination role of most other EU agencies. The empowerment of the medicines agency in this way, indeed its very creation, reflects equally the growing regulatory role of the EU (Hératier et al 1996, Wallace & Young 2000), as it does the specific needs of the pharmaceutical sector in Europe.

The regulatory history this Community involvement in pharmaceuticals represents is one which is considerably longer than for other industrial sectors, and it relates to both the product and market. Yet, despite being one of the most highly regulated sectors at European level – and almost eight years having passed since the inauguration of the EMEA amid much fanfare – there is still ~~no single market~~ for pharmaceuticals in Europe. ↵

The reasons for this are numerous and interwoven. They relate to certain unique characteristics of the pharmaceutical market and the nature of the EU's competencies which result. Nevertheless, there is a broad-ranging regulatory framework for medicines in place – in which the EMEA is a major element – and the lack of a single market has not precluded the Community from acquiring considerable regulatory powers. It is the purpose of this study to examine this framework, to consider its development and shape, and to address several important issues not dealt with in the existing literature about how pharmaceutical policy has been made in the EU.

1-1 Unique issues

It is first necessary to set out some of the issues relevant to any examination of pharmaceutical policy in the EU. The foremost of these is the widely-acknowledged point that the pharmaceutical market is 'peculiar' in comparison to other industrial sectors in developed countries⁶. Although the reasons for this are examined later, it should at the outset be noted that medicines involve 'life and death' matter unlike any other industrial product. In addition, the market dynamic involves the patient (consumer) being reliant on a prescribing doctor for most of the medicines he or she consumes, with the state (or health

⁵ The EMEA is more widely known as the European Medicines Evaluation Agency.

⁶ For instance Schweitzer (1997), Mossialos & Abel-Smith (1997) or McIntyre (1999).

insurance funds) as the largest purchaser. Not just because of health issues then, but as medicines are directly tied to social security and healthcare budgets – with the exception of defence, no industry is financed to such a degree through public expenditure – governments have an unduly large say in the market. These are just three of the features which serve to distinguish pharmaceuticals from traditional products and markets.

The policy issues these characteristics raise represent a constant challenge for decision-makers. It means that there are three different policy inputs in medicines regulation: public health (drug quality, safety and efficacy); healthcare (financing and reimbursing medicines); and, in some countries, industrial policy (ensuring a successful and productive pharmaceutical sector). National governments thus seek to ensure their citizens the best possible access to the highest quality medicines, along with keeping healthcare costs down and drugs affordable. At the same time, many are interested in supporting local industry and generating employment. These objectives are not always complimentary. Moreover, they invoke numerous important actors and interests beyond the state, and the result is often a balancing-act or trade-off; in particular between healthcare policy interests on the one hand, and industrial policy interests on the other.

Reconciling such sensitive interests at supranational level is even more complex. The policy trade-off over pharmaceuticals exposes a gap between the EU's legal and policy frameworks. It translates into a dissonance between the principle of subsidiarity on the one hand – a Treaty-based legal stipulation whereby policy competence lies at the lowest level at which it can be effectively undertaken⁷ – and the free movement goals (of goods, persons, services and capital) of the single European market on the other. The former enables member states to determine national healthcare policy, while under the latter, pharmaceuticals are treated as an industrial good and fall within the Community's scope of competence under the SEM. Here, medicines are the remit of the European Commission's internal market or industrial affairs office, the Directorate-General for Enterprise⁸. Responsibility for pharmaceutical policy is thus divided; between the EMEA and DG Enterprise at Community level, and the member state governments (generally ministries of health) at the national level. Member states' unwillingness to accept any direct Community involvement in healthcare matters has been recently reaffirmed under Article 152 of the 1999 Amsterdam Treaty, which requires the Community to "... respect the responsibility of

⁷ Article 3(b) of the 1992 Maastricht Treaty, the subsidiarity principle, specifies that the EU may act "only if and in so far as the objectives of the proposed action cannot be sufficiently achieved by the member states and can therefore, by reason of the scale or effects of the proposed action, be better achieved by the Community".

⁸ Before the establishment of DG Enterprise in 1999, Directorate-General V (Industrial Affairs) was responsible for pharmaceutical policy in the Community. Prior to that the responsible office was DG1A, the Directorate-General for the Internal Market.

the Member States for the organization and delivery of health services and medical care⁹. This, however, clashes with the free movement articles, as several rulings delivered by the European Court of Justice (ECJ) in recent years have demonstrated (Kanavos 2000). There are also other articles, pertaining to the environment or workplace health and safety for example, which do impact on healthcare¹⁰.

Nevertheless, in practice, this means that while the Commission legislates over (single market) industrial policy issues such as common standards for advertising and package labelling – and the EMEA has some say over public health policy – the Community has no competence over healthcare matters such as the pricing and reimbursement of medicines. The implications of having EU policy-makers take decisions over healthcare budgets and social insurance systems, along with the potential accountability questions which would arise, are such that member states refuse to permit the Community a wider regulatory remit. It is for this reason that there is also no single market in healthcare¹¹, and contributes to the considerable fragmentation of the European pharmaceutical market.

This fragmentation stems in part from the *Thalidomide* tragedy, in that member states' regulatory regimes have since evolved in parallel, though in relative isolation. Each has developed its own approach to maintaining a regulatory equilibrium between health(care) requirements and industrial policy interests. As these relate to the organisation and structure of health services, healthcare financing and provision systems, and the sustenance of local industry, they reflect particular national circumstances and requirements. In a climate of increasing healthcare costs in Europe (Mossialos & Le Grand 1999) the divergence has become even greater, hardening member states' resolve over restricting Community influence. The result is fifteen separate pharmaceutical markets, industries and regulatory regimes within the SEM, such that convergence over any aspect implies considerable political will, effort and sacrifice. Bringing these national regimes together under a supranational framework has been an expressed goal of the European Commission since its original 1985 White Paper on the Internal Market (CEC 1985)¹².

Beyond their concerns over public health and the organisation and financing of their healthcare systems, another reason for the member states' insistence on national autonomy in the sector is the contribution that pharmaceuticals represent to national

⁹ Article 152 also grants the Community a role in public health policy, which has an indirect influence on national healthcare priorities.

¹⁰ For example, Article 138 (ex 118) pertains to the prevention of occupational accidents and disease, and occupational hygiene; or Article 174 (ex 130r) or the protection of human health within the context of the environmental policy.

¹¹ Via a growing number of ECJ rulings, an EU health framework is emerging (Mossialos & McKee 2001).

¹² The White Paper in fact specifically cited pharmaceuticals as a problem area regarding the removal of barriers.

economies. Medicines are an extremely profitable industry and one which generates a considerable number of jobs. As a single medicines market would mean both job and industry rationalisation¹³ – and would undoubtedly favour the more established and globally-oriented industries – national governments are unwilling to gamble over this potential winners and losers scenario. Hence their use of subsidiarity to prevent regulatory competence being devolved to the European Commission (ostensibly on healthcare grounds). This intransigence might, initially, seem to defy much theorising about the EU as a 'regulatory state' (e.g. McGowan & Wallace 1996); the 'spill-over' of Community economic regulation into social regulation (e.g. Liebfried & Pierson 1995); and the European Commission's growing regulatory remit (e.g. Majone 1996). However, the reasons for the member states' rigidity clearly relate to the interests at stake. This constraint on the Commission's capacity for action has seen EU pharmaceutical competencies develop on an *ad hoc* basis, rather than reflecting a particular strategy.

A further issue, therefore, is that because of the sensitivities involved, pharmaceuticals are a highly politicised arena, with four main policy actors: consumer/patient interests, the member states, the industry and the Commission, all of whom are forwarding their own agendas. Consumers are primarily interested in efficacious medicines; the industry seeks a propitious regulatory environment to remain competitive (and profitable); the Commission is pushing for a more integrated market, though one which maintains jobs; and member states face the parallel challenges of ensuring access to quality medicines, cost-containment in healthcare, and (in some cases) providing support for a productive, high-employment industry. These potentially conflicting goals are developed at a later stage. But the result of the three policy inputs is that the stakeholders will agree (and co-operate) over some issues, but disagree and oppose each other over others.

For instance, while the Commission and industry may favour easing the ban on medicine advertising in the Community¹⁴ to support or promote the industry, many governments, medical groups and consumer organisations are opposed on the basis of potential negative public health effects. Another example is the parallel importation of branded medicines¹⁵ resulting from price differences for the same medicines between member states. The practice is supported by consumer groups, the Commission, and several member state governments as a means of keeping healthcare spending down. But it is

¹³ The Commission's first report on employment identified the pharmaceutical sector as an industry where rationalisation was likely in view of a single market (CEC IP 1989).

¹⁴ Directive 92/26/EEC bans direct-to-consumer advertising of medicines, but the Commission has recently taken the first steps towards liberalising this. See footnote 183.

¹⁵ Parallel importing involves the purchase of branded medicines by a distributor (generally from wholesalers) in a less expensive member state (e.g. Spain, Portugal), and their export and resale at a lower than market price in a more expensive member state (e.g. UK). Typically, they are sold on to local wholesalers or even directly to pharmacies. See Chapter 7.

contested by the companies and other governments as it affects the profitability of industry. The point to be stressed from the outset then, is that pharmaceuticals, and EU pharmaceutical policy in particular, are an inherently political matter where the main interests (and actors) can converge or clash depending on the issue at hand. This study seeks to analyse these clashes and the nature of the policy outcomes they generate.

1-2 A constraint on further harmonisation

Pharmaceutical policy at EU level, at least in terms of how the Community can make and exercise competence, is thus compromised by a conflict between subsidiarity and national healthcare competence on the one hand, and the free movement principles of the SEM and Community industrial policy competence on the other. This dissonance results in a clash between the authority of the member states to set their own national medicine prices and reimbursement rates, and that of the Community which treats medicines as a tradable commodity demanding that there be no hindrance to their circulation within the EU. The former undermines the latter, something which the member states – adamant on retaining their autonomy over healthcare provision issues – have been able to exploit in limiting further development of the Community mandate. How this is played out in practice will be analysed throughout the study. But it leads to a situation where the European Commission has no authority to take the harmonisation process forward on its own.

Harmonising national policies under EU law along the lines of 'minimum content in programming' legislation in the EU television sector¹⁶, or the standardisation of national foodstuffs legislation towards the establishment of a Directive on food law¹⁷, is not therefore possible for pharmaceuticals. The integration of the EU telecommunications sector is also not a comparable case¹⁸. It was completed through a slow and deliberate process to which medicines cannot be subject¹⁹. For not only are national pharmaceutical sectors very divergent, but so too are member state healthcare systems; and this divergence is compounded by the lack of a single EU healthcare regime.

As suggested, the ECJ plays a major role where medicines policy is concerned. Although exercising no regulatory capacity *per se*, by delivering decisions in respect of many issues relating to healthcare policy, competition policy, and pharmaceuticals specifically, it has contributed to the environment in which decisions on pharmaceutical policy are taken. This

¹⁶ Directive 89/552/EEC.

¹⁷ COM (97) 176.

¹⁸ Directive 90/388/EEC.

¹⁹ Differences in speed of integration between member states' markets would create imbalances in access to, and price differentials between, medicines; something neither the Commission nor the member states could defend.

too represents a complexity to be taken into account when looking at how the EU medicines framework has come about.

It is therefore the disharmony between subsidiarity and the single market over medicines policy, along with the actors' conflicting interests, which currently hinders further harmonisation. The dissonance also has a bearing on how and what sort of policy can be agreed. But while this point has been widely recognised in much of the literature on the EU sector, it is more observation than analysis. In looking at the complex, even if incomplete, supranational regulatory framework for medicines, the study analyses how this framework has been achieved. It examines the Community's history of pharmaceutical regulation against the backdrop of how the healthcare-industrial policy balancing-act is played out. The study explores the development of the EU framework for pharmaceuticals, particularly since the early 1990s, to the continuing impasse over pricing which precludes completion of the single market today²⁰.

2 Towards an Understanding of Pharmaceutical Policy-Making in the EU

In doing-so, the study raises questions and issues which have generally not been dealt with in the existing literature. Simply noting that pricing and reimbursement is the main sticking-point does not provide any insight into the development of the regulatory framework. How policy has been achieved within the subsidiarity-free movement clash, and whether the need for a successful pharmaceutical industry in Europe – from both health and industrial policy perspectives – influences the type of regulatory outcome reached, have for example not really been scrutinised.

For instance, it has not been asked why, if the Community is in essence empowered to act only in those (industrial) policy areas associated with the single market programme, has it been possible to establish a European licensing agency which is responsible for deciding upon the safety and efficacy of new drugs (what is essentially a public health role with healthcare policy implications). With the exception of Shechter (1998), how the Community agreed exceptional patent protection for medicines in 1992 – given that longer patent times impact on drug prices – has only been described rather than critically analysed. And if pricing is such a sticking-point, how is it that one of the pre-single market pieces of legislation is in fact a 1989 Directive requiring pricing and reimbursement transparency within the Community? These questions hint at some important considerations in regulatory policy-setting for medicines at EU level, and suggest that insufficient attention has been paid to the issues surrounding the accommodation of the

²⁰ Although not looked at, the framework also covers biotechnology products, veterinary medicines and, now, orphan as well as 'traditional' medicines.

oft-times divergent interests of the stakeholders, and how their requirements have or have not been served. Why, in spite of subsidiarity, there has been some progress beyond the industrial policy aspects of pharmaceutical regulation has not really been analysed.

2-1 The role of 'politics'

One reason that such questions have not really been addressed, is that the political dimension of EU pharmaceutical regulation has generally been mentioned only in passing. Discussions on pharmaceutical regulation in general, and the Community's role specifically, have for the most part focused on the economic and, to a lesser degree, the legal aspects. The majority of this material has taken the form of sector and management studies undertaken by private consulting companies, textbooks on pharmaceutical and health economics, or else as issue-specific articles published in law and economics journals. The tendency to examine only the economic determinants of policy outcomes may not seem surprising given the free movement goals of the single market. But what these studies generally fail to take into account is that the European Union (and European integration itself), although an outwardly economic construct, is in fact driven primarily by political impetuses. The preponderance of economic and legally-oriented research has been valuable in discerning certain industry and sector issues, not to mention helping understand the (global) legal and economic context in which policy is made. But it has generally not sought to address policy-making itself.

There are a scant number of articles about the sector to be found in political science or public policy publications, and even fewer expressly political studies (specific aspects of the wider regulatory regime have, occasionally, been looked at individually). That said, such pieces have been more descriptive, historical or legal than analytical in orientation. Three exceptions are Mossialos et al (1994a), Shechter (1998) and Abraham & Lewis (2000). Respectively, they are a collection of papers addressing various aspects of the EU framework and the interests of the member states in the immediate post-1992 period; a study looking at whether institutions matter with regard to where and how pharmaceutical and biotechnology firms lobby over EU policy; and research into the degree to which the European regulatory framework is geared primarily towards drug approval. There is, however, a growing number of policy-oriented articles looking at how EU regulation is working in practice (with regard to the number and speed of new drug approvals)²¹. These are relevant to this study and are taken up at various stages. But even so, most of this research is concerned with the basis for drug authorisation rather than how policy is-made.

²¹ For instance Abassi & Herxheimer (1998) and Lewis & Abraham (2001).

What has been missing is an examination of the 'politics' of the sector. That is, a study which looks at (the political constraints on and behind) how EU pharmaceutical policy is actually made within the subsidiarity-free movement dissonance. As noted earlier, the sector is characterised by competing tensions: governments struggling to keep healthcare costs down and yet retain local industry; European companies seeking to remain profitable and competitive (*vis-à-vis* the United States and Japan in particular); and the European Commission pushing for at least some degree of (price) harmonisation. In addition, patients and healthcare professionals are increasingly demanding access to the best available medicines, and elements of the industry are fighting amongst themselves over how best to tackle declining global competitiveness. These all carry clear political implications. And as these competing objectives overlap, it would seem crucial to understanding how these tensions (and the actors they implicate) have contributed towards establishing the current framework. Furthermore, it would allow for a more complete picture of how the sector in fact operates and is governed at European level.

This gap in the literature exists primarily because research into EU healthcare policy has been a somewhat neglected field. Although this is changing as the effects of the EU integrationist dynamic on the national healthcare environment is increasingly being recognised – particularly given the ECJ's role in pushing the agenda (Palm et al 2000) – such articles or reports nevertheless tend towards overviews or summaries rather than being detailed analyses. As such, it is a political and policy-making perspective which the present study proposes. It endeavours to shed light on the politics of EU pharmaceutical regulation by offering a different lens through which to view the development of supranational competencies than is currently found in much of the literature. Bearing in mind that: i) pricing and reimbursement issues represent the main hurdle in the pursuit of further market harmonisation; and ii) that this is due to the clash between the requirements of the single market and the principle of subsidiarity in particular, the study examines how decisions have been reached and how policies have been taken forward. Amongst other things, this involves analysing/understanding:

- the special characteristics of the pharmaceutical market;
- the trade-off between industrial and healthcare policy interests;
- the policy context in which EU pharmaceutical regulation is agreed;
- the priorities and requirements of the major actors; and
- an assessment of what harmonisation might mean to these actors in terms of their own interests (*vis-à-vis* single market completion) and the role they have played in achieving policy outcomes.

The premise then is that politics matter. And based on this premise, this study assesses the politics behind the making of EU regulatory policy. No conclusions on how to breach the impasse and complete the single pharmaceutical market are proffered (beyond changing the Treaties, it is not clear that anything can be done). The study simply aims to

highlight the constraints faced by policy-makers *vis-à-vis* Community medicine policy. It also assesses the influence of these constraints on the resultant regulatory framework.

2-2 Hypothesis and objectives

Within this broad aim to offer a political view of the sector, the study has a more specific and twofold purpose. First is to develop a wider understanding of how supranational policy for the sector is actually made. Secondly, the study seeks to test an underlying hypothesis. This being that the pharmaceutical industry is the prime beneficiary of the EU regulatory framework for medicines. The two are reinforcing in that it is via undertaking the former that the latter can be pursued.

Beginning with the hypothesis, this involves testing a contention which seems to run counter to existing views on the nature of EU regulation – that consumer interests generally prevail over producer interests (Wallace & Young 2000). More importantly, it is one which carries potentially serious social implications given that national regulatory frameworks for medicines have developed primarily as a means of protecting patients (consumers) rather than serving the industry (Anon 1991). The Commission may claim that policies designed to foster the single market are a benefit to the European patient first (e.g. CEC IP 1995, CEC 2000), but as this is predicated on the assumption that quicker market access for new drugs automatically means a health benefit, it seems more intuitive than empirical. Indeed, studies have shown that there is no evidence patients have actually benefited from the quicker approvals the EMEA delivers (e.g. Edmonds et al 2000). It has even been argued by a member of the agency's Committee for Proprietary Medicinal Products (which undertakes new drug assessments) that industry interests prevail in the work it has carried out to-date (Garattini & Bertele 2000). Simply saying that this inclination towards industrial policy and industry reflects the Community's comparative impotence in health(care) affairs, or is the unintentional result of the push towards the single market, while true, is slightly superficial and does not adequately explain how this situation was attained²².

The contention is based on the claim that industry and industrial interests dominate the pharmaceutical policy arena, and the study posits three reasons for this: first, that there is a natural confluence between industry's interests and the Commission's industrial policy priorities; second, the institutional leaning within the Community framework – where the

²² This industry-leaning at EU level has been noted by consumer and patient groups (e.g. NCC 1994) and in the odd journal article (e.g. Orzack 1996), but has not generally been dealt with from a policy-making standpoint. An exception is the work carried out by John Abraham and Graham Lewis. They have argued a 'neo-liberal corporate bias' in European medicines regulation and remain fierce critics of the industry's influence in drug authorisations (e.g. Abraham & Lewis 1998, Abraham & Lewis 2000, Lewis & Abraham 2001).

Commission has industrial but not healthcare policy competence – supports industry arguments; and third, the fragmented nature of the market enables the industry to exert undue influence within the policy arena. This latter point is perhaps the most contentious, it may even seem paradoxical. For if the market is fragmented it ought to be more difficult for a single actor to dominate. But as will be shown, not only is the industry the most stable actor within the policy-process, and with a consistent set of demands, but because of certain informational asymmetries which characterise the sector, the industry has been able to convince other actors of its arguments.

Indeed, one of the key issues raised in this study concerns the part played by the industry in the policy-process, along with the role of information. The latter issue has received a great deal of attention in policy-making generally, but it seems especially important here for several reasons. First is the lack of transparency which characterises the sector. Access to pharmaceutical industry information and activities, such as the results of clinical trials and the focus of investment, is notoriously difficult to come by²³. As a high technology and high investment industry, companies are reluctant to share information, often citing 'commercial secrecy' as grounds for not doing so. Second, even where the industry does make information available, it is really only accessible to those with specialised knowledge i.e. those with medical and/or scientific training. Third, because of this virtual 'informational monopoly' held by the industry, non-industry sourced data that is accurate and objective – such as on industry performance, R&D costs, market shares, and data on time to market periods for new drugs – is severely lacking. And fourth, as will be shown, the information around which policy-makers tend to base their policy decisions (at both national and EU levels) is generally that provided by the industry itself. While the issue of informational asymmetries in the sector could constitute a study all of its own, it is dealt with here within the context of the policy-process.

In order to test this hypothesis of an industry-leaning framework, it is first important to understand how EU pharmaceutical policy is made. The approach adopted to do so must be able to take into account the complexities and policy-making constraints already raised. It is argued that existing theories of European integration and policy-making, while they provide important insights, are unable to provide a complete picture of how and why the framework for medicines regulation developed in the manner and shape that it has. Macro-theories are precisely that, *macro*; they highlight general patterns and tendencies. They can be used to identify broad influences and establish policy environments for pharmaceuticals, such as the integrationist pressure of the single market programme, but cannot really be used to assess how policy is made. Policy-making theories meanwhile

²³ For instance IJRM (1996) or HAI (1997).

are able to explain the dynamics at play in the sector, but are unable to account for the fact that pharmaceutical policy is a divided competence between the member states and the Community. While they may provide insight into a given policy decision, they do not really help to explain the Community approach to pharmaceutical regulation on a larger scale. Further, they are often process-oriented, and thus unable to take the actions of specific actors in specific circumstances into account. This is not to deny the value of both integration and policy-making approaches, but simply to point out that on their own they do not answer certain specific questions raised. What is needed alongside them, therefore, is a more meso(-level) analysis²⁴. Here the umbrella of public policy theory provides more specific levels of analyses in terms of institutional and actor behaviour, the analysis of problem definition, agenda-setting, and the role of preferences amongst others – approaches which have already been transposed to the supranational context. More specifically, the policy network concept proves the most useful given the focus on actors.

As policy networks enable the student to focus on actors and their interactions in the policy process, it is a meso-level approach which lends itself to the study of EU pharmaceutical policy-making. Community pharmaceutical policy, it is argued, takes place in tight (network) configurations of four main actors at the supranational level. These are the member states, the industry, the European Commission, and consumer interests; which are presented as the sector's primary stakeholders. Moreover, given the oft-times conflicting interests at stake where balancing public health, healthcare and industrial policy is concerned, pharmaceuticals can therefore be seen as an arena of 'antagonistic cooperation'²⁵ between the stakeholders involved in such configurations. Decisions have to be reached, and policy networks are used in this context.

Importantly, policy networks can be tied into the macro environment. The study therefore seeks to be consistent with wider established perspectives on both the nature of European integration and the dynamics of EU policy-making. By way of contextualising the meso-analysis, the development of EU pharmaceutical competencies is first considered from a European integration perspective. In particular, neo-functionalism and intergovernmentalist thinking, the 'multi-level governance' view of the EU policy-process (Marks et al 1996, Christiansen 1997), and the so-called 'regulatory state' conception of the Community (Majone 1996, McGowan & Wallace 1996) are consulted. Importantly, the latter two

²⁴ This study's use of the term 'meso-level' is based on Parsons' (1995) definition: "Meso analysis is the way in which issues and problems are defined and agendas set. 'Meso' – or a level of analysis which cuts across or through various phases of the policy process – explores approaches which link the input side of the policy-making process with the policy/decision-making and output process by focusing on the relationship between the 'pre-decisional' dimensions of policy-making and its decisional and post-decisional contexts." (82)

²⁵ 'Antagonistic cooperation' is a term coined by Marin (1990) with regard to public policy-making over social welfare issues.

approaches reflect a tacit acceptance of the EU as a new system of governance, and one which has spawned a growing body of academic research (e.g. Richardson 1997, Scharpf 1999). As such, these approaches are examined in relation to the pharmaceutical sector later in the study, where their relevance and value are developed.

This multi-dimensional approach to understanding how Community regulatory policy for pharmaceuticals is made, is developed as the means via which the study's contention can be tested. The idea is not a *telos* or single theory of EU pharmaceutical policy-making, but rather a lens through which to better understand the shape and development of supranational policy for the sector; one which can account for the claim that industry is the main beneficiary (before consumer interests).

3 Method and Study Outline

Before outlining the remainder of the study, a brief explanation of (and justification for) the choice of policy networks to underpin the theoretical framework is necessary; especially as it is an approach, the nature of which continues to be debated.

3-1 Using policy networks

Specific to an examination of those policy-processes which characterise an EU sector, a framework which is able to analyse decision-making with respect to political interactions (institutional or personal), 'pressure politics', and the balancing of economic and social priorities, is crucial. The stakeholders and their place in the pharmaceutical policy clash make it clear that the approach must be able to account for their interests. It needs to be flexible enough to accommodate both institutional and inter-actor behaviour, and it ought to be based on verifiable (observed) examples within various empirical settings. Such an approach is being advanced as public policy scholars continue to develop the field of policy network analysis.

The policy network is a concept which has been given much attention in both the national and EU contexts. By focusing on actors and interactions in the policy-process, it is an approach which can take meso-level factors into account; that is, the linkages between the definition of a problem or issue, the setting of an agenda and decision-making process to address it, and implementation²⁶. Although there is disagreement within the field – that which is taken up later – policy network analysis is here employed as a manner of understanding the nature of actor relationships and behaviour in the pharmaceutical sector,

²⁶ For a discussion see Parsons (1995), 85-243.

as well as to consider the manner in which the EU itself makes such policy. This is in keeping with Börzel's (1997a) definition of the policy network as analytical tool for the study of policy-making which "... allows a more 'fine grain' analysis by taking into account sectoral and sub-sectoral differences, the role played by private and public actors, and formal as well as informal relationships between them." (10) Employing this type of analysis also endorses Josselin's (1994) definition of a policy network as consisting of "... a set of linkages among a set of organisations sharing the same concerns about a substantive area, and whose preferences and actions must be taken into account." (42). This acknowledges that while the main actors are in relationships of mutual dependence given certain shared interests (over pharmaceutical policy as the 'substantive area'), they nevertheless seek to push their own specific agenda.

On this basis of these initial definitions, the study demonstrates that policy is made within policy networks comprised of the main stakeholders, representing various interests within the public health, healthcare and industrial sides of the sector. In this manner a distinction is made between the policy *community* and the policy *network* concepts. The actor groupings over specific pharmaceutical policy matters within the dichotomy are conceived of as the 'networks', and the division between healthcare and industrial interests can be seen as the two 'communities' within which the policy debate is undertaken. This endorses the view wherein "... the policy network is a statement of bound interests in a policy problem: a policy community exists where there are effective shared 'community' views on the problems." (Jordan 1990, 327) It is a perspective which accommodates the policy network as an analytical *tool* for studying sectoral (in this case, pharmaceutical) policy-making, with the locus, therefore, on interest-intermediation rather than governance²⁷. As mentioned, however, in this study policy networks are meshed with broader perspectives to give a more complete understanding of the politics involved; to offer a conceptual framework rather than simple description of the policy-process as these definitions imply.

In arguing that EU pharmaceutical policy is made in network configurations of actors, it becomes necessary to understand the grounds for their behaviour. This is especially the case as the stakeholders are often 'antagonistically co-operative' in light of the competing interests already outlined. Here, the study looks to Wilson's (1980) 'politics of policy' framework. It is an approach which characterises regulatory policies according to the perceived costs and benefits they bring to involved parties, and the type of politicking which results. Wilson differentiates between 'economics' and 'politics' in regulation. Consumers' wants from the economic marketplace are shaped by external factors, while politics (and politicians) do not just provide these wants, but actually determine them in

²⁷ This division in the policy network literature is elaborated at a later stage.

many cases. It is argued that this framework – which is outlined in more detail later – helps to explain actor behaviour within EU pharmaceutical policy networks, by showing how politics can decide or at least shape regulatory outcomes (and even preferences).

The study acknowledges that the policy network approach is not without its problems. It is not an entirely novel one in examining the place and role of actors or interests in policy-making. Similar concepts such as 'policy communities', 'sub-governments', 'iron triangles', 'issue domains', and their linkages to systems or structural analysis, as well as to exchange network theory and sociological network analysis have all preceded the policy network as a concept unto itself. There are also more contemporary constructs such as the 'epistemic community', 'advocacy coalition', and 'policy curtain', all which encompass similar premises in addressing inter-actor or interorganisational behaviour and relations. Accordingly, it is the relationship to, and oft-times interchangeable use with, these other concepts – along with the lack of consensus over a definition (or usage) within the policy network literature itself – which has led some scholars to question the policy network as being a truly relevant, let alone distinctive, contribution to the study of policy-making²⁸.

Without going into such critiques here –a more detailed discussion of the policy network and how it is used in this study will be provided at a later stage – it should be noted that such differences are not definitive, and that the applicability of any given theoretical approach is often a largely subjective question. An approach which may not function within a particular context though works in another, cannot be deemed without merit simply because it is not all-encompassing. Policy-making itself has, after all, continued to defy theorists in make-up and manner since it was first developed into a field of academic study. There are no fixed rules and certainly no one theoretical approach is wholly satisfactory. The debate between the broader political science macro-concepts of pluralism and (neo-)corporatism, or the persistence of the realism/idealism schism in international relations theory, should serve as reminders of the difficulties in studying policy-making. So although one may be initially inclined to accept the critics' view that "... while networks certainly have an intellectual pre-history, there is no conscious continuity" (Jordan 1990, 320), it must be left up to the individual student to formulate their own interpretations and applications as to the viability of the approach – both as something distinctive and relevant to their own area of analysis. This is notwithstanding the fact that doing so proves a challenge given the variety (and resulting depth of disagreement) within the field.

In accepting the policy network as concept in its own right, therefore, what should be noted here, is that by using it alongside broader theories and Wilson's politics of policy

²⁸ For instance Jordan (1990), Mills & Saward (1994), Kassim (1994) or Dowding (1994, 1995).

framework, the study aims to provide a more conceptual understanding of policy-making in the EU pharmaceutical sector, such that the underlying hypothesis can be demonstrated. The project seeks to offer a political perspective on the EU pharmaceutical sector and the regulatory regime; to understand the politics of the policy process given the dissonance between subsidiarity and the single market; and to provide evidence for the contention that industry is the main beneficiary of the EU regulatory framework. The study can also be seen to contribute to the continuing debate on the validity of the policy network approach by providing a further application in an empirical setting. The first and last purposes are mutually reinforcing in that the chosen setting, the EU pharmaceutical sector, is one which is not often studied from a political science perspective.

3-2 Empirical questions and case-studies

Towards showing how industry is the prime beneficiary of the current EU pharmaceutical regime, the study seeks to understand which of the stakeholders undertook what action(s), when, and why, and what the limiting factors might have been. It interprets these from a policy network perspective showing how each actor has been involved in specific policy outcomes. Questions thus include: what were the practical effects of their actions, how were they brought to bear, and whether or not the final policy outcome reflected the stakeholders' preferences and actions. As the scope of this study does not allow for an in-depth analysis of all EU pharmaceutical policies, case-study examinations of how outcomes were or were not reached in three specific areas are laid out. Attention is given to: i) the Community's 1992 decision to grant medicines a special intellectual property protection regime; ii) the background to the 1995 launch of the European Medicines Evaluation Agency and its operation since; and iii) the political wrangling and continued intractability over medicines pricing and reimbursement policy in the Community. Here, the various attempts made by the Commission towards promoting price harmonisation (or at least liberalisation) and the reactions of the other stakeholders are analysed.

These cases have been selected as they represent separate and crucial policy initiatives within the EU medicines framework and give a clear indication of the complexity in making policy at this level. As they are also ones which involved or continue to involve protracted negotiation amongst the main stakeholders, they have been chosen to show the relevance of the theoretical approach. Each is treated as a separate policy network, although as the third case-study involves looking at several initiatives, these are presented as individual networks. Within these case-studies, other, wider issues to be considered include transparency and access to information, parallel importation, attempts to establish a Community 'industrial policy' for pharmaceuticals, and the place of consumers/patients in the policy-process. These too reflect political agendas within the sector.

Specific research questions are therefore developed in relation to the broad theoretical rubric proposed. If, as mentioned, traditional theories of European integration do not fit, what then is their relevance to harmonisation in the sector, and what do they reveal about the health-industrial policy clash? How do policy networks operate in the pharmaceutical sector, especially within the constraints posed by the regulatory context? Does the composition of the networks affect the final policy outcome; does the nature of the policy at stake affect the type of settlement reached; or both? In what way can the industry be said to be the most 'stable' actor within the policy networks? And, does the theoretical lens employed provide a clearer understanding of the policy-process as is posited?

Consequently, it must be noted that this study is not about EU (economic) regulation *per se*. A detailed examination and application of regulatory theory is not provided. But as the discussion does centre around the Community's competencies in a particular sector – competencies which by their nature are regulatory – a brief consideration of the unique nature of regulation in the EU is offered. The emphasis will be on explaining how certain interests are galvanised around specific issues into policy networks where EU pharmaceutical policy is concerned.

3-3 Qualitative analysis

With the empirical element of the study being an analysis of stakeholder interactions (via policy networks) at supranational level, this involves examining the behaviour and preferences of the European Commission, the member states, the industry, and consumers *vis-à-vis* certain policy issues (within the context of harmonising the market)²⁹. Again, these are the primary policy actors for pharmaceuticals in the EU. How they push their agenda, how their agenda in fact change given the issue at hand, and how these agendas are (or are not) reconciled in the final policy decisions represents an important part of the project.

In examining these interactions, qualitative analysis not only proves itself more valuable than quantitative analysis, but so too more manageable. This is in part because of the earlier-cited lack of transparency in the sector. Independent data and information (i.e. non-industry sourced) about the industry is difficult to come by, and companies tend to only to disseminate/share such information as is useful to their interests. Moreover, policy negotiations involving the industry, national governments and the EU, given the sensitive interests at stake, tend to be very secretive. The opaqueness and secrecy of the policy-process means that it is difficult to establish with any certainty which links were/are

²⁹ The positions of other actors involved in the EU policy-process, such at the European Parliament and various consultative committees are also referred to where relevant.

strongest, let alone when and why. In addition, the sheer number of actors, their interests, and the varying nature of their influence, along with the multitude of structures and avenues relevant to the policy-process in the EU, would all seem to preclude a numerical representation of the policy-making frame.

Consequently, although the focus is on stakeholders, the study does not aim to develop graded assessments of actor interactions in policy discussions, nor to attempt to quantify the relative strength of their relationships. Josselin (1994) has suggested a quantitative statistical assessment of policy network involvement in a sectoral context towards further developing the applicability of the approach at EU level, but it is too complicated in the context of the pharmaceutical sector. The practical difficulties of quantifying or valuing one interaction over another in a given policy network situation are too considerable to be overcome. As such, qualitative case-studies of policy outcomes are employed instead. They can be used to clearly show how decisions were reached, rather than attempting hollow quantitative valuations of the actors' interactions (within networks).

Methodological issues

Despite the thrust of the study being qualitative and the stakeholders' views being a central component, the methodology does not involve elite interviews. Interviews were originally expected to form the core empirical element; the case-studies in particular it was felt would benefit from the opinions of those key decision-makers who had been involved in the policy-process. As the research progressed, however, interviews were ruled out because of numerous difficulties regarding their implementation.

First, consultation with others working in the field of European pharmaceutical policy revealed the difficulty in securing interviews, far less using any that might be granted. The sensitivity of the issues at hand mean that many key officials (from industry, national governments and the EU) are either unwilling to be interviewed or prepared to answer only very general questions. And as EU pharmaceutical policy is still a developing field, many European policy-makers are therefore reticent about revealing too much³⁰. In particular, several key officials in the ex-DGV/F (unit for pharmaceuticals and cosmetics) now have other positions in the Commission and cannot comment in detail on their previous posts. Moreover, getting interviewees to approve the context in which their views were to be used has posed a challenge to several (graduate) researchers spoken to. This was likely to be especially problematic for this study given the contentious nature of its hypothesis.

³⁰ Fernand Sauer for instance, former Executive-Director of the EMEA, and now Director of the Public Health Unit of the Commission's Health and Consumer Protection Directorate-General, was unwilling to be interviewed when approached during his time at the agency.

Related to this was concern over the potential for 'revisionist history'. In the course of the research it became clear that in some instances there were differing accounts of the part played by specific individuals in certain policy negotiations or discussions. Published interviews with parties who had been privy to specific events sometimes revealed a different view of their role than that described by others. Here, the historical nature of the case-studies also posed a problem regarding interviews. Most potential interviewees have left the posts they then held and many have retired. This is particularly at EU level since the 1999 resignation *en masse* of the 20 European Commissioners.

Source material

Despite ruling out interviews, it was clear that understanding the stakeholders' 'views' and positions was crucial to support the arguments. Hence, much of the basis for the case-studies is provided via by official documentation and recorded statements which reveal their priorities and interests. Position papers, press releases, published interviews and other primary source material put out by the stakeholders themselves – as well as minutes of relevant meetings – were consulted. Not only did such material offer clear indication of stakeholders' interests and actions, but reviewing it over a 20-25 year period permitted a historical perspective on their arguments (something bland interviews would have been unlikely to provide). Admittedly, the ideal scenario would have been to combine interviews with such primary source material. Nevertheless, with extensive reviews of all manner of official documentation having been undertaken, the study has been able to accurately represent the stakeholders views. Supplementary and supporting material came from the usual secondary sources, including articles taken from specialist trade publications and magazines, reports by interested parties such as non-governmental organisations (NGOs), and studies undertaken by private firms.

As regards the case-studies, Commission Communications and draft documents; press releases; speeches by Commissioners and other key EU officials; internal Commission memos (where available); member state government (ministry) papers; minutes of European Parliament sittings and members' questions as put to the Commission; letters exchanged amongst EU officials, other stakeholders and interested parties; and records of discussions held during various EU committee meetings, have all been consulted. Much information was sourced via EU databases; in particular, RAPID, EUR-LEX (and CELEX), PRE-LEX and CURIA³¹. As not all Community documentation is available via these

³¹ All available via the EU's website (www.europa.eu.int). RAPID provides access to EU press releases. EUR-LEX enables a search of the *Official Journal of the European Communities* and European Parliament documentation. PRE-LEX is the "database on inter-institutional procedures which follows the major stages of the decision-making process between the Commission and the other institutions". And CURIA provides the text of all case-law from the European Court of Justice and Court of First Instance.

sources, much of the earlier material required for the case-studies was obtained through library searches, and written requests for information/documents. So-called 'grey literature' and unpublished official material has also been used where available.

Additional information on discussions and meetings which took place behind closed doors – and for which minutes or transcripts were not available – was sourced via two main pharmaceutical publications: *SCRIP World Pharmaceutical News* (including its insert *SCRIP Magazine*) and *MARKETLETTER*. Both report on regulatory developments in the EU sector, and a hand-search of the issues published from 1985 onwards was conducted. It is worth noting that each has expensive subscription charges as these contribute to the lack of transparency in the sector. Other specialist magazines reviewed included *Pharmaceutical Executive*, *Pharmaceutical Technology Europe* and *Pharmaceutical Technology International*. Of especial value with regard to policy-makers' views was the publication *Eurohealth*. A policy journal billing itself a forum for discussion, it publishes the opinions of European and national officials, along with those of academics, on a range of health issues. 'Pharmaceuticals and the single market' has been a special section on four occasions. Industry data was sourced primarily from the European Federation of Pharmaceutical Industries and Associations (EFPIA), EUROSTAT (the EU's statistical office), Organization of Economic Cooperation and Development (OECD) statistics, and IMS Health, a private organisation which provides global pharmaceutical information.

In addition, two broader literature reviews were undertaken. The first, pertaining to the theoretical element of the study, involved academic work on policy network theory/analysis and European integration and policy-making. The second, more empirical review, was of material/commentary on the EU pharmaceutical sector in general and that relevant to the case-studies specifically. Here the major information and bibliographic services, including BIDS, PAIS and PubMed³² were searched. The material sourced via these databases was used to supplement the primary source material, and often helped to guide the research, lending weight to the study's main contentions.

3-4 Structure of the study

Broadly, the study consists of four parts. Part one identifies the issues surrounding the EU pharmaceutical market and examines the sector and its peculiarities. Part two develops the theoretical framework, tying it to the stakeholders and their agenda. The third provides case-study examples relating to elements of the regulatory framework for medicines; how

³² In order: Bath Information and Data Services (BIDS) which includes the International Bibliography of the Social Sciences (IBSS); Public Affairs Information Service (PAIS); and PubMed which provides access to medical journal citations.

they were or were not reached, and what roles were played by the stakeholders. The final part offers selected conclusions in view of the case-studies. These relate to the main findings of the study as well as the future of medicines regulation in the Community and the use of policy networks at supranational level.

Chapter 2 discusses the peculiarities of the sector and outlines the issues involved in regulating medicines at national and EU levels. It profiles the EU's competencies, thereby highlighting the gaps in its remit. The policy issues raised here set the stage for the remainder of the study by developing the backdrop to the discussions and divisions between actors which are highlighted.

Chapter 3 assesses the value of European integration and policy-making theory to understanding the *ad hoc* development of Community pharmaceutical competencies. It traces the evolution of the regulatory framework and initial insights from a macro-perspective are drawn. The chapter argues such perspectives are useful in a contextual sense, but that a more encompassing understanding is only offered through the addition of a meso-level line of analysis which looks at actor behaviour. Meanwhile Chapter 4 makes the case for a meso-analysis, outlining the more salient aspects of policy network theory to show the approach's relevance to the study. To demonstrate why this type of analysis is necessary – given that wider political dynamics can affect policy outcomes in the sector – the discussion also examines the nature of regulation in the Community. And here, Wilson's earlier-mentioned 'politics of policy' approach is outlined. This is used towards providing a wider contextual framework of regulatory policy-making, and is shown to have repercussions for networks in terms of when and how they can form over specific issues. In this vein, the main stakeholders and their agendas are also detailed. With this wider view of regulatory policy-making in place, the study goes on to focus on three specific policy areas which form the case-studies of subsequent chapters.

The three case-study chapters relate to the development of the Supplementary Protection Certificate which concerns the extension of patent coverage for therapeutic drugs in the Community (Chapter 5); the rationale behind the creation of the European Agency for the Evaluation of Medicinal Products and what its mandate reflects in this regard (Chapter 6); and an examination of the impasse over pricing and reimbursement policy (Chapter 7). The case-studies reveal the depth of disagreement amongst the stakeholders, that which precludes further harmonisation.

Chapter 8 closes the study from both theoretical and empirical perspectives. It recaps the main arguments and condenses the findings from the case-studies, drawing out the main points and delivering some concluding remarks on the future of EU pharmaceutical policy

within the single market. The chapter also looks at the 'policy network-politics of policy' lens, and assess its merits and restrictions as they relate to the study. By way of conclusion, potential further research and lines of enquiry are suggested.

Finally, it must be stressed that although the study focuses on the EU regulatory regime for pharmaceuticals, it does not aim to appraise its performance beyond showing industry as the prime beneficiary. Instead, it simply aims to answer the more basic question of 'how did we get here?' But as will be shown, the answer is not nearly as simple nor as straightforward as the question.

CHAPTER 2

REGULATING THE (EUROPEAN) MEDICINES SECTOR

Introduction

The previous chapter asserted that the pharmaceutical sector is unique compared to other industries, resulting in complex regulatory issues. Divided into three sections, this chapter aims to develop this point. The first outlines the 'peculiarities' and dynamics of the market in order to explain why pharmaceuticals are such a highly regulated sector. Section two examines medicine regulation in the EU member states, and highlights governments' competing interests in catering for health(care) and industrial policies. The third section examines the place medicines occupy in the EU frame and reveals the shape of the regulatory regime. The policy trade-off at the supranational level is detailed – the Community's role is shown to be obfuscated by the clash between its legal and policy frameworks – particularly in relation to the competing priorities between the member states and the European Commission. This sets the stage for later examining how policy is made. By explaining how the industry operates and where regulation is applied, the discussion also shows why political considerations ought to be given more weight in explaining sectoral policy outcomes than has otherwise been the case.

1 What's so 'Peculiar' About the Pharmaceutical Sector?

"All industries are different, but some are more different than others. The pharmaceutical industry fits the latter category." (Scherer 1996, 336)

This designation stems from the fact that "The pharmaceutical industry resembles no other industry, first, as to the nature of its products, and second, as to economic structure and development." (Pharma Info 1982, 9) As will be shown, the wider social implications that medicines carry, and the unusual economic conditions they generate, result in a sector subject to regulatory influences unlike those in any other industrial domain; particularly so with respect to issues of product quality (Scherer 1996). Exploring the peculiarities of the product, the market, and the structure of industry will enable a clearer appreciation of the (regulatory) policy issues they raise for national and supranational decision-makers.

1-1 A unique product

The first peculiarity is that medicines are manufactured to bring a direct health benefit to consumers. In essence – and this contrasts them from related products such as vitamins, cosmetics and food supplements – they provide and ensure, if not create, health. No other

industrial product can make the same claim. The two main categories of medicine are ethical or prescription, and over-the-counter (OTC).

Prescription medicines require a doctor's prescription and differ from country to country according to criteria established by national governments or health bodies. They can be divided into proprietary medicines – generally sold by brand-name – and generic medicines. The former enjoy patent protection and represent the most profitable market segment, with Germany, Sweden and the UK as the main EU producers. A generic has the same active ingredient as an existing brand-name product and is interchangeable with it where patents or other legal regulations no longer apply. It is marketed either under its own brand-name, else by the internationally-approved non proprietary scientific name (INN), and many are available for consumer purchase. Generics can themselves be with or without patent coverage, and differ with respect to therapeutic value and price. The main generic producers in the EU are Germany, France and Italy.

Over-the-counter drugs are bought directly by consumers from a variety of outlets (though not to the same degree in all EU member states), generally without the need for a doctor's prescription. They offer a wide range of choice and are procured from multiple producers. Within therapeutic categories, medicinal value and dosage tend to be very similar between products, and prices – because they are generally government-set – are also more or less equal. Unlike for prescription or branded generic preparations in the EU, 'direct to consumer advertising' (DTC) is permitted for OTC medicines.

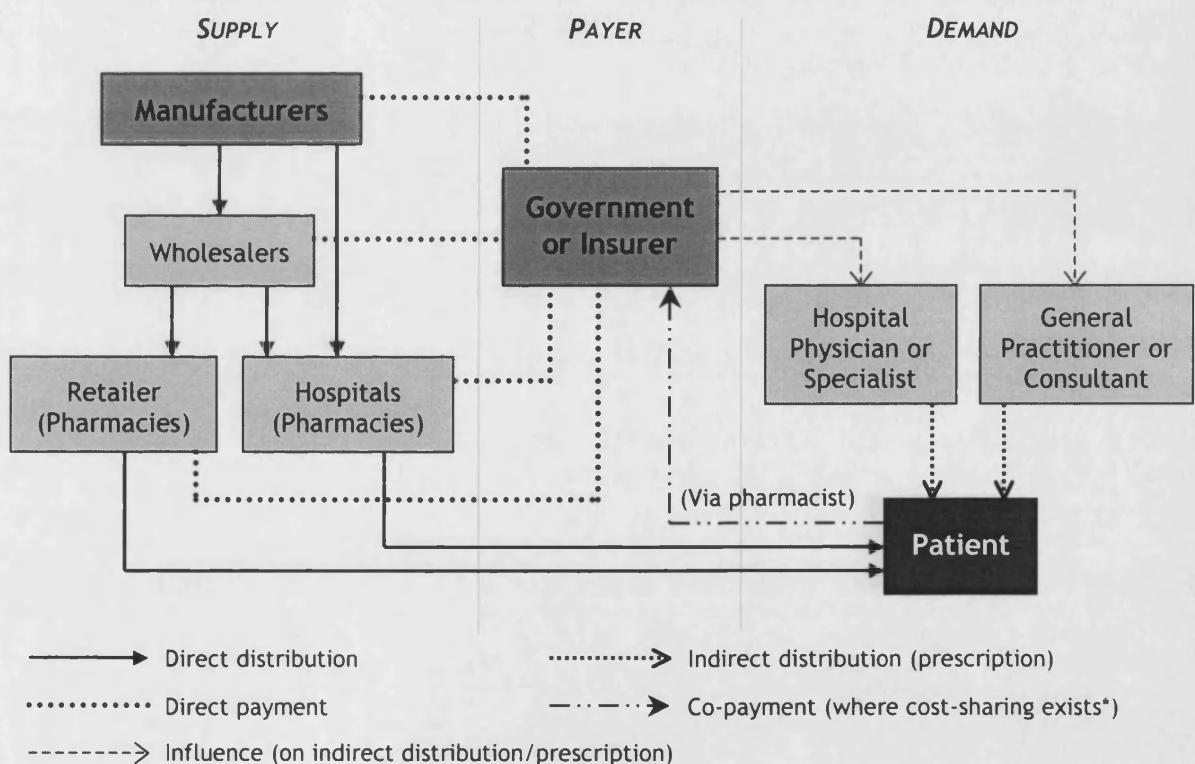
There is a further category of drug, known as the 'me-too' product. This refers to a new proprietary pharmaceutical which has the same, or close to the same, therapeutic value as a product already on the market. The me-too drug differs in chemical composition from the original product, but its target group and therapeutic value remains very similar if not the same; and it too enjoys patent protection. Not many products have such subtle and nuanced differentiation between their sub-sectors.

This study focuses on prescription drugs, including generics. Beyond being the most profitable segment, unique issues pertaining to patent protection, research and development (R&D), pricing, consumer access, market structure and therapeutic value, raise important policy questions. Further, as prescription medicines are in essence supplied by national governments via the healthcare system, the industry does not operate like a traditional manufacturing sector. A brief overview of the demand and supply dynamic reveals several unusual characteristics and market imperfections which represent the second reason for designating the sector as peculiar.

1-2 Atypical demand and supply

Demand for medicines is unique as the consumer does not usually choose the product; nor do patients generally choose to be sick. Instead, it is generally prescribed by a clinician. (In the case of OTC, however, patients do demand specific products, though their choices are often based on a doctor or pharmacist's recommendation.) The 'restaurant dinner for three' analogy, which compares the demand structure of the prescription segment of the market with ordering a meal in a restaurant, captures this³³: the pharmaceutical market (restaurant) is one wherein the consumer (customer) neither demands (orders) nor pays for (buys) the product (meal) she or he consumes. Demand comes from the prescribing doctor, and there is a third-party – generally the state via some form of medical scheme or insurance – which pays for the medicines. This characteristic three-tier demand system has been well-documented, and is a structure wherein doctors (and to a lesser degree consumers) make up the demand-side, and industry the supply-side (Figure 2-1).

Figure 2-1: Structure of Supply and Demand in the Pharmaceutical Sector



* Cost-sharing is a healthcare financing mechanism whereby part of the cost of medicines is passed to the patient e.g. prescription charges (See Section 2-3).
Source: adapted from Moore (1997), pg. 82.

The market imperfection captured in the restaurant analogy is furthered by the fact that the demand for medicines means that they are very price-inelastic. This is due to:

³³ For instance Furniss (1996).

... the debility-easing or even life-saving benefits unique drugs provide, because drug outlays are often covered at least in part by insurance, and because many physicians place little weight on price and much on good past therapeutic experiences in their prescribing decisions. (Scherer 1998, 205)

Consumers are "... *basically egoistic* about healthcare especially when [we] are ill and have little cost awareness... we simply want the best, most effective treatment regardless of the cost and the principle of solidarity tells us that we have a right to health." (Belcher 1994, 109) Indeed, as many politicians recognise that campaigning on the basis of a heavily-subsidised system of healthcare provision is a vote-winner, access to (the best) medicines (regardless of cost) is often portrayed as an electoral goal, if not fundamental right of the consumer. Thus, price tends not to affect demand (whether consumer or doctor-driven) as it would in other industries. It may affect doctors' prescribing patterns, and does factor in government's healthcare cost-containment calculations, but it does not influence consumer demand *per se*. As the general premise of 'health having no price' is a pervasive one – again, particularly in Europe – this price-inelasticity underlines the fact that medicines are not subject to traditional supply and demand forces.

Central to this demand-supply dynamic are certain informational asymmetries³⁴ which represent a further market imperfection. Consumers' lack of knowledge about the product means that doctors and pharmacists act as intermediaries in prescribing or advising on drugs for their patients, leading to so-called 'proxy-demand'. However, doctors and pharmacy staff are themselves often unable to properly assess the clinical value of a medicine. Thus, treatment is generally based on the expectation that the assigned medicine will provide the health required (demanded) by the consumer. A further informational asymmetry lies in the fact that the public authorities who decide on licensing are dependent on the information provided to them by the industry. For in seeking regulatory approval for their products, companies are required to submit detailed files on the proposed drug with regard to its safety, efficacy and quality as measured in controlled conditions over certain periods of time (see Section 2-2).

It should be noted, however, that this proxy-demand framework in Europe is changing. Direct-to-Consumer (DTC) advertising of medicines is not permitted in the EU as it is in the US, but the European Commission has recently indicated its willingness to permit drug companies to provide information on their products if requested (see Chapter 8). Limited to AIDS, diabetes and asthma drugs only, this may indicate a readiness to slowly liberalise advertising. The move was in part driven by concerns over so-called 'e-health', where consumers are increasingly accessing health information via the internet – much of this is unregulated – or else looking up specific medicines on the companies' own websites.

³⁴ For a wider discussion see Davis (1997), 145-149.

1-3 Market Structure: The 'high-profits-low-entrants' enigma

A further peculiarity lies in the structure of the supply-side of the market. First, it is characterised by considerable fragmentation. This is unusual compared to other sectors in that fragmentation takes place not just in terms of traditional market segmentation, but more with respect to the numerous sub-sectors of therapeutic category within product groups. Therapeutic drugs serve different needs, often specific to individual cases, and are not interchangeable; there can be no direct competition between medicines designed to treat different conditions. Competition between brands and manufacturers is at its most pronounced within rather than between therapeutic categories.³⁵

Second, profits are exceedingly high in the pharmaceutical industry, both on its own merit and compared to other manufacturing sectors (Scherer 1996). While commercial success is not guaranteed – even when an NCE is synthesised into a product which is granted market approval, it may not sell sufficiently to make back its development costs – the top selling drugs in 2000 together had over US\$34 billion in sales (Table 2-1).

Table 2-1: Global Pharmaceutical Sales in 2000 - leading products

RANK	PRODUCT	2000 GLOBAL SALES (US\$ BILLION)
1	<i>Losec/Prilosec</i> - antiulcerant	6.1
2	<i>Lipitor</i> - cholesterol-lowering	5.4
3	<i>Zocor</i> - cholesterol-lowering	4.4
4	<i>Norvasc</i> - anti-hypertension	3.3
5	<i>Ogastro/Prevacid</i> - antiulcerant	3.1
6	<i>Prozac</i> - antidepressant	2.9
7	<i>Seroxat/Paxil</i> - antidepressant	2.4
8	<i>Zyprexa</i> - antipsychotic (treats schizophrenia)	2.4
9	<i>Celebrex</i> - treats adult osteoarthritis	2.4
10	<i>Zoloft</i> - antidepressant	2.2
TOTAL		34.5

Source: IMS Health data (2001).

A further peculiarity is that despite being extremely profitable, the pharmaceutical market is dominated by only a few genuine manufacturers. This is particularly in the ethical segment where eleven companies make up 47% of the global market (IMS Health 2001). In the generics and OTC segments, despite more players – Mossialos & Abel-Smith (1997) estimated approximately 2,500 companies in 1996 – it remains the case that 85% of therapeutic categories are controlled by the larger firms. This is partly because medicines tend not to be price-elastic, but also relates to the significant research and development costs involved in producing medicines. The length of the R&D process and, indeed, the

³⁵ In the OTC market, because of the lack of consumer knowledge, this may have the negative effect of actually leading to competition between products not designed to treat the same condition.

costs involved are considerably longer and more extensive than for traditional consumer goods (see Section 1-3). In specific therapeutic categories, therefore, several companies have achieved near monopoly positions (Mossialos et al 1994b). This is not the case to the same degree in more traditional industries where product substitution and market segmentation are more easily defined.

That said, the question of competition is a point of contention amongst analysts:

Taking a static approach there are high concentration ratios, high prices and profits, a small number of large companies dominating a large number of smaller companies and a considerable lack of price competition... with a dynamic approach the impression is of cut-throat competition not only through product competition and differentiation, but through prices. (McIntyre 1999, 66)

This suggests that it is a matter of perspective: those with a pro-industry leaning, like McIntyre (1999), take the view that the market structure is natural and competitive, driven mainly by the dynamism, costs and risks associated with the R&D process; meanwhile those with a more sceptical view of the industry, such as consumer groups (e.g. NCC 1994), consider the limited number of companies a situation of oligopolistic structure at best and monopolistic structure at worst. Their interpretation is a static and uncompetitive market because of the power wielded by so few players, which in turn helps to explain why profits in the industry are so high.

Regarding the dynamic approach, it is argued that as there is strong competition between brands within therapeutic categories, competitors not only have to ensure that their products are affordable but moreover that they are more innovative or efficacious than those of their competitors. Because of economies of scale, it is suggested that only a small number of large firms will ever be able to afford the R&D required of new drug discovery in the first place. Here the argument focuses on cost-effectiveness as a natural market element. The struggle to produce drugs cost-effectively is viewed as a guarantee of competition in the market, and market concentration is thus seen as the product of a natural evolution given the sector's peculiarities.

The static approach is reflected in Davis's (1997) view that "On closer inspection, however, it soon becomes evident that competition of this kind is more apparent than real." (84) The contention here is that: "The moral to be drawn is that under conditions like those found in pharmaceuticals, first movers have natural product differentiation advantages that permit them to charge high prices and retain substantial market shares – the essence of

monopoly power." (Scherer & Ross 1990, 592)³⁶ Ardent critics, primarily from non-governmental organisations (NGOs) are often less measured, suggesting the over-pricing of products by a cartel of globally-dominant companies. A brief look at entry possibilities for new players helps to assess to what extent the unusual degree of market concentration is either natural or competitive. For this apparent enigma of high profits but few players raises some important questions about market structure and industry behaviour.

Barriers to entry?

In consulting Porter's (1980) widely-cited work on approaches to the analysis of industrial competition, it can be seen that the pharmaceutical market is characterised by significant barriers to entry. Moreover, these barriers are especially high compared to other industries³⁷. Porter cites seven main impediments typical of traditional markets: economies of scale; product differentiation; capital requirements; switching costs; access to distribution channels; cost disadvantages (independent of scale); and government policy (Porter 1980, 7-17).

The size of the major drug producers obviously allows them to enjoy significant economies of scale in production capacity. However, it is not so much drug production itself, but the research and development costs behind the discovery and synthesis of the new chemical entities upon which medicines are based, which is the most expensive part of medicines development. The industry puts the cost of bringing a new drug to market at €500-560 million (EFPIA 2001a). Although this figure may be somewhat generous (see Section 1-3), the industry is clearly dependent on continuous and high-cost innovation. It is here, therefore, that the large companies enjoy major scale advantages, and not simply with regard to existing facilities, but more in terms of the finance needed to undertake research.

Product differentiation, in terms of competing with well-known products, brands, and established firms, also acts as a deterrent to new entrants. The market shares which are achievable by individual products, and the fact that many of the large pharmaceutical multinationals are household names (often because they are also associated with a wide range of consumer products via subsidiaries), is indicative of the extent to which pre-existing loyalties characterise the market. Doctors too may have preferences in terms of what they prescribe. This in turn discourages competition, with even the major manufacturers often specialising in specific sub sectors or therapeutic categories.

³⁶ The authors make the point that this monopoly power can be 'eroded' or 'undermined', though only when consumers have sufficient financial incentive to make cost-saving decisions, and providing that objective product information is available. As neither of these conditions yet exist, the case for at least a quasi-monopolistic structure to the pharmaceutical sector can indeed be made.

³⁷ Significant entry barriers are refuted by the industry, for instance:
www.pfizer.com/pfizerinc/policy/stake.html.

In terms of capital requirements, as the high R&D costs represent potentially unrecoverable spending, prospective entrants are immediately disadvantaged. The established firms thus claim that R&D is a natural impediment, arguing that entry barriers have more to do with knowledge accumulation *vis-à-vis* developing products and markets than they do with traditional economies of scale, and are not indicative of an uncompetitive market. Still, the resource question remains a hurdle to further competition and is also relevant to distribution access as another of Porter's barriers. For the resources available to the dominant companies enable them to operate massive sales forces and extensive marketing³⁸. Unlike for other industrial products, the commercial success of medicines is dependent on the number of markets the drugs are granted access to, rather than simply doing well in any one: "...it will be readily seen that, to render its activities profitable, the pharmaceutical industry must have access to as extensive a market as is possible." (Pharma Info 1982, 9) Only the largest companies have distribution infrastructures strong enough to penetrate several countries' markets simultaneously. Competing here is a struggle for new entrants, especially as long-standing advertising may result in doctors prescribing only those products they know best. This relates to the proxy-demand structure – it also raises the possibility of monopoly behaviour by the big players – and means that the large companies can dominate the main distribution channel, allowing them to enforce brand loyalty.

In that they are higher than in traditional industries, switching costs are another impediment to increased competition. The one-off costs incurred by switching from one product or service to another – which includes not only purchase costs, but also the related costs of changing the production system – are not simply expensive where medicines are concerned, but are almost impossible. Medicine producers cannot simply swap products and production lines as is the case in other industries. The multinationals are also susceptible to switching costs in terms of potential loss of revenue, but the blow is considerably less than for new entrants. Most of the world's leading medicine producers not only have established market shares, but are also involved in related industries such as chemicals, cosmetics or biotechnology, where there may be R&D and production overlap.

Because they are often mutually reinforcing, cost disadvantages (independent of economies of scale) and government policy can be lumped together as the final two of Porter's seven barriers. Access to materials, patent protection, favourable locations, and the learning curve – where costs decline relative to increased expertise – all favour the existing players. Further advantages can be extended to the existing companies via government policy e.g. extremely strict and/or expensive industry-wide safety or

³⁸ Unlike in the US, marketing and advertising of pharmaceuticals in Europe does not take place in the public domain, and direct-to-consumer advertising of drugs has been banned since 1992.

environmental guidelines which may discourage new-comers. Or else they are able to secure favourable financial and tax deals.

At this stage the question of research and development warrants a closer look. For not only does it represent a unique feature of the pharmaceutical market in its own right, but it lies at the heart of many issues concerning the industry and its regulation. These include market structure, profits, competition and market barriers (dynamic versus static approaches), and indeed healthcare and welfare gains (or losses). It should be stressed that much of the data cited in this section, even if from apparently non-industry sources, are in fact the industry's own³⁹. As mentioned in Section 1-2, this (necessary) reliance on industry for data is one of the informational asymmetries which characterise the sector. It is therefore advisable to treat such figures with some caution.

Research and development: pressure or smokescreen?

The modern R&D process for therapeutic drugs is unlike that in any other industry. Companies must first 'discover' and patent new chemical entities (NCEs) as the basis for their medicinal preparations, before harnessing these compounds to produce new drugs and treatments. These they are then required to test for safety, efficacy and quality (not to mention cost-effectiveness) before proving this to national authorities. Public/regulatory bodies carry out their own reviews, also against the three public health 'hurdles'. This culminates in a market approval process which, depending on the source, can take up to between ten and thirteen years⁴⁰. No other sector is characterised by such a lengthy and strictly controlled market authorisation process, far less such a research-intensive and costly one (Danzon 1997).

As mentioned, the process of discovering new medicines is extremely high technology-oriented and expensive. Industry sources show that as the number of new discoveries is on the wane (EFPIA 2001b), R&D costs have been rising steadily since the 1980s, doubling in the last ten years alone⁴¹. The European industry claims that bringing a new drug to market costs €500-560 million (EFPIA 2001a). Along with the risks – only 1-2 products out of every 10,000 substances synthesised in a laboratory are said to pass all the tests and make it to market as a new drug (EFPIA 1998) – this sees companies under

³⁹ For instance, many scholars and commentators rely on data put out by the Tufts Centre for the Study of Drug Development (TCSDD) at Tufts University. The centre enjoys considerable sponsorship from several of the major pharmaceutical multinationals who themselves use this information to support their claims regarding approval times, declining competitiveness, etc. This is not to say that the TCDD is necessarily compromised in its work, but rather to point out that even so-called 'independent' sources of information are not without industry links.

⁴⁰ For example Matthews & Wilson (1998) or EFPIA (2001b).

⁴¹ EFPIA – 'Did you know?' (available at: www.efpia.org/2_indust/didyouknow.htm)

intense R&D pressures. Sub-markets in which new and innovative firms can acquire expertise and specialisation, as characterise other industries, do not exist in the pharmaceutical sector. There are different therapeutic categories in which companies can concentrate their activities, but the research platform is high across the board. Established market-leaders thus enjoy an aggregate of latent knowledge which took years to build up and which they understandably wish to safeguard. Moreover, it is on the basis of such knowledge accumulation and its protection that the industry justifies its market shares and counters any charges of excess profit-making or a lack of competition. Looking at the growing emphasis on outcomes research for instance, there is much interest in:

... the comparative impact of pharmaceutical therapies on endpoints such as survival and disease progression in patients with chronic diseases; but such studies can take 5-15 years, require thousands of patients, and cost millions of dollars. When firms that are established in a chronic therapy market (e.g. hypertension) invest in such research, they... raise the ante for any newcomer wishing to enter the market [and] they create a "time-buffered" competitive advantage... (Gelijns & Dawkins 1994, 169)

The knowledge-base developed by the established firms thus gives them a massive advantage over new competitors, especially in the future acquisition of knowledge. The expense and duration of R&D leads to the claim that it is the initial cost and potential lack of return on investment which discourages new entrants, not the behaviour of the established companies. R&D is here regarded as a pressure, and a natural feature of the market, making it unlikely that the market could bear any more than a handful of players.

According to company officials, the consolidation of the sector over the past few years is in large part due to these research-related pressures. As in other industries, drug companies seek to streamline their operations, improve the product pipeline, and eliminate overlaps. Between 1999 and the first half of 2001 there were some 678 mergers, acquisitions and strategic alliances in the global sector, with 243 of these in western Europe (PWC 2001). Even in the so-called £114 billion 'merger of equals' – *Glaxo Wellcome*'s December 2000 coming together with *SmithKline Beecham* (now *GlaxoSmithKline* or GSK) – amongst the rationale offered by company officials was the improvement of the research-base and product pipeline (Pharma J 2000). For these reasons, not only do industry representatives expect to see sufficient gains to make their R&D investment worthwhile, but as drug development is almost exclusively carried out in the private sector, they seek government incentives and an unfettered environment in which to operate. The lobbying of governments by drug companies is commonplace. With regard to extra patent protection, for instance, the global industry's fight has been especially energetic, with success in extending patent times in all the major markets: the EU, the US, Japan, and South Korea.

The industry's claims about costs and risks, as well as the data it employs are, however, being increasingly queried. The fact that the public sector cannot afford to undertake drug development is not disputed by critics, nor is the relationship between costly research and new medicines. But to what extent R&D is a pressure given existing profits is questioned, and several commentators have noted that the major research-oriented companies have generally spent more on promotion and marketing than they do on R&D (e.g. Wertheimer & Gruner 1992, Davis 1997). Moreover, the R&D cost data cited by the industry includes a host of inputs which do not directly apply to the generation of any single product. Included for instance are the costs of NCEs which were not/could not be synthesised into a new drug, as well as products which failed clinical testing (i.e. the industry's claims of only 1 or 2 of every 10,000 NCEs making it to market). For those who criticise the market's dominance by only a limited number of players, not only does industry 'massage' its statistics to make its case, but R&D is not seen as a pressure. It is viewed a barrier which industry relies on as a smokescreen in pursuing favourable government policy.

Here, wide-ranging intellectual property rights are said to consolidate the position of the market-leaders, and mergers and alliances are thus more about profit than staying competitive. A look at the resultant market shares of several of the more high-profile mergers in recent years provides some of the basis for these arguments (Table 2-2).

Table 2-2: Major Mergers and Market Shares in the Global Pharmaceutical Market⁴²

MERGED COMPANY	COMPANIES MERGED	DATE	MARKET SHARE
Pfizer Inc*	Pfizer AND Warner-Lambert	06.00	7.3%
GlaxoSmithKline	Glaxo Wellcome AND SmithKline Beecham	12.00	7.0%
Astra Zeneca	Astra AB AND Zeneca	02.99	4.55%
Bristol Myers Squibb	Bristol Myers AND Squibb Corp	07.89	4.0%
Aventis	Hoechst Marion Roussel AND Rhône-Poulenc Rorer	11.99	3.95%
Novartis	Ciba Geigy AND Sandoz	12.96	3.95%
Johnson & Johnson	Johnson & Johnson AND ALZA Corp	06.01	3.84%
Pharmacia Corporation	Pharmacia & Upjohn AND Monsanto	04.00	3.2%
American Home Products	American Home Products AND Cyanamid Dow	11.94	3.1%
Sanofi-Synthélabo	Sanofi AND Synthélabo	04.99	1.1%

Source: IMS Health data (2000, 2001).

* In July 2002 *Pfizer Inc* indicated that it will take over the *Pharmacia Corporation* in a stock-for-stock agreement - potentially giving the new company over 10% of the global market.

It should also be noted that the 'new' companies are themselves often mergers between two previously merged enterprises. Smaller manufactures suffer in terms of a lack of financial as well as informational resources. The result is that they often sell their own

⁴² Together, these represent 10 of the top 11 companies in the global pharmaceutical market. Missing is *Merck & Co. Inc.* with a 5.1% market share. The 12 firms represent some 47% of the global market (IMS Health data 2001).

(incomplete) research to the market leaders. Or else, they are simply amalgamated in what appears the ceaseless consolidation of the industry. This only widens the knowledge gap, further cementing the position of the very few global market leaders.

Not only are entry barriers high, therefore, but in medicines they manifest themselves differently than in other industries. The uniqueness of these barriers to increased competition are all reinforced by the research and development task (cost and knowledge accumulation). Nevertheless, as has also been argued, industry's claims about increasing R&D costs, decreasing discoveries, and the need to consolidate – along with the data used to make their case – should not be unquestioningly accepted. Nor should it be forgotten that notwithstanding these claims, profits for the major companies remain high.

Multinational oligopoly or quasi-monopoly?

Irrespective of in which of the 'high-profits-low-entrants' camps one sits, it remains the case that the structure and operation of the market is in stark contrast to the higher levels of competition in other sectors. The greater demand and choice, and possibility for new entrants to exploit niche markets as exists in other industrial domains does not characterise pharmaceuticals. Traditional arguments about start-up costs, capital and marketing are alone not responsible for the dominance of so few firms. And though it is not clear whether this reflects an uncompetitive industry or not, it does, at best, reflect a structure which is less competitive than it could be⁴³. So although scholars such as Feldstein (1988), Grabowski & Vernon (1994) and McIntyre (1999) argue that the dynamic approach is the more valid, this still accounts mainly for competition amongst those already in the market, rather than why there are so few companies.

In combination with the value and profitability of the sector, this lack of competition underlines the strength of position wielded by the industry where any (regulatory) policy may be concerned. Moreover, as patients (or the state) are obliged to pay high prices in order to secure a health benefit, this gives the producer of medicines a considerable hold on the market. According to one economist, the pharmaceutical industry is "extraordinary" "... for the amount of monopoly power held by sellers of important new products" (Scherer 1998, 204-205). There is no hard proof that companies behave in monopolistic fashion, though there have been legal cases in both Europe and the United States which have found the industry to be guilty of cartel-like practices in areas such as pricing or in

⁴³ With manufacturers focusing their activities in specific sub-markets and a few therapeutic categories, their power (and market concentration) is even greater than might initially appear.

influencing the prescribing patterns of doctors⁴⁴. As such, it is perhaps more accurate to deem the pharmaceutical market 'quasi-monopolistic'. For irrespective of whether or not the existing players contribute to the market concentration, the pharmaceutical market does suffer from a lack of competition, and the leading companies are extremely powerful. The market structure should, therefore, be of concern.

A quasi-monopolistic view of the industry is important in the context of aims to complete the single market. First, because a fifteen-country medicines market concentrated in the hands of only a few multinationals is not going to inspire confidence in the provision of drugs for any other sake than profit (and profit for only some companies and some countries). And second, that as this market concentration becomes even greater given the continuing consolidation of the industry, it leads to questions about the Commission's ability to act as a non-partisan regulator. Indeed, the power of so few companies is an important consideration given this study's contention that the current EU regulatory framework favours the industry.

Here, given prevalent market barriers economic theory suggests oligopolistic behaviour by the established players – indeed, McIntyre (1999) uses the term "multinational oligopoly" to describe the industry (57)⁴⁵. An example would be predatory pricing where established companies exploit their cost advantages to bring medicine prices down to levels at which prospective entrants would be unable to recoup R&D expenditures. Squeezing out competition in the EU market in this way could be particularly egregious. Medical research is dependent on not just quality of research, but so too quantity. The more firms and member states engaged in medicine research, the better the chances of break-throughs. Ideally, more competition also means a better quality of product.

With respect to the Commission's non-partisanship, as with national governments, it is nevertheless in its interest to see a profitable (Euro-)industry. More mergers and strategic alliances in the sector will strengthen the industry, and may therefore compromise the Commission's position *vis-à-vis* its continued efforts at harmonisation. This raises the prospect of 'regulatory capture' i.e. when regulators advocate the interests of the industry they are intended to regulate. It is a concern in any industrial domain, but takes on especial significance where medicines (people's health) are involved.

⁴⁴ For example, in June 2001, the US Federal Trade Commission launched an investigation into complaints about companies having paid generic competitors to keep lower-priced drugs off the market. And in Europe, German drugs giant *Bayer* has been fined by the Commission for uncompetitive practices regarding distribution of its cardiovascular drug *Adalat*.

⁴⁵ McIntyre (1999, 25-69) assesses the industry against numerous structural and behavioural criteria. She finds that it reflects several aspects of both an oligopoly and multinational enterprise, and concludes that it is a competitive industry.

Regulatory capture

Briefly, regulatory capture is well-established both in theory and practice, particularly in the United States where the regulatory tradition has hinged on the state's intervention in the market as a means of correcting failures, rather than it assuming a leading role in macroeconomic stability as is the case in Europe. Capture stems from a dichotomy between 'public interest' and 'private interest' theories of regulation.

The public interest view has a long history and is premised on a tension between producer and consumer. To what extent this tension exists in the pharmaceutical sector is debatable. But what is clear is that the companies aim to make a profit at the same time as consumers want the best possible medicines. Equally clear is the potential for harm (in terms of ineffectual or over-priced medicines) that an unregulated industry could inflict. The pro-industry view is equally well-developed. Amongst the first to articulate it was Stigler (1971) who argued that rather than being designed and implemented to protect the public's interest, "... regulation is acquired by industry and is designed and operated for its benefit." (3) This is particularly egregious in the context of medicines, for the 'public interest' is in fact public health, and regulating for industry implies reinforcing an already well-performing industry, one which is not necessarily delivering innovative medicines ahead of profitable ones. Nevertheless, the market structure of the EU pharmaceutical sector does seem to reflect several characteristics which make it amenable to capture.

Its quasi-monopolistic constitution and the peculiar role of the member states as purchaser and regulator (along with the Commission) mean that independent, objective regulation is difficult to achieve, making the market susceptible to capture. This is because of the position of strength held by the industry, based in particular on three bargaining-chips which it wields. First is the ethical or health policy argument that medicines research *ought* to be promoted given the direct health benefit that newer and better therapies can bring. Second is the argument that newer and more efficacious drugs will mean decreased healthcare expenditure, especially with regard to long-term or chronic illness. Third is the industrial policy argument focusing on balance of trade and employment concerns. This carries especial weight with pharmaceuticals representing one of the few high technology industries where Europe is a global leader.

Related to this is the 'informational monopoly' held by the companies. With the public sector not involved in the development of medicines, it is reliant on industry both for the provision of new drugs and the information which public bodies use to make their assessments on these products. This makes the market further susceptible to capture on two fronts. First is the potential for selective information being strategically provided, and

second, it creates the potential for collusion between companies. Here the industry can be seen simply to present a unified front in trying to maximise its interests. As this study demonstrates, this it indeed does when it comes to specific instances of regulatory policy-making (at both national and EU levels). More worryingly, however, such co-operation, given the strength of industry, may allow companies to pressure the regulators (whether national governments, the European Commission, or the EMEA). Without proffering an opinion on industry operations here – as its behaviour and influence are examined in subsequent chapters – the point to be made is that the structure of the market too warrants regulation, but that capture is a very real possibility.

1-4 So, why regulate?

In concluding this part of the chapter, recalling that the discussion sought to provide reasons as to why regulation in the pharmaceutical sector differs from that in other industrial arenas, the discussion has advanced several responses. First, pharmaceuticals are a unique product. Medicinal preparations are researched, designed, and sold for profit in order to bring a positive health effect in the event of illness (whether cure or control). No other industrial product can make the same claim. Other industries are required to take consumer safety into account – with some specialising in this area – but consumer safety is in no way the same thing as public health. Governments need to ensure that medicines are safe, efficacious and efficient. And as drugs are costly, they have a further vested interested in regulating to ensure affordable prices.

The atypical supply-demand dynamic requires regulatory oversight given the market imperfections it creates. Here the patient/consumer does not choose their medication, nor does (s)he pay for it. In addition, a fear of illness can provoke a demand for medicine often irrespective of cost considerations, as most medication in Europe is reimbursed under health insurance. Governments must intervene to control the costs of programmes which serve to ensure access to medicines. The informational asymmetries which result from this demand-supply configuration also necessitate regulation. This relates to patients' reliance on doctors given their inability to make independent, informed decisions on use, and doctors' reliance on pharmaceutical companies for information on the therapeutic value of specific drugs; even governments and national regulatory authorities are reliant on industry for scientific information.

The market structure too warrants regulation. The imperfections mean that traditional market forces are unable to ensure adequate and beneficial competition; entry barriers are especially high. Moreover, given the at least quasi-monopolistic structure of the market, governments' role in ensuring that this does not affect the provision of high quality,

affordable medicines, is central. Manufacturers should not be able to collude in such a way that profit maximisation is placed ahead of the delivery of required medicines. And with a strong patent system in place, governments need to ensure that companies do not behave in a monopolistic manner with regard to the prices they charge for their medicines.

Ultimately, as 'life and death' questions characterise both the nature of the product and the operation of the market, there exists an ethical imperative which is stronger than in other sectors. Business interests cannot be permitted to over-ride it, and national governments are socially bound to ensure this. To what extent the ethical imperative actually prevails is debatable, and represents a pervasive theme in discussions about the industry.

2 Regulating Medicines

The next part of the discussion addresses the health(care)-industrial policy clash raised in the opening chapter. But before looking at how EU pharmaceutical regulation is pursued, a brief overview of the role of national governments *vis-à-vis* the regulation of their own medicines markets is necessary. This is important on two fronts. First because it reveals the incomplete nature of the EU regulatory framework. And second for "... while the Europeanisation of medicines control has undoubtedly been a supranational and transnational phenomenon, it has been built on existing national systems of drug regulation." (Abraham & Lewis 2000, 43)

2-1 Pharmaceutical regulation in practice

Governments' role is a complicated and multi-faceted one:

Public bodies determine which drugs can be provided to the public, exercise surveillance over production processes, limit distribution systems, control how patients obtain medication, establish standards for advertising as well as for printed inserts in packages, and often specify prices, insurance coverage, and reimbursement methods. (Orzack et al 1992, 850)

The remit is broad-ranging and diverse, and involves regulating not simply demand and supply, but so too market structure, industry conduct and market performance. This role spans both product and market regulation, and includes taking into account the wider social aspects of medicines. These are competencies which go well beyond their role in other sectors. And recalling the discussion on multiple policy inputs from Chapter 1, national governments must pursue overlapping economic and political interests over health and industrial policy. At the same time, the role of regulatory officials in pharmaceuticals is also to ensure that industry structure and/or conduct are enabling good economic performance (Scherer & Ross 1990).

In addition, governments are generally responsible for a nation's health. In their capacity as regulator and purchaser of drugs, this means ensuring that the safest and most efficacious medicines affordable within social security budgets reach the market. Given the economic contribution of the industry – and the fact that a successful industry is a prerequisite for the production of high quality medicines – so too must policies be conducive to good business. Industry representatives argue that the two need not be incompatible⁴⁶, but there is no model; especially as governments have different priorities *vis-à-vis* cost-containment. This creates a policy overlap where regulation must enable manufacturers sufficient returns to produce as high quality medicines as possible, but must also serve to keep the prices of these drugs as low as possible. In other words, it meshes public health, healthcare and industrial policy (Table 2-3).

Table 2-3: Competing Pharmaceutical Policy Interests*

HEALTHCARE POLICY	INDUSTRIAL POLICY	PUBLIC HEALTH POLICY
Cost-containment and improving efficiency in health services and care	Promoting local research and development capacity	Safe medicines
Cost-effective medication	Intellectual property rights protection	High quality preparations
Regulating doctor and consumer behaviour <i>vis-à-vis</i> medicines	Supporting local scientific community	Efficacious treatments
Generic promotion and/or substitution	Generating and protecting employment	Innovative cures
Improving prescribing	Promoting small and medium enterprise policies	Patient access to medicines
Ensuring access to medicines	Contributing to positive trade balance	
	Sustaining the university research base	

* This is a simple listing and does not indicate priority.

It is with any eye to balancing these policy interests and meeting the specific requirements they represent that governments regulate both the product and market aspects of the pharmaceutical sector. As their methods vary at times considerably, a brief profile of the main types of regulatory measure used in the member states is provided in following (Appendix 2-1 offers a country-by-country comparison).

2-2 Product regulation – public health policy

Pharmaceuticals must pass three regulatory 'hurdles' before they are permitted to enter the market. The first is often called the 'public health test'. Manufacturers are required to prove the quality and safety of new substances in terms of delivering a therapeutic benefit to patients under specific conditions and at a particular dosage. These assessments of

⁴⁶ For example Lawton (2001).

new chemical entities (NCEs) involve up to 10 years of pre-clinical and clinical evaluations, and entail tests on specific groups of individuals.

The second hurdle is one of review and approval. Regulatory authorities assess the 'dossier' of a new drug that is submitted by the manufacturer after the completion of the trials. The *dossier*, or New Drug Application (NDA), contains the detailed results of the tests and outlines the purpose and target group of the proposed drug. It also specifies under what conditions the product can be administered. Review and approval can take up to 3 years, after which, if the regulator is satisfied that the public health test has been met, the medicine can be registered and marketed.

The final hurdle is that of pricing and reimbursement, and is:

... the most contentious issue in pharmaceutical production and one where health policy objectives clash directly with the objectives of industrial policy [as] it is the public bodies' [regulator's] intention to achieve the highest outcome with the lowest possible cost. (Kanavos 1998, 77)

Manufacturers engage in negotiations with ministries of health regarding the price of their new product and its inclusion in national formularies (drug-lists). Such discussions generally take place behind closed doors. The talks are crucial to both industry and health interests, as all EU governments (save Germany) directly influence pharmaceutical prices through a variety of measures. Both sides have a considerable amount to lose if a mutually agreeable price is not decided upon.

2-3 Market regulation – balancing policy goals

In addition to setting the public health test for new medicines, governments are responsible for managing the market; the need for which, as has been shown, is perhaps greater than in other sectors given the market structure and welfare issues at hand. Market regulation involves supply and demand-side measures, both of which are geared towards promoting healthcare and industrial policy goals. The former implies regulating industry – essentially through price or profit controls – the latter involves regulating the consumer with regard to their demand for drugs (consumption behaviour). Methods of each have become more sophisticated as EU governments have sought to manage ballooning healthcare costs since the 1980s (Mossialos & Le Grand 1999).

Healthcare policy and cost-containment

Cost-containment has generally been the priority for most member states and supply-side measures have often involved targeting the industry. As this plays on popular opinion

which holds that if not medicine prices, then manufacturer profits, are too high, it proves politically more viable to regulate the industry rather than consumers. With political mileage to be earned, price controls are favoured by most EU states, and these take the form of: direct price controls on individual medicinal products; profit controls or other limitations on industry; and reference pricing formulae (which involve setting benchmark prices by grouping similar products together and establishing a relative price for reimbursement by insurance). Table 2-4 reveals further approaches and shows that most governments use a combination of these methodologies. With countries exercising such varied types of control, it is the harmonisation (or at least standardisation) of national pricing regimes which the Commission has pinpointed as the foremost obstacle towards completing the Single Market (Bangemann 1997a).

Table 2-4: Drug Pricing and Reimbursement Methodologies in EU Member States

MEMBER STATE	FREE PRICE	PROFIT CONTROL	PRICE CONTROL	AVERAGE PRICING	CROSS-COUNTRY COMPARISON	REFERENCE PRICING (FOR GENERICS)	PROMOTION OF GENERIC COMPETITION
Austria			✓				
Belgium			✓		✓		
Denmark			✓		✓	✓	✓
Finland			✓				
France			✓				✓
Germany	✓					✓	✓
Greece			✓		✓		
Ireland			✓		✓		✓
Italy			✓	✓	✓	✓	
Luxembourg			✓		✓		
Netherlands			✓	✓	✓	✓	✓
Portugal			✓		✓		
Spain			✓		✓		
Sweden			✓			✓	
United Kingdom		✓					✓

Source: adapted from Kanavos (1998).

The different cost-reduction policies mirror differences in health systems and health culture. This is important because such policy differences contribute to (considerable) price differentials within the EU for the same product. In the southern European states, particularly Italy, Portugal and Spain, medicines are relatively inexpensive compared to their equivalent prices in northern states such as Denmark, Germany, and the UK. This accounts for the former group of countries' general preference for price controls and the latter's use of reference pricing schemes⁴⁷. It also reflects a range of national variances in

⁴⁷ The UK is an exception within this group. For although medicines are expensive in comparison to the rest of Europe, prices are regulated in secret between the Department of Health and the industry through the Pharmaceutical Profit Regulation Scheme (PPRS), and are based on manufacturers' profits through sales via the National Health Service.

health and economic concerns, including: structural differences in healthcare system and drug reimbursement mechanism; drug consumption patterns; variations in tax systems and value-added-tax (VAT) rates applied to medicinal products; doctors' prescribing habits; and the type and development of local pharmaceutical sectors. A single market for medicines would have to overcome such national differences.

Governments see price controls as the most effective manner to both regulate the market and cut back on costs incurred by health systems⁴⁸. However, there is no consensus on their impact. Proponents point to lower prices, decreasing national drug expenditures and a tighter rein on a market where traditional market forces do not necessarily guarantee competition. Opponents – primarily the industry – claim that price controls: reduce innovation by limiting the returns companies can put into research and development; are awkward to implement and manage; they may create scarcities (real and artificial); and that they have no clear impact on the national drug bill as this is as much dependent on prescribing habits and consumption patterns as anything else. A detailed discussion of the merits and problems of price regulation, including the complex variations which exist, is not necessary here. But it does serve to underscore what potentially needs to be overcome if the single market is to be completed.

Looking at demand-side measures, cost-sharing and specifically co-payments is generally the most popular system in the EU. This means shifting some of the price for medicines to the consumer, and generally involves the establishment of a flat-rate payment for all prescription drugs. The premise being that patients are encouraged to think more cost-effectively when sharing in the cost of their medicines. However, cost-sharing has equity implications i.e. welfare being based on the ability to pay. Not all groups in society can be expected to share in the costs of their medicines to the same degree. The unemployed or elderly are generally exempt, whilst those in employment pay the same flat-rate (or percentage) irrespective of their earnings. Thus, it is a policy which has been said to discriminate against those more able to afford.

As with price controls, there is no firm proof that co-payments are effective in containing costs. Mainly this is because savings depend on the nature and size of the exemption group. Still, it proves a popular option given its relative simplicity to implement. When combined with a system of budgeting for doctors (e.g. fundholding), cost-sharing can also affect prescribing and thus consumption patterns. This allows governments to not only affect drug costs – albeit indirectly – but also to retain prices which are high enough to act as an incentive for the industry.

⁴⁸ Though supply-side measures are the most popular method of cost-containment (and not just in Europe), member states are increasingly using a combination of supply-side and demand-side measures.

This ability to influence indirectly relates to the use of drug formularies (lists), which dictate which drugs can and cannot be prescribed. 'Positive' lists identify those medicines which are reimbursed under national insurance systems, while 'negative' lists delineate those which are not – these are subject to co-payment charges. All EU countries employ either a positive or negative list, and sometimes both. Again, there is again no conclusive proof as to the effectiveness of lists in reducing drug costs. Positive lists often cover only cheaper drugs for example, while a change in a patient's course of treatment may involve switching them from a negative to positive list medicine. Here too the differences amongst the member states are considerable, with the financing aspects of national healthcare systems directly implicated.

A final demand-side measure necessitating mention given its increased use in Europe is generic substitution. While countries such as France, Italy and Spain⁴⁹ may not yet have well-established generic markets, the policy of substituting branded medicines for generic equivalents is widely regarded as an easy way by which governments can cut costs and promote competition. Implementation can prove difficult, especially as doctors are generally against the practice, arguing that it undermines their autonomy (Burstell 1997). Despite growing in popularity, generic substitution is therefore likely to take a considerable time before becoming a standard policy option across the EU. And though the European Commission has strongly supported the use of generic policies (i.e. substitution, promotion, prescribing) in the member states, it has no competence to enforce this.

Industrial policy

Beyond controlling costs, national regulatory systems are also designed to serve governments' industrial policy objectives (recall Table 2-3). The specifics of these goals differ between EU member states, even amongst those with a domestic manufacturing industry. In general, however, with pharmaceuticals representing an extremely profitable industry, governments are keen to support it for the economic rewards it brings. This is especially so for those countries with a research-oriented industry. In the UK for example, pharmaceutical production was worth some €18,478 million in 1999 (EFPIA 2001a). As to the sector's value to the EU economy as a whole, it is the fifth-largest industrial sector, representing some 3.5% of total industrial production, and production was worth some €95 billion in 1999 at current prices (Gambardella et al 2000)⁵⁰. Much of the value of EU production is via exports – particularly to the US where medicine consumption is much higher than in Europe – which contributes to the Community retaining a favourable balance

⁴⁹ This is due to pharmaceutical prices being considerably cheaper than in other member states, such that the need for cheaper generics is not necessarily an issue.

⁵⁰ See Appendix 2-2 for EU production broken down by member state.

of trade. Measured by sales, the combined European industry (the EU plus Switzerland) contributes almost a quarter (43%) of the world's total output of pharmaceuticals (EFPIA 2001a).

Medicines are an extremely research-intensive and high technology industry. In 1997 for example, *Pfizer*'s R&D spending was some US\$1,710 million on one product alone: its much vaunted impotence drug *Viagra*. Although the drug did then achieve sales in excess of US\$400 million in just the first three months of being on the market (Kanavos 2000), such returns are not the norm. Nevertheless, medicine research and production requires considerable investment and is therefore important in the domestic manufacturing context. Moreover, the industry is a major employer. From those involved in the 'hands-on' development of a new chemical entity (NCE) to those responsible for product distribution, the industry requires a range of skills. According to the Association of British Pharmaceutical Industry (ABPI), the UK industry not only employs some 60,000 workers directly, but it generates a further 250,000 jobs in related industries (ABPI 2001a). And the European sector as a whole directly provides around 520,000 jobs across the Community (Gambardella et al 2000). Here it should be noted that the number of jobs grew at a steady average of 2% per year throughout the 1980s (Appendix 2-3), representing a healthy increase considered against employment rates for other EU manufacturing industries. Understandably, this is something that all European governments and the Commission are keen to maintain⁵¹. The industry and the Commission continually stress the employment card in all supranational policy discussions regarding the future of the sector. In both employment and investment terms, therefore, the success of the pharmaceutical industry is crucial to national economies, and many governments are thus keen to promote R&D capacity in particular.

It is unsurprising then that governments seek to keep pharmaceutical firms on home soil. Recent murmuring by several of the larger European firms about relocating their R&D elsewhere (specifically to the United States where the research environment is said to be more conducive) has seen not just national governments, but so too the European Commission seek to placate the industry on a number of levels (Lewis & Abraham 2001) e.g. intellectual property rights and preferential tax arrangements. This has led to accusations of bias and unfair competition from several fronts, not least of which is the generics industry which feels that the research-oriented companies already enjoy favoured conditions. Where both a generic and research industry is present, therefore, governments face an even more delicate problem in balancing interests. Nevertheless, the reason for

⁵¹ See Appendix 2-4 for current employment figures by member state.

the Commission's conciliatory approach to the industry in general is clear: the pharmaceutical industry is central to the European economy.

2-4 Regulatory diversity in Europe

Before turning to the supranational context, it should be noted that the divergences in national regulatory method mentioned stem from country-specific factors. Different healthcare systems mean that relative government shares of total drug expenditures are considerably different, as is health spending (Appendices 2-5 and 2-6). The number of products available in national markets is not the same (Taylor 1992). This may reflect the subjective nature of therapeutic judgements (Dukes 1985), resulting in one country granting market approval to a given product and another not – in turn reflecting medical differences between countries, both in training and practice. Ethnic and cultural factors, along with demography and relative wealth have also contributed to the evolution of differing regulatory systems. So too have different national consumer and patient attitudes towards medicines), as have different medical requirements (not all countries have similar patterns of disease). Economic performance has also helped to mould distinct pharmaceutical regulation practices and systems in Europe. Such socio-economic or medico-historic differences pose a considerable obstacle to be overcome if the EU is realistically to regulate over a single medicines market.

It is worth noting that these national differences have been increasing since the beginning of the 1990s. Beyond the countries having different industries, other reasons for this include: growing pressures on healthcare systems; patients' changing drug consumption and lifestyle patterns; the realisation that current systems are inadequate in controlling costs; and – despite the establishment of a European medicines agency – the lack of a truly comprehensive European regulatory scheme. The result is that some member states are now looking to favour volume controls on pharmaceuticals in addition to price controls, others are working to stimulate the local industry, whilst yet others continue to tinker with their co-payment systems.

More recently, debate about combining clinical-effectiveness with cost-effectiveness as a so-called 'forth hurdle' has arisen in several countries. Again, this is because EU countries do not have the same history and experience with pharmaceutical regulation, nor do they have the same resource and administrative capacities dedicated to the purpose. Having seen how governments balance the sector's competing interests, the discussion now turns to the supranational level to look at how the EU has addressed these issues.

3 The EU Regulatory Framework for Medicinal Products

In looking at EU regulatory competencies for medicines, a far less reaching role than at national level can be seen. This is perhaps surprising in light of not only the volume of European legislation pertaining to pharmaceuticals, but so too a Commission whose role has been deemed as 'entrepreneurial' in pushing Community regulation forwards; a role which has in some cases granted it wider regulatory competencies than exist at national level (Majone 1996). On the other hand, it reflects not simply the member states' interests in pegging the Commission back, but their ability to do so under the subsidiarity principle. In order to better understand what the Community – and in particular the Commission and EMEA – can and cannot do, along with what is at stake at supranational level, the discussion turns first to the context in which EU pharmaceutical policy is made.

3-1 Contextualising the EU pharmaceutical industry: A complex environment

In looking at the policy environment for the EU sector, important is the global nature of the industry: "Few industries are as multinational as pharmaceuticals" (Schweitzer 1997, 2). This may seem self-evident given that the leading producers are multinational enterprises, several of which are household names. But in practice it means that medicine manufacturers must remain abreast of and successful within a process of increasing globalisation (one reason for the number of mergers and acquisitions), yet their activities are decided predominantly by national interests (resulting, for example, in different prices for the same product in Europe). So while this international dimension has seen the EU industry benefit from global trade liberalisation measures via the General Agreement on Tariffs and Trade (GATT), the World Trade Organisation (WTO), and indeed through the emergence of free trade areas such as the North American Free Trade Agreement (NAFTA) and the EU single market programme, industry activities are nonetheless framed within national policy interests and subject to domestic influences.

For European policy-makers, this means balancing the industry's global concerns with member states' requirements. Consequently, arguments about maintaining a 'strong European industry' are more involved than they might initially sound. Although several of the world's leading research-based companies are European, this is not to say that they necessarily carry out their business in Europe. While they may be headquartered in the EU (though even this is not clear in terms of corporate versus operational headquarters), most European pharmaceutical multinationals seek to exploit cost and location advantages where possible. They therefore outsource much of their activities to foreign affiliates.

In addition, European companies generate most of their considerable profits outside of Europe, most notably in the American market. In part this is due to a combination of cost-containment measures by European governments, low tax rates and higher profit margins in the US, and the lack of a unified EU market. Consequently, the more important issue is to what extent the companies' research and development activities are undertaken in Europe. Domestic R&D spending has been decreasing over the past ten years in particular – down from 73% in 1990 to 59% in 1999 – with the US being the main beneficiary in this shift in research expenditure (Appendix 2-7)⁵².

It is this apparent declining competitiveness of the European industry which has seen the European Commission and member states keen to maintain a strong pharmaceutical presence in Europe; equally in terms of the local employment the industry generates, the considerable profitability of the sector, and in its contribution to the EU trade balance (in high technology and research-intensive sectors). Western Europe currently accounts for 23.7% of the global market in sales terms, and its trade surplus in pharmaceuticals is approximately €28 million (EFPIA 2002). These domestic versus global concerns are especially complex given policy-makers' attempts to balance national industrial and health concerns, and have contributed to the current shape of the EU regulatory environment. With these factors in mind, the discussion now turns to an overview of competencies which make up the Community's regulatory remit in the pharmaceutical field.

3.2 Official EU competencies in pharmaceuticals

In looking at the competencies which make up the EU framework it is striking that the Community's role is limited to industrial policy concerns such as product EU licensing, product marketing and sale, and patent protection. This is reflected in Table 2-5 (overleaf) which lists several of the major legislation for medicines central to the Community's framework. The Table is limited to selected Directives and Regulations as binding instruments⁵³ and hints at the breadth of Community competencies. More importantly, it captures the flurry of activity and around the time of the single market programme. So while the Community's leaning towards economic and industrial policy competencies may seem logical given the aims of the SEM, it belies the fact that market harmonisation has progressed under a political banner, one which is equally responsible for the impasse over completing the market.

⁵² As recognised by both the European and US trade associations (e.g. EFPIA 2002, PhRMA 2002).

⁵³ Although not listed in the Table, the Community also has competence with regard to immunological and homeopathic medicines, radiopharmaceuticals, medicines derived from human blood or plasma, and patent protection for products derived from plants.

Table 2-5: Selected Community Pharmaceutical Legislation (*vis-à-vis* medicines for human use)*

	Legislative Tool	Year	Purpose
Pre-Single European Market	Directive 65/65/EEC	1965	Approximation of provisions relating to proprietary medicinal products
	Directive 75/318/EEC	1975	Approximation of laws relating to analytical, pharmacotoxicological and clinical standards
	Directive 75/319/EEC	1975	Approximation of provisions laid down by law, regulation or administrative action relating to medicinal products
	Directive 83/570/EEC	1983	Amending Directives 65/65/EEC, 75/318/EEC and 75/319/EEC
	Directive 89/105/EEC	1989	Relating to the transparency of measures regulating the pricing of medicinal products and their inclusion within the scope of national health insurance systems
	Directive 91/356/EEC	1991	Laying down the principles and guidelines of good manufacturing practice
Post-Single European Market	Directive 92/25/EEC	1992	On the wholesale distribution of medicinal products
	Directive 92/26/EEC	1992	Concerning the classification for the supply of medicinal products
	Directive 92/27/EEC	1992	On the labelling of medicinal products and on package leaflets
	Directive 92/28/EEC	1992	On the advertising of medicinal products
	Directive 92/73/EEC	1992	Widening the scope of Directives 65/65/EEC and 75/319/EEC ... and laying down additional provisions on homeopathic medicinal products
	Regulation (EEC) No 1768/92	1992	Concerning the creation of a supplementary protection certificate
	Directive 93/39/EEC	1993	Amending Directives 65/65/EEC, 75/318/EEC and 75/319/EEC in respect of medicinal products
	Regulation (EEC) No 2309/93	1993	Laying down Community procedures for the authorisation and supervision of medicinal products and establishing a European Agency for the Evaluation of Medicinal Products
	Regulation (EC) No 540/95	1995	Arrangements for reporting adverse reactions, whether arising in the Community or in a third country
	Regulation (EC) No 541/95	1995	Concerning the examination of variations to the terms of a marketing authorisation granted by a competent authority of a member state
	Directive 1999/83/EC	1999	... amending Annex to Directive 75/318/EEC concerning testing requirements and introducing the notion of 'well established medicinal use'...
	Regulation (EC) 141/2000	2000	On orphan medicinal products

Source: adapted from EudraLex Volume 1: Medical Products for Human Use.

* The complete listing can be found in Appendix 2-8.

Another important point to be noted from Table 2-5 is that, despite the number of decisions agreed, the table shows what is missing from the EU's role. Beyond Directive 89/105/EEC (and perhaps Regulation (EEC) No 2309/93 creating the EMEA) there is nothing pertaining to healthcare policy. Again, this is because of the Community's formal exclusion from healthcare matters, both in relation to Article 152 and the member states' use of the subsidiarity principle. Unlike in the member states therefore, market harmonisation

motivations rather than health interests *per se* have led to the establishment of most EU responsibilities in the pharmaceutical sector.

3-3 Institutional capacity *vis-à-vis* medicines policy

The EU bodies charged with overseeing the pharmaceutical sector are, primarily, the European Commission and the European Agency for the Evaluation of Medicines. Specifically, it is the Commission's Pharmaceuticals Unit ('F2') within the Directorate-General (DG) for Enterprise – the DG for industrial affairs – that has competence. Together, the two bodies work towards promoting the free movement of medicines. In addition, DG Enterprise, along with the European Court of Justice, is responsible for seeing that the legislation listed in Table 2-5 is applied. It should be noted that unlike for public health and healthcare, there are no Treaty references to pharmaceutical products *per se*.

What is important here is that pharmaceutical policy befalls the Directorate-General responsible for industrial affairs and promoting European competitiveness. This was the case from the outset when pharmaceuticals were first the domain of the industrial affairs DG1A until its replacement by DGIII, and now DG Enterprise. The DG for Health and Consumer Protection (DG Sanco) has no formal authority over pharmaceutical policy whatsoever. Although there is consultation between the two offices, this imbalance and neglect of the health policy dimension contributes to the industrial policy leaning of the Community framework, and is one of the sources for criticism of the EU's role; particularly as the EMEA itself is located within DG Enterprise⁵⁴. Nevertheless, it would also be inappropriate for DG Sanco to have authority. Its mission statement is to "ensure a high level of protection of consumers' health, safety and economic interests as well as of public health at the level of the European Union." The last of these is undertaken by its Public Health Unit (Directorate 'G') whose main responsibilities are the analysis, co-ordination and development of policies and programmes in the field of public health – particularly those involving health promotion, disease surveillance, and matters of health and safety at work. Still, it is clear that DG Sanco should have a more formalised role. And its predecessor – DGV (Employment, Industrial Relations and Social Affairs) – has traditionally had to fight for its voice to be heard in pharmaceutical policy discussions.

This question of which office should regulate (or be involved) is further complicated by the fact that health issues play an important, even if indirect, role in areas such as the Common Agricultural Policy (CAP), VAT policy and 'e-commerce'. Thus, there are numerous other EU offices with a role or interest in the Community's health and social

⁵⁴ For instance Garattini & Bertele (2001).

policy objectives as well, and these too are affected by or have an effect on pharmaceutical policy. A survey prior to the 1999 reform of the Commission, for instance, showed that of the old 24 Directorates-General, at least 16 had a significant involvement in matters related to health (Merkel & Hübel 1999); which itself is part of the problem in forming a comprehensive European public health policy (Holland & Mossialos 1999). According to Hancher (1991) this raises problems with respect to what she terms the “horizontal multi-regulation” of the EU medicines sector. This multi-layered regulatory structure is made more difficult by the so-called ‘public health article’ of the Treaties. The 1992 Treaty on European Union introduced Article 129 and the provision that “... health protection requirements shall form a constituent part of the Community’s other policies”. This has been bolstered under Article 152 of the Amsterdam Treaty to now read: “A high level of human health protection shall be ensured in the definition and implementation of all Community policies and activities”; responsibility falls to DG Sanco.

In terms of how the Community exercises regulatory policy over medicines, the European Commission has several legislative instruments at its disposal. The Commission is empowered to propose, and later adopt, proposals for Regulations, Directives, and Decisions (all which are legislatively binding on the member states), as well as providing Recommendations and Opinions (which are not binding). Unlike Regulations, which have to be implemented into national law as they are, Directives allow the member states considerable leverage in terms of choosing their mode of implementation, provided the effect is ensured. Given this discretion, it is not surprising that the majority of EU pharmaceutical legislation (indeed EU legislation in general) consists of Directives. For with the sensitivities involved, the member states are unwilling to countenance the complete replacement of their national frameworks with rules from the Commission. This creates difficulties with respect to enforcement and, in conjunction with Treaty stipulations, exposes some gaps. As a result, the European Court of Justice too has a prominent role in the pharmaceutical field.

With regard to the ECJ, although not empowered to act in a regulatory capacity *per se*, as the guardian and interpreter of European law it does establish certain ‘rules of the game’. By insisting that national legal systems comply with European dictates, the development of European law complements the regulatory function of the Community. From relieving national decision-makers of certain responsibilities, to being integrated in full into national legislation, it continues to shape domestic legal systems and policy interests. As the Court also fills the gaps where the harmonisation of national provisions are concerned, it has helped establish the working rules of the SEM. Indeed, the ECJ’s ‘constitutional’ role in establishing European law as a *sui generis* system has had a major role in advancing integration in Europe generally (Wincott 1996).

That said, the Court has at times been accused of undue judicial activism. Decisions are sometimes said to impinge on the member states' decision-making sovereignty by underlining the principle of 'direct effect' and the 'doctrine of supremacy' of European law⁵⁵. Nonetheless, the Court acts to smooth the surface where national and EU legislation are not concordant. Further, it makes clear any outstanding issues within the context of the single market. In the case of pharmaceuticals this has to do with the clash between the subsidiarity principle and the free movement of goods and services principles.

Via numerous rulings pre and post-SEM, the ECJ has had a considerable hand in shaping the Community's market/free movement approach to pharmaceutical policy, and in promoting the evolution of a European healthcare policy more specifically (Mossialos & McKee 2001). With the Commission unable to make use of the public health related law of the Community to address pharmaceutical regulation, it has, under European law, concentrated on the harmonisation of national legislation through the dismantling of barriers to free movement. Several of the Court's pharmaceutical rulings aimed at facilitating the free movement of products within the internal market, especially in terms of competition and industrial property rights issues, are taken up in Chapter 7.

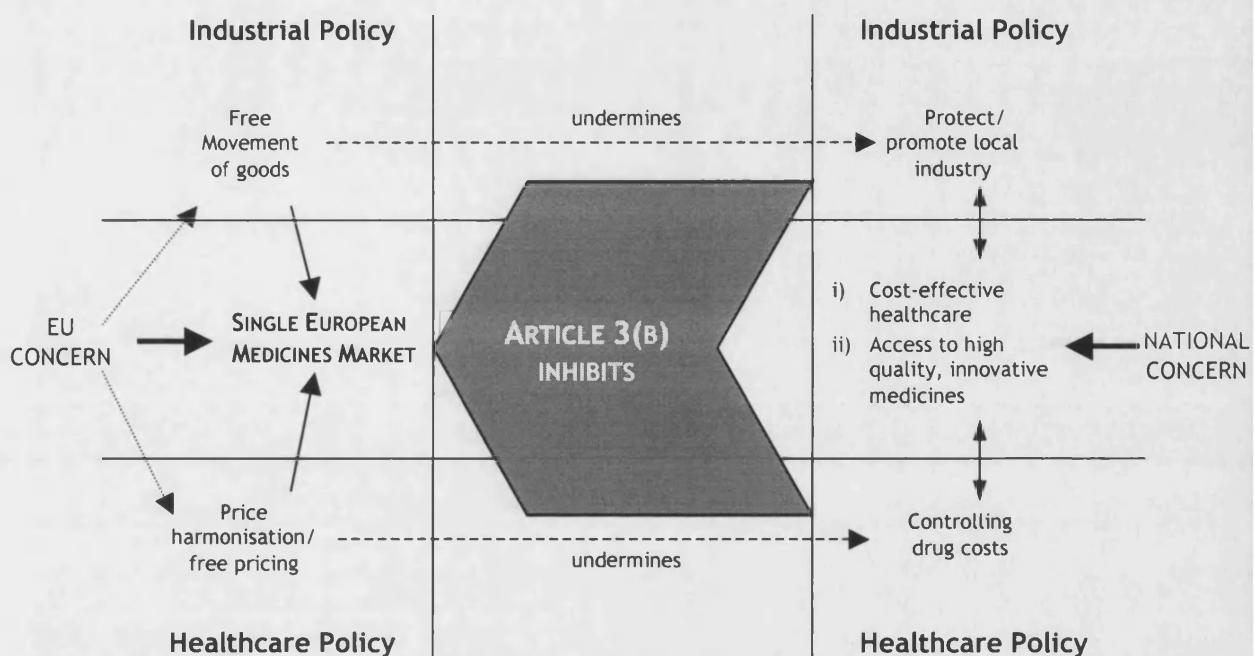
Currently, therefore, the institutional capacity for pharmaceutical regulation in the EU is somewhat stilted. This is the direct result of the health-industrial policy trade-off as it manifests itself in the dissonance between subsidiarity and the single market programme, and the horizontal multi-regulation structure within the Commission. The gaps and clashes this reveals have given the ECJ an unduly prominent place in establishing policy in an industrial sector. Accordingly, it is now necessary to examine this clash more closely, and to elaborate how the health(care) and industrial policy interests of the EU *vis-à-vis* the pharmaceutical industry are played out.

3-4 National versus Community interests

In view of the overlap between health(care) and industrial policy interests in medicines regulation at national level, the picture which emerges in the Community context is even more complex. The reason being the dissonance between Articles 3(b) and 100(a). That the clash in interests takes on an added dimension is represented in Figure 2-2 (overleaf).

⁵⁵ Cases C-26/62 *Van Gend en Loos v. Nederlandse Administratie der Belastingen* [ECR-1], and C-06/64 *Costa v. ENEL* [ECR-585]. Direct effect means member states must directly enforce European law such that it requires no additional implementing legislation. The doctrine of supremacy established the precept that, in the event of conflict, national law was to cede to European law.

Figure 2-2: National versus Community Concerns in EU Pharmaceutical Policy



The figure attempts to capture the nature of the policy deadlock which arises out of competing national and supranational interests and frameworks for action in the pharmaceutical sector. It shows the division between healthcare and industrial policy in the national and supranational contexts, and emphasises the result. Although the Commission and member states may share an interest in a strong pharmaceutical industry their visions are not entirely complimentary. What is not included is the place of public health in this equation. Public health interests are obviously part of medicines regulation on the national side, but as the EU has no formal competence in the area, it does not formally fall within the framework of pursuing a single medicines market. The diagram is limited to showing where national and EU interests collide over EU pharmaceutical policy.

Important in the centre of the figure therefore is reference to the subsidiarity principle, or Article 3(b). While the Community has pursued its designs for the sector under the banner of the single market, the member states have been able to opt out given that subsidiarity permits derogations to the SEM where important national interests are at stake. Here the Community's free movement goals (Article 100) clash directly with the member states' own industrial policy objectives. A single market would render many national sector jobs as superfluous capacity, impacting negatively on the economies of several member states.

Another of the Commission's goals is reducing intra-EU price differentials for medicines. This would compromise member states' authority to set their own pharmaceutical prices, as well as impacting on the manner in which they organise and finance their healthcare systems. Cost-containment may be a shared goal, but the manner in which the member

states regulate the pharmaceuticals market towards this end is not. Because of the clash in interests and subsidiarity (not to mention Article 152), the result is an impasse over completion of the market. An examination of the pricing issue is taken up in Chapter 7.

3-5 Taking the discussion forward

This constricted competence over pharmaceutical policy appears to defy contemporary theorising about the nature of Community regulation. For it is generally held that the jurisdiction of EU regulation is not simply bound to the economic – market-correcting – aspects of the single market. This wider role has given rise to the emergent perception of regulation as a new form of governance in the Community. Perhaps the most cited view on this is that of the EU as a so-called 'regulatory state'⁵⁶. The regulatory state model is dealt with in Chapter 4, but its mention here serves simply to make the point that the EU's function *vis-à-vis* regulation is a complex one, and one which includes a considerable social policy element as well. Yet, even with such a broad-ranging role in regulation – and the considerable volume of pharmaceutical legislation in force – the Commission is unable to force the pricing issue, far less wider harmonisation.

The EU's regulatory competencies thus extend principally to the market aspects of EU integration. Since the SEM, the European Commission has sought a market-oriented approach to the pharmaceutical sector. The emphasis has clearly been on liberalisation and the securing of an interventionist regulatory role with regard to ensuring the free movement of goods underpinnings of the single market, rather than outright harmonisation *per se*. In this vein, it is supported by a considerable body of European law which, in this case, is mainly concerned with freeing impediments to inter-EU trade. More recently, and particularly now with the establishment of DG Enterprise, the Commission has involved itself in promoting the competitiveness of EU industry. Regarding pharmaceuticals, its first major move in this direction was the publication in 1994 of a Communication on Industrial Policy for the industry (COM 1993). Though it should be added that this followed protracted negotiations and multiple drafts over several years (see Chapter 7).

There have been a spate of further initiatives since then. These have taken the form of meetings, advisory groups, commissioned studies, and policy papers by different EU offices. The most recent was the grounding of the 'High Level Group' (or G10) in 2001. Made up of what DG Enterprise considers key stakeholders, the G10 was established to "... explore how Europe as a whole can become more attractive for the pharmaceutical industry" (Lawton 2001), and reflects the Commission's current thinking (see Chapter 7).

⁵⁶ For instance Majone (1994, 1996) and McGowan & Wallace (1996).

Both the liberalisation and competitiveness approaches are ultimately aimed at achieving a single market, but represent different paths given the limitation imposed by subsidiarity. It is interesting to note that fostering the competitiveness of EU industry (and promoting industrial policy in general) was not a Treaty-based authority until 1992. Article 130 of the Maastricht Treaty outlined the Commission's industrial objectives and enabled it to initiate and adopt policies towards this end. The only restriction being that such policies would not in any way distort competition or undermine single market objectives. As has been noted, the question of competition – more specifically a lack thereof – is important in the context of the pharmaceutical sector. Although not dealt with specifically in this study, it is worth considering whether the current industrial policy focus (and indeed, pro-industry bias) of the EMEA and the EU framework in general, thus poses a threat to what is already a case of limited competition.

As the Community is limited in its capacity for action, it is not surprising that the Commission has pursued its industrial policy mandate with some vigour. The result is a Commission interested in reducing intra-Community tariffs and promoting the competitiveness of the EU industry; both as a means of breaching the impasse and in order to ensure a strong European presence in the pharmaceutical arena. However, the sector still suffers from the lack of a singular EU policy direction. Strachan Heppell, former Chairman of the EMEA Management Board, recognised this in a discussion about harmonisation several years ago when he asked whether the industry is "... to be taken in a healthcare context or in a single market context [for] the answer to that question will determine the sort of regime which develops." (Heppell 1994, 44) The Commission may be interested in pursuing the latter, but not only do the member states appear unwilling to support this unequivocally, the approach is in any event insufficient. For the healthcare and single market contexts are not so easily divisible where medicines policy is concerned.

With the problems and issues now laid out, the study can turn to its more specific aims. Towards understanding how the EU regulatory framework for pharmaceuticals developed and why an integrated analytical approach is employed to address the research questions and hypothesis raised in the opening chapter, the next chapter turns to existing theories of European integration and policy-making for some initial and crucial insight. The discussion aims to provide a theoretical perspective on the development of EU pharmaceutical competencies and assesses both the relevance and failings of the more accepted theories in terms of the trade-off in policy interests.

CHAPTER 3

THEORISING THE DEVELOPMENT OF COMMUNITY COMPETENCE IN PHARMACEUTICALS

Introduction

It has been argued that the national level clash between health and industry interests over pharmaceutical policy is not simply mirrored in EU policy-making, but is in fact manifest in the inability to complete the single market. Still, there are numerous Community Directives and Regulations pertaining to medicines specifically. This chapter now turns to the history and 'europeanisation' of pharmaceutical regulation. It aims to show the historical lack of a comprehensive pharmaceutical strategy at EU level, and how, as a result, policies have developed on a somewhat piecemeal basis. The discussion reveals that predominantly market harmonisation motivations rather than health interests have led to the establishment of those measures the EU currently oversees in the sector, and it highlights the incomplete nature of the regulatory framework. The second part of the chapter analyses this within the parameters set by wider theories of European integration and EU (regulatory) policy-making. This is to underline why meso-analysis is crucial to understanding the politics involved in setting pharmaceutical policy at supranational level.

1 The Development of European Pharmaceutical Regulation: A synoptic history

In reviewing this history it is useful to divide it into four phases: i) the initial establishment of Community rules for medicines beginning with the first piece of pharmaceutical legislation in 1965; ii) multiple state market authorisation commencing in 1975; iii) the need to address increasing international competition and the Single European Act of 1986; and iv) an agency approach to facilitating market access since 1995. It should again be noted that this study looks only at proprietary pharmaceuticals designed for human consumption.

1-1 Establishing Community rules for medicines

Casual observation would seem to suggest that the focus of EU pharmaceutical regulation is improving the authorisation process (and promoting the industry's competitiveness). In accepting that national divergence in member state pricing and reimbursement regimes precludes harmonisation, recent analysis has turned to improving 'time to market' (TTM) periods for new drugs, and much of the commentary on the European Medicines Evaluation Agency's work of the last seven years has sought to assess its performance in

this regard⁵⁷. Although reviews of the agency have generally been positive, as will be shown later, not everyone shares this perception. Nevertheless, all this industrial policy attention belies the fact that it was a health disaster which initiated the member states' (and hence Community's) interest in medicines regulation. As mentioned in the opening chapter, the *Thalidomide* tragedy crudely exposed the need for stricter medicines testing and market authorisation mechanisms.

In September 1963 the European Commission convened a meeting of industry representatives, trades union officials, pharmacists, doctors and consumers to discuss the prospective harmonisation of national pharmaceutical legislation. However, disagreement over whether proof of a drug's 'therapeutic potency' was a necessary criterion for market authorisation meant that no consensus was reached. As the Commission noted in its subsequent press release: "... the doctors', pharmacists', consumers' and trade union representatives took the view that the requirement was indispensable. The representatives of the industry... disagreed." (CEC IP 1963). Notwithstanding this early hiccup, Community guidelines for the sector, and rules for medicines registration in particular, were an inevitability as European policy-makers sought to bring their countries closer together under the common market. Indeed, two years later, in addition to having established stricter guidelines at home, the six member states of the European Economic Community (EEC) agreed to Community-wide controls and standards.

Directive 65/65/EEC was the earliest piece of Community pharmaceutical legislation. It represented the first official recognition of the need for a separate policy area for medicines, and lay down two important definitions. A medicinal product was defined as:

... any substance or combinations of substances presented for treating or preventing disease in human beings or animals or any substance or combination of substances which may be administered to human beings or animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings or animals.

And it deemed a proprietary medicine as "...any ready prepared medicinal product placed on the market under a special name and in a special pack". These definitions have been at the heart of all Community drug legislation since. Equally important were the rules regarding the development and manufacture of medicines which the Directive set out, along with guidelines for post-market monitoring of drug safety (pharmacovigilance). As these were agreed within the context of the free movement principles of the common market, rules for market authorisation were also elucidated. It was stipulated that a product would be granted market authorisation only if it was accompanied by

⁵⁷ For instance Walsh (1999) or Hennings (2000).

documentation indicating the product's safety, efficacy and therapeutic benefit, as verified by the signatures of accredited experts. The Community was thus setting out the criteria against which the safeguarding of public health was to be measured in order for a drug to be launched. Accordingly, European industrial policy interests were to be balanced against national health policy concerns. And though some member states initially baulked at the use of the 'proven therapeutic benefit' criterion on the basis that it was too strict (Hancher 1990), the proposal was eventually accepted in 1965.

Importantly, the Directive established the precept that medicinal products could not to be released onto the market of another member state without the prior agreement and authorisation (by a relevant public medical authority) of that state. It also set forth the Community's original guidelines for the authorisation of medicines with respect to quality, time requirements, and decision-making procedures. The emphasis was decidedly on product safety and efficacy first, rather than market concerns. The Community's initial move into pharmaceutical policy was thus a common health threat, which prompted a proactive approach fully endorsed by the member states.

1-2 Early European authorisations

With the basis laid, and progress on tariff elimination in other sectors progressing, the Commission's next step was to facilitate intra-Community movement of medicines. Two new pieces of legislation were introduced in 1975. Directive 75/318/EEC created the so-called mutual recognition or Committee for Proprietary Medicinal Products (CPMP) procedure, whereby a product that had been granted market authorisation by the regulatory authority of one member state could be then granted multiple authorisations to other member states' markets. Prior to 1975 applications had to be made separately to each national authority. Directive 75/319/EEC set forth the original Community rules governing the conduct of clinical trials towards product quality and safety, and harmonised "... conditions for granting manufacturing authorisations, based on the principle of mutual recognition of national authorizations." (Hankin 1996, 9) Where a product had been tested subject to these requirements it was then valid across the entire Community without the need for the individual member states to carry out their own tests.

Further, the Directive established the CPMP. Comprised representatives from each member states, it was to act as a single authorisation body for the EC market, reviewing all drug applications on the basis of the Community's safety, quality and efficacy standards. Following this review, the Committee would issue an opinion on marketing approval. The Committee was also to arbitrate should a member state object to a product being granted automatic access to its market via the new procedure. However, despite being a "...

landmark in European medicines harmonisation [which] attempted to alter the market behaviour of pharmaceutical companies" (Lewis & Abraham 2001, 62), the CPMP procedure did not fulfil its desired role.

First, the Committee's opinions were only advisory and member states could choose to ignore them; which they generally did. Second, the sensitivity of healthcare concerns to national governments and the resulting derogation to the free movement rules under Article 36 (now 30) of the Treaty – where products could have potential negative health effects – meant that the new rules did not speed market authorisation as envisaged. In fact, the procedure caused major delays as the member states regularly raised objections. Quite simply, the national governments were unwilling to accept each other's assessments.

The Commission sought to overcome this via amendments to the mutual recognition route. In 1983 Directive 83/570/EEC introduced the multi-state procedure under which the minimum number of countries to which authorisation would be extended was dropped from five to two. Manufacturers were no longer bound to seek approval in more than two markets unless they so chose. Although more successful than its predecessor in terms of the number of applications submitted (Mossialos & Abel-Smith 1997), the multi-state procedure also proved cumbersome. In 1994, its final year of operation, objections by one or more member states were registered for every product put before it (CPMP 1994). Although the Directives made a point of underlining that health matters were of primary concern, there was no hiding the fact that they were more aimed at progress towards a unified medicines market. This would become the Commission's main agenda for future initiatives, especially following the Single European Act in 1986⁵⁸.

A divisive issue to emerge during this period was parallel trade in medicines. Beginning in the 1970s it had become widespread by the mid-1980s (Macarthur 2001) and has continued since. Price differentials were up to 10 times between EC countries in the mid-1980s (BEUC 1989), and European wholesalers and sellers of bulk pharmaceuticals became active parallel traders. The development of this *arbitrage* met with different reactions. Some member states supported it for the healthcare savings it brought, while others disputed it as it damaged local industry. Consumer and patient groups were in favour as the practice ensured cheaper and quicker access to high quality medication, while those companies whose products were being 'parallel traded' opposed it because of the lost earnings it carried. With the practice burgeoning, it was contested before the European Court of Justice on numerous occasions, and was essentially sanctioned by the

⁵⁸ From 1986 onwards, legislation pertaining to the manufacture, assessment, and sale of various other types of medicinal product were also set down, each by separate Directive e.g. immunological products, veterinary products, homeopathic products, etc.

Court in the seminal *de Peijper* case of 1976. The ECJ ruled that national medicine licensing rules were not to be regarded as a restriction on intra-Community movement until full market harmonisation in pharmaceuticals was attained⁵⁹. This position has not changed, and has been given more scope in several rulings since then (see Chapter 7).

1-3 The Single European Market programme

The Single European Act (SEA) of 1986 re-ignited the integration process following the 'eurosclerosis' of the 1960s and 1970s⁶⁰. It elaborated a vision to establish a Single European Market for the free movement of all goods, services and capital by 1992. This was the Community's response to the need to compete more effectively in global markets, especially with the US and Japan setting up free trade areas of their own. Despite derogations again pertaining to sensitive areas such as public health and national security, the single market measures laid down by the SEA demanded member state compliance. Policy decisions thus came to be taken within the context of meeting the 1992 deadline.

In 1986 the Commission asked a retired Commission official, Paolo Cecchini, to lead an investigation into the costs of 'non-Europe'. This was to underline the benefits of a single market. Despite its optimism with regard to the market liberalisation process, the Cecchini Report, published in 1988, pointed out areas which required attention. In an echo of the 1985 White Paper, pharmaceuticals were cited as a problem given that they were "irretrievably linked to public health". Nevertheless, with the 1992 deadline looming it was clear that future regulatory decisions for medicines would now be taken under the auspices of the SEM rather than on the basis of public health requirements. Just as the push towards the single market has affected the nature of Community health and healthcare competencies⁶¹, so too has it impacted on pharmaceutical policy.

In 1987, once more with a view to rationalising the authorisation process, Directive 87/22/EEC was agreed. This represented a major departure by the Commission from its previous approach to regulating the market. The Directive created a new process known as the concertation or centralised procedure, and was applicable only to biotechnologically-developed and other 'high technology' products. Manufacturers were obliged to simultaneously submit their applications to the CPMP and one member state (the intended market). Once both had completed their evaluations, together they facilitated discussions between the applicant and the other national authorities regarding access to their markets. This meant that the "... competent authorities [were required] to consult with each other

⁵⁹ Case C-104/75 *Officier van Justitie v. De Peijper* [1976] ECR 613.

⁶⁰ 'Eurosclerosis' refers to the slowdown in measures to facilitate European integration from the mid-1960s through the late 1970s which followed the 'empty chair' crisis of 1965 (see Section 2-1).

⁶¹ For a discussion see Theofilatou & Maarse (1998).

systematically within the framework of the CPMP, from the moment an application was received." (Hankin 1996, 11) Although biotechnology is not part of this study, the Directive's mention here is to underline the Commission's agenda. For with biotechnology at the time an emerging field, the Commission was seeking harmonised standards before they had even created (Vogel 1998). This was with a view towards 1992 and the resultant need for a single evaluation procedure. Second, by limiting the products subject to this procedure, the Commission sought to allow a more general transfer of regulatory authority from the member states to the Community (Friedel & Freundlich 1994). The member states were thus not so much losing authority as the Community was gaining it.

Also important in the post-SEA period was the still-troublesome question of parallel trade; now in terms of a future single market. Price divergences between the member states on single products of up to five times in late 1980s (Chambers & Belcher 1994) had only consolidated the practice. Furthermore, via rulings in cases such as *Stephar* (1981)⁶², the ECJ continued to permit it. In this somewhat unsettled environment, Directive 89/105/EEC, the 'Transparency Directive', was passed. This required the member states adopt "transparent, objective and verifiable criteria" in setting medicine prices and their inclusion in national health insurance systems (see case-study in Chapter 7). Further legislation pertaining to labelling and packaging, advertising and sales promotion, and wholesale distribution followed⁶³, all taken within the context of meeting the provisions of the SEM.

So too were intellectual property rights for medicinal products legislated for during this period. In 1992 Regulation (EEC) 1769/92 – the Supplementary Protection Certificate – (SPC) set down details of a certification of extended patent protection for those drugs deemed to have had too short a period of coverage compared to the costs of their development (see case-study in Chapter 5). Despite the Community passing exceptional patent protection for medicines, and the other single market-related policies already mentioned, it was unable to tackle the issue of pricing. Its proposals for a second or at least amended Transparency Directive were shelved in 1992 due to the lack of member state support. The intractability of the pricing issue – in terms of at least reducing intra-EU price (and product) differentials – led in 1996 to the publication of a Communication on the development of an official EU 'industrial policy' for pharmaceuticals⁶⁴. Agreed after several years of negotiation, the publication of the Communication was another major turning-point. It represented an acknowledgement by the Commission that there still remained considerable barriers to market harmonisation and that the requirements of the single market were not being adequately served (see Chapter 7).

⁶² Case C-187/80 *Merck v. Stephar* [1981] ECR 2063. See Chapter 7.

⁶³ Directives 92/27/EEC, 92/26/EEC, and 92/25/EEC.

⁶⁴ Resolution 96/C136/04.

Eight years prior, the Cecchini Report had concluded that "...[regulation of] the market registration procedure for new products and price controls [is] the most important from the standpoint of the European market" (Cecchini et al 1988, 66). Yet, by the mid-1990s there was still no effective centralised authorisation process. The main problem was that the recommendations of the advisement board were not binding under either the multi-state or concertation procedures, and unanimity was seldom. Because of the failure of the former in particular, the Commission instigated a series of extensive consultations from the late 1980s onwards regarding the need for a new, and more independent authority capable of binding decision-making. The end-result, some five years later, was the institution of a Community medicines agency designed to function as a centralised authorisation office for medicinal products in the single market. Despite little real progress on further 'europeanising' the market since the Communication and EMEA, it is clear that the SEM had a major influence on the direction of EU pharmaceutical policy.

1-4 An agency approach to market authorisation

Established in 1993, the European Medicines Evaluation Agency represented the coming to fruition of many years of political 'wheeling-and-dealing' over medicines and the single market. Governments, consumer/patient groups, and various sectors of the industry were all, at different stages, involved in the negotiations. Ruling on applications for market authorisation, the agency is mandated the task of product assessment and approval for all prospective new medicines aimed for the European market. Complementary to the EMEA was Directive 93/39/EEC under which the multi-state procedure was replaced by a 'decentralised' procedure via which applications are made directly to the agency. The new rules are much along the same lines of the multi-state avenue though in this case the decentralised procedure is binding. Member states are only able to query the agency's authorisation decisions on the grounds that they can be shown to have a negative public health impact on their populations. The CPMP is again the arbiter where a member state may disagree with the agency's decision, though applications rarely get this far.

Seven years since its launch and debate about the agency continues. Although it has already contributed to addressing the range of issues associated with pharmaceuticals and the single market, in looking at much of the literature on the EMEA, one could be forgiven for thinking that its role lies simply in the issuing of market authorisations for new products. This, however, is only the final step in its wider remit decide on which drugs are safe, efficacious and of high enough quality to be granted market access. Still, the agency is not – as some originally thought it might become – a European version of the US Food and Drug Agency. First, it is not responsible for anything beyond therapeutic medicines. Second, it lacks the FDA's executive powers i.e. the ability to penalise any derogation from

or misapplication of its rules. Further, healthcare considerations (i.e. pricing) are beyond its remit, and its relationship with industry has been much-criticised (e.g. Abraham & Lewis 2000, Garattini & Bertele 2001). And unlike the FDA, which is a federal body, the EMEA regime co-exists with national procedures. It does not replace them. Still, given the clout it carries in terms of the Commission acting on its recommendations, it does represent the only quasi-regulatory body of its kind in the EU.

As will be shown in Chapter 6, the rationale for the agency's creation are not entirely clear. The reasons cited by the Commission at the time of the EMEA's inauguration in 1995 were not those invoked during discussions in the late 1980s when the plan for a medicines agency was still in its formative stages. What should be borne in mind here, however, is that since the SEM and the creation of the agency, there has been a new decision-making approach for medicine policy in the Community. The use of a US-style regulatory agency reflects the acknowledged need by both the Commission and the member states for independent regulation of industrial sectors within the single market. While the actual operations of the EMEA will be analysed later, its inclusion in this history serves to indicate the direction of Community objectives regarding pharmaceutical regulation.

1-5 The 'europeanisation' of medicine policy – lack of a coherent strategy

At this stage of the discussion, two things are clear. First, the history of EU pharmaceutical regulation reflects an uneven pattern. The earliest medicines legislation was passed in 1965 in the wake of the *Thalidomide* tragedy and addressed public health concerns. Since then most competencies have fallen under the industrial policy frame, having been enacted under the single market programme. Second, while the SEM may have prompted much policy (from the Commission), a considerable amount of policy has been generated by other factors. Obligations under international trade regime agreements like the GATT have meant loosening the national protection of industry. And mounting pressure to address the question of affordable access to medicines for the world's poorer countries has seen the member states recently agree to the suspending of drug patent rights in the case of a public health emergency. Other European institutions have also had a hand, even if indirectly, in shaping the regulatory framework as it currently exists. Most notable has been the role of the ECJ which, through various judgements in relation to healthcare, competition and the free movement principles, has fundamentally affected the policy environment in which pharmaceutical policy is set.

As a result, despite Community involvement in pharmaceutical regulation since 1965, there has not been a consistent strategy. There have been major steps forward in grounding EU-wide standards in some areas but stalemate and even backward steps in others.

Because pricing and reimbursement remain national level concerns, the result for the Commission is a 'mixed bag' of competencies with an ability to legislate primarily over industrial policy concerns. This is in comparison to related sectors such as biotechnology or medical devices where the Community's history may be comparatively shorter, but reflects a clearer purpose with wider powers (Altenstetter 2001). The lack of a singular strategy has also meant that policy developments have been somewhat reactive in response to particular requirements or obligations. Competencies have been added as necessary or even, as the case-studies will show, when pushed for by specific actors.

This section has shown that pharmaceutical policy does not have a truly clear status within the Community's range of competencies. In order to make sense of this in some consistent manner, the discussion now turns to academic treatment of the integration and policy-making dynamics in Europe. The question to bear in mind is whether they are sufficient to explain the stop-and-start development of the EU regulatory framework, and to see if they help to explain how and why the industry is the main beneficiary of the regulatory regime as this study argues.

2 Medicines and Traditional Integration Theory

In consulting theories of European integration and policy-making, discussions and ideas can be found which are helpful towards understanding this history in terms of where and why specific pharmaceutical policies developed in the EU. These relate to both the macro- and meso-levels. This acknowledges the important and meaningful distinction made by Hix (1994) between theories of European integration in *stricto sensu*, and what he identifies as the 'politics of the EU policy-process'. Beginning with the former, neo-functionalism and intergovernmentalism, as the two main theories of European integration, offer some initial and important insights.

2-1 Neo-functionalism: Pharmaceutical policy and 'spill-over'

Depending on their point of departure, the early European integration scholars of the 1940s tended to follow one of two main lines. The federalists and functionalists were led by the visions of Jean Monnet and the work of Mitrany (1966) respectively. Their focus was on the end-product of integration, that is, what form the integrated Europe should take. The transactionalists meanwhile, headed by Deutsch (1966), sought to understand the conditions requisite for political integration to be in the first place possible. Both approaches served to generate the academic debate that would later culminate in the development of neo-functionalism as the then leading theory of European integration.

During the 1950s and 1960s, as a critique of deficiencies in the earlier functionalist conception, neo-functionalism became the theory of choice, particularly amongst American social scientists with Haas (1968) at the fore. By combining the competition element in the political process of traditional pluralist thinking with the (necessarily) gradual nature of political change understanding proffered by Mitrany, the neo-functionalists sought to show how the European political process was as much dependent on political action as economic determinism. Central to this was disproving the functionalist idea that a meaningful and lasting distinction could be made between policies involving functional or technical questions, and those which were more political or constitutional in nature. Pharmaceutical policy proves the point given its inextricability from the healthcare context. For while other industrial commodities and sectors may, from the EU standpoint at least, comply with the functional/technical category (i.e. where economic interests are concerned), medicines do not. The market remains unharmonised precisely because of political factors. The health and industrial policy implications mean that pharmaceuticals are both a functional (political) and technical matter, and member states are therefore particularly sensitive where any European policy is concerned.

Nevertheless, neo-functionalism does, initially, prove useful in terms of explaining the impetus behind how the Community framework for pharmaceutical regulation developed. What is arguably its best-known premise, the concept of 'spill-over' – where Community authority develops or evolves as a result of policy developments in related fields – is particularly relevant. Central to the spill-over premise was that the integration process would prove self-sustaining. Developing this idea as an inheritance from Mitrany, the neo-functionalists attempted to gauge the relevance and role of the new European Community institutions in the integration process. They argued that as supranational constructs, these new bodies could (and did) foster integration of their own accord. And while the role of the ECJ as guardian and instigator of Community law (superseding national legislation via the principle of 'direct effect' and the doctrine of supremacy) may have been the embodiment of this idea, some member states were not entirely comfortable with a dynamic that they felt they might not be in control of. In this vein, the Luxembourg Compromise of 1966 represented a watershed and put paid to any illusions those who sought a federalist European 'super-state' might at the time have had.

The Compromise followed French President de Gaulle's precipitation of a constitutional crisis over the use of qualified majority voting for decisions affecting the common market. The 'empty chair' crisis, when France refused to take its seat in the Council, culminated in agreement on the need for unanimity to pass legislation in instances where "very important [national] interests are at stake". Along with defence and national security, health and welfare policy fell within this qualification. Bound to national healthcare systems and social

security budgets, pharmaceutical policy is also an issue of important national sensitivity and interest. Without engaging the specifics of the Luxembourg Compromise – especially as it has not frequently been invoked – it served to underline that the integration process was not self-sustaining without member state support. Later, however, with the SEA of 1986 the integration process was revived and a new brand of spill-over emerged. This related to establishing a common European market by 1992.

The SEM demanded the elimination of inter-Community tariffs and other access to market barriers, towards creating an arena for the free movement of goods, persons, services and capital. Despite the 1992 deadline having long since passed and there still being no single medicines market, it was earlier shown that most aspects of the Community's regulatory framework can in fact be attributed to the pursuit of the SEM. Many Community medicine competencies thus evolved as spill-over from other provisions relating to the '1992 programme'. As Table 2-5 showed, legislation pertaining to the standardisation of packaging guidelines for medicines, the type and manner of presenting information on package inserts/leaflets, and common rules on the advertising of medicines, all reflect priorities related to the single market. Thus, the idea of integration taking place in small steps where "... pressure in one sector could demand integration (or changes in standards) in order to complete the process of policy change" (Church 1996, 17), not only coincides with efforts to establish a single market for medicines, but in fact defines much of the regulatory framework. Neo-functionalism, and spill-over more specifically, thus goes some way to explaining how the single market programme came to dominate the Commission's approach to pharmaceutical policy during the 1990s.

Nevertheless, spill-over is not the sole influence on the EU's competencies in the sector. As cited several times so far, important questions relating to both the pricing and reimbursement of medicines have not been addressed at EU level. This gap in supranational policy makes it clear that the member states retain a considerable degree of autonomy where important national interests are concerned. It was established in the previous chapter that this lack of progress can be attributed to the explicit exclusion of healthcare matters from Community competencies under the Treaties, and that Article 152 of the Amsterdam Treaty was penned at the request of the member states. Neo-functionalism may explain developments within the industrial side of the policy dichotomy, but it cannot explain why the national governments pursued this line; nor indeed why SEM spill-over did not flow into pricing and reimbursement competencies. That European integration does not succeed without member state support – that spill-over is not an unchecked momentum generated by the European institutions – is one of the key tenets of intergovernmentalism as the other classical theory of European integration.

2-2 Intergovernmentalism: No Community role in healthcare

Developed out of the realist position in traditional international relations theory with Hoffmann (1966) as its leading proponent, the intergovernmentalist perspective evolved as a critique of neo-functionalism. It offers a check on the spill-over idea by showing that the member states, particularly via the policy-making structure and procedures of the Community, remain firmly in control of both the pace and direction of integration. There are numerous variations on intergovernmental theory⁶⁵, but the discussion here keeps within a basic understanding which asserts the pre-eminence of the member states over the Community institutions in the integration process. This is not to underplay the relevance of the institutions, for there is an increasingly impressive body of 'institutions matter' literature; particularly under the banner of 'new institutionalism'⁶⁶. Rather, it is to simply accept that the member states are the primary actors in the integration process.

As considerable a simplification as this is, relating it to pharmaceutical policy reveals several important points. First, that the issue of national self-interest may help to explain why the member states have not devolved the healthcare aspect of medicines regulation to Community authority i.e. why subsidiarity plays such a major role. Governments are neither practically nor ideologically prepared to have the EU legislate over national healthcare structure and spending as would be required of a single medicines market. It is for this reason that the member states insisted on the exclusion of healthcare from Community competencies at the 1996 Intergovernmental Conference (IGC) in Amsterdam. The unambiguous language of Article 152 of the Amsterdam Treaty compared to that in the Maastricht text (ex 129), makes clear the strength of their resolves.

Hoffman's (1966) distinction between high' and 'low' politics matters also provides a useful backdrop to understanding the place of pharmaceutical policy. The former encompasses security, defence and foreign policy, while the latter is concerned with welfare and economic policy. The division was designed to reveal the limits of the neo-functionalism premise that integration was a self-sustaining dynamic. The argument was that it could not be taken as a foregone conclusion that the member states would accept integration in areas of high politics simply because they were more or less agreed on low politics concerns such as single market tariff elimination and any social policy implications. In terms of positioning pharmaceutical policy in this division, it might initially seem to fall within the low politics category, as a welfare matter; especially since, as was observed

⁶⁵ For a discussion see Haltern (1995).

⁶⁶ A growing stream in political science which reasserts (through redefinition of) the role and place of 'institutions'; that which includes structures, treaties, legislation, etc. Policy-making does not simply take place via such institutions as neutral vehicles, but rather they contribute to the policy environment, thereby affecting outcomes e.g. Armstrong & Bulmer (1998), Checkel (1998), Bulmer (1997, 1998) or Warleigh (2001).

prior to the Maastricht Treaty: "In sum, health is an EC-policy of minor priority." (Leidl 1990) Yet, given that intergovernmental co-operation towards achieving common policies is to be expected in areas of low politics (e.g. the single market), why then does the pharmaceutical market remain incomplete? The reason is that while healthcare concerns may be a 'low' political area for the Community, they are in fact a 'high politics' area for national governments. Consequently, there *is* intergovernmental agreement. It is simply with regard to *not* mandating the Community a wider role rather than doing so. Community pharmaceutical policies exist, therefore, where economic priorities are at stake (low politics) but do not involve the exercise of executive powers over areas such as the pricing and reimbursement of medicines (high politics). This reflects the policy clash which lies at the heart of the sector. As such, a competence division exists over pharmaceutical policy on two levels. Not only does it remain a shared responsibility between the Community and member states, but the EU has to-date only been able to legislate in areas relating to industrial policy. According to intergovernmentalist thinking then, it ought not be surprising that medicines policy remains in large part a national level concern.

This competence-sharing can also be seen as the manifestation of European law being supranational and European policy-making being intergovernmental (Weiler 1994). The national sensitivity of health and healthcare means that governments are cautious with respect to any expansion of the EU's competencies. Meanwhile, as European legislation on the single market aspects of the sector finds its constitutional basis in the Treaties, much of it supersedes that of the member states. Infringements against Treaty stipulations can result in sanction, though the development of EU policies/competencies within the framework set down by the Treaties first requires each member state to agree in the Council of Ministers. Pharmaceutical policy finds itself in the grey area of the middle given that its industrial policy side fits within the SEM and is therefore supranational, while its healthcare aspects ensure that it remains an intergovernmental matter.

Two important points are to be noted from the discussion. First, neo-functionalism spill-over is perhaps more intuitive than it is empirical. According to Pollack (1997), It has not been shown to generate testable hypotheses regarding the conditions under which supranational institutions exert an "independent causal influence" on the integration process. Institutions may indeed matter in the integration and policy-process, but neo-functionalism theory is not really able to go beyond suggesting a *de jure* link between them. Second, the intergovernmental focus on member states pursuing self-interested goals may serve to elucidate their behaviour in the integration process, but does not necessarily explain policy outcomes. And where both theories are deficient is in accounting for non-EU factors i.e. circumstances which exert integrationist pressures from outside the immediate Community

frame i.e. where policy decisions are taken neither on the basis of 'simple' member state self-interest, nor the result of an inherent supranational dynamic.

2-3 Liberal intergovernmentalism: Domestic priorities and supranational policies?

Recognising this common failing, more recent work has focused on how member state agendas are shaped. Here, the liberal intergovernmentalist perspective generally accredited to Moravcsik (1993) concentrates on links between national decision-making and international co-operation. The intergovernmental accent on the member states is taken one step further with the very idea of supranational decision-making questioned. As a two-pronged approach, liberal intergovernmentalism is a "... liberal theory of how dependence influences national interests, and an intergovernmentalist theory of international negotiation" (Moravcsik 1993, 474). It sees integration from a demand and supply perspective. The former results from member states' domestic priorities while the latter is manifest in bargaining at the EU level. Moravcsik's premise is that "An understanding of domestic politics is a precondition for, not a supplement to, the analysis of strategic interaction among states" (481) for the member states do not have fixed preferences as these change just as governments change. And as the priority for any government is to remain in office, this influences the demand side in any given intergovernmental bargaining on the supply-side.

In arguing that national governments are the main actors, they may be motivated to co-operate in the pursuit of further integration because of a combination of externalities and particular internal circumstances which affect them all. More specifically, common goals, although deriving from differing national circumstances, may promote integrationist tendencies. Because of this, "... fundamental decisions in the EC can be viewed as taking place in a non-coercive unanimity voting system." (Moravcsik 1993, 498) Here, one can look to the pressures exerted by the global trade liberalisation regimes of the GATT, and now the World Trade Organization (WTO) on domestic politics. Or else, it may in part be because of the local effects of negative externalities such as air and water pollution that member states have agreed EU environmental standards. Pertaining more specifically to pharmaceuticals, the International Conference on Harmonisation (ICH) – which aims to negotiate common standards for the regulation of pharmaceutical preparations in Europe, the US and Japan, with a view to speeding the market approval process – exerts a pressure on European governments both individually and within the context of the SEM. The ICH is co-sponsored by the national regulatory bodies and medicines manufacturers' trade organisations in each country. So too does the Pharmaceutical Inspections Convention (PIC) push for common policies – towards the mutual recognition of inspections of pharmaceutical manufacturing companies.

In other words, EU governments are willing to pool effort towards further integration, both in order to fulfil domestic requirements and as manner of consolidating their position relative to each other. They are agreeable to the concession of authority over issues where they feel the Community is more likely to be able to conserve their interests – particularly in a redistributive and equalising manner – with the single market being the prime example. At the same time they remain steadfast over issues where national interests are at stake. Applying this again to medicines, since member states accept that certain aspects of policy – such as market access and advertising (i.e. those matters relating to the single market) – are better regulated on their behalf by the Community, there is intergovernmental co-operation. Other areas which are more sensitive, such as the pricing of medicines, they continue to guard jealously. That national governments may share objectives which are driven by domestic impetuses is relevant to medicines policy in that all countries may be agreed on not conceding pricing and reimbursement to the Commission, but their reasons stem from domestic factors. Their respective lack of interest in a consolidated single medicines market – and indeed the variance in their support for specific initiatives – are based on individualistic concerns. These may in many respects be common concerns e.g. cost-containment, but they are not necessarily shared given each country's particular requirements.

Where Moravcsik's assessment flounders, however, is the degree to which it minimises the role played by the European institutions. Although there are other critiques of the theory, this is the main one⁶⁷. In their examination of the Single European Market, Armstrong & Bulmer (1998) argue that Moravcsik's original work reduces the part played by the European Parliament, the Commission, the European Council and the European Court of Justice (30-33). They also note his neglect of the burgeoning comparative politics literature on how actors' agendas are shaped, arguing that "... there is a danger in Moravcsik's analysis that it overly rationalises the negotiation process through a reductionist emphasis on the role of national governments." (33) These criticisms are relevant to the emergence of EU medicines regulation as well. As the later case-studies will show, the European institutions have played a considerable part in developing the regulatory framework. Moreover, medicines policy cannot simply be slipped into a two-level analogy. Specific regulatory policies may be shaped by national circumstances, which member states seek to protect at EU level. But common health threats and wider duties regarding (public health) criteria for market authorisation medicine testing interest all member states equally.

⁶⁷ See for instance Rosamond (2000), 136-147.

On their own, therefore, the neo-functional and intergovernmentalist theories are incomplete in accounting for the development of EU pharmaceutical policy⁶⁸. While the former (spill-over in particular) is relevant to understanding the economic rationale and industrial policy nature of the majority of Community pharmaceutical policy (single market-related), it fails when the healthcare aspect is invoked. The latter can explain why healthcare policy concerns, including pricing, remain a sticking-point, but does not necessarily explain policy outcomes. And the 'liberal' version can (to a degree at least) account for exogenous factors such as the ICH in influencing integration and member state co-operation, but cannot sufficiently account for the roles of the ECJ and Commission in shaping the framework; nor why the EMEA has a remit which goes beyond industrial policy functions to include elements of public health policy. The reason these are not decisive is that although macro-theories are germane to 'history-making' decisions, they 'tend to lose their explanatory power' when it comes to policy decisions (Peterson 1995, 84).

Nevertheless, as "Integration is an inherently dynamic, expansionary process which serves, amongst other things, to construct and reconstruct the contexts in which governmental choices and intergovernmental bargaining takes place" (Stone Sweet & Caporaso 1998, 119), they do establish certain over-arching characteristics of Community policy-making. As this is particularly with respect to where and when the EU is able to act, they are useful in relation to the pharmaceutical sector. So although offering only a fleeting consideration of European integration theory, the discussion has served to contextualise the development of EU pharmaceutical policy from a wider perspective.

2-4 Multi-level governance and contemporary perspectives

Because of this lack of explanatory power, and particularly since the Maastricht Treaty, there has been a shift away from the broader perspectives proffered by the neo-functionalists and intergovernmentalists. Notwithstanding liberal intergovernmentalism, the focus has become more specific and inward-looking. The internal dynamics of the Community polity have become an area of considerable academic discourse e.g. the 'agenda-setting' role of the European Commission (Peters 1996); interest group activities in driving policy (Mazey & Richardson 1993); and the *de facto* integration role of the ECJ and European legislation (Wincott 1996). Much contemporary work has also focused on the role of specific institutional actors – the question has often been to what extent Parliament, the ECJ or the Commission push an integrationist agenda in their own right.

⁶⁸ It is acknowledged that since macro theories delineate the pattern and impetus for integration, neither neo-functionalism nor intergovernmentalism makes any claim to be able to explain all elements of EU policy-making. As already mentioned, Hix has pointed to the need to differentiate between the 'politics of the EU policy process' and theories of European integration.

This reflects an acceptance of the EU as a new system of governance⁶⁹, and one which does not readily lend itself to any singular theoretical categorisation. More importantly, it also acknowledges Hix's distinction between the process of European integration and the 'politics of the EU policy-process'. There has generally been a renewed focus on the Community institutions – new institutionalist theory – though in a more explicit and less assumed manner than expressed under (neo-)functionalism.

Much attention has recently been paid to an emergent form of governance in the EU based on subnational dynamics at European level⁷⁰. The most widely-cited of these perspectives is multi-level governance. It forwards the notion of a blurring between domestic and international politics wherein the Community plays the lead role by fostering co-operation between member states. They "share... rather than monopolise, control over many activities that take place within their respective territories." (Marks et al 1996, 96) The EU is treated as a *sui generis* form of policy-making which breaks with traditional levels of analysis⁷¹, resulting in Hooghe's (1995) conclusion that "The European polity has come to resemble multi-level governance much closer than either the state-centric or supranational model." (33) This view sees Community policy-making as "... a series of multi-level games fought out between an increasingly large number of policy actors – public and private – who exploit the many opportunities presented by different policy arenas..." leading to the conclusion that "... there is some kind of internal dynamic which has the capacity to generate new policy proposals over time." (Richardson 1997, xi) This is in place of an all-encompassing theory and, since it highlights the role of national and subnational actors, it focuses on the policy-process. It is at the level of policy analysis that the evolution of EU pharmaceutical competencies can be best understood, and this 'multi-level' view thus relates to the regulatory framework. It accommodates the argument that medicines regulation at EU level results from the interplay between many actors spanning both the healthcare and industrial policy communities, all of whom are embedded in the policy process in a manner not typical of other industries.

Critiques of this internal gaming view of the EU polity centre around multi-level governance offering a good description but being limited in terms of offering an explanatory or analytical perspective (Pierson 1996). However, such theoretical disagreement is not of concern here. The conception of the EU as a new form of governance is of interest insofar as it *is* descriptive. This captures the dispersal of power within EU policy-making and accommodates that there are a host of subnational actors beyond the Community

⁶⁹ For instance Sbragia (1991), Peterson (1995), and Scharpf (1999).

⁷⁰ The governance conception of policy networks relates to this 'multi-tiered' governance conception of EU policy-making and integration (see Börzel 1997a,b).

⁷¹ For instance Marks et al (1995), Risse-Kappen (1995, 1996), Cram (1996), Héritier et al (1996), Kohler-Koch (1996), and Richardson (1997).

institutions and member state agencies which are also involved in the pharmaceutical policy-process. In other words, that it is not a simple case of intergovernmental bargaining. Consequently, it is the fact that such a criss-crossing of actors and interests does characterise the policy-process – not whether or not this amounts to a predictive view thereof – which is relevant.

A more detailed examination of multi-level governance or these newer approaches is beyond the purposes of this study. What should be noted is that they all relate to specific levels of *policy analysis* rather than singular theoretical explanations. For it is the inability of macro-level analyses (integration theories) to offer explanatory insight into EU policy *vis-à-vis* medicines which has led to this study's use of a policy-making frame of analysis. Accordingly, the next element of the discussion is how the EU regulates or sets policy within the multi-level governance conception. This provides further insight into how EU regulatory competencies for medicines have developed.

3 Regulatory Policy in the EU: Medicines and the 'regulatory state'

The continuing 'encroachment' of Brussels into many areas of national public policy has EU regulation become an area of much academic work. In particular, the Community's shift from 'simply' controlling the economic reins of the single market to exercising a role which encompasses wider and more complex social policy responsibilities has generated much of the research (Majone 1996). For while this progression may fit with the spill-over logic of neo-functionalism, it might at the same time seem somewhat strange from an intergovernmentalist point of view in light of the widespread feeling amongst many European citizens and politicians that Brussels already has too much power. How this transfer of authority could have taken place when – at least publicly – so many national politicians are keen to keep the 'Eurocrats' out of domestic affairs, is a question several scholars have sought to investigate. The practice of regulation in and by the Community has been central to the integration process, especially since the SEM.

3-1 The practice of regulation in the EU

The increasingly broad nature of EU regulation can in part be traced to the long histories of the European state being responsible for not only the prosperity of the market through public ownership of enterprise and centralised administration, but also for social control. It is a tradition that helped give rise to the European welfare democracies which emerged in the post-World War II era, and which many countries are now struggling to maintain. This European approach is distinctly opposed to statutory regulation in the United States. The American model involves the use of independent, autonomous agencies which exercise

legislative and administrative functions beyond state control. In keeping with the American *laissez-faire* approach to business, these multi-functional agencies have been employed to ensure the correct functioning of the market. So while American regulation has developed primarily as a means of correcting market failures through a restrained state function, in Europe the state has been at the heart of macroeconomic stabilisation by serving a redistributive function in society.

Looking at the EU model which is emerging, it would seem to incorporate aspects of both American and European practices. For while on the one hand Community regulation involves a direct hand in the operation of the single market and, as a result, certain social responsibilities as well, it is also the case that more recently the EU has turned to a variety of quasi-independent agencies to oversee particular policy areas. Where industry is concerned, the EMEA oversees the pharmaceuticals sector, while for social policy concerns, the European Agency for Safety and Health at Work and the European Environment Agency are models. This is a relatively new trend which mirrors developments in some member states (e.g. France and the UK) themselves.

In light of this changing environment (both supranational and domestic), the in part constricted competence the Community currently exercises over pharmaceutical policy would appear to defy contemporary theorising about the nature of Community regulation. For it is generally held that the jurisdiction of EU regulation is not simply bound to the economic aspects of the single market⁷². Instead, given the Community's unique status, the perception has arisen that the EU is predominately concerned with regulation in a broader sense – the Community has been forced to "... embark upon the task of mediating between mainly functional needs of market integration and broader regulatory concerns of the European Polity." (Joerges 1997, 1) More specifically, this view holds that the Commission's role – abetted by ECJ decisions – is predominantly concerned with:

... the shaping of market processes i.e. with defining the conditions for market access and market operation (old or classical regulatory theory); and second with curbing negative external impacts on the public or workforce from productive activities and individual consumption (new regulatory policy). (Héritier et al 1996, 9)

Accordingly, it ought not be surprising that the EU's role has extended beyond an economic remit to cover social areas as well; at least insofar as they are related to the single market. Nor should one be surprised at the ever-growing volume of Community law being generated under this broad-ranging function. Since the 1960s there has been a marked proliferation in Community legislation such that the yearly increase in the number of new Directives and Regulations in the EU (binding legislation) has been referred to as

⁷² For example Majone (1996) and Wallace & Young (2001).

"almost exponential". (Majone 1996, 57) Looking at the EU in this light offers a perspective which can help account for the increasing pervasiveness of Community influence in member state affairs. It is also a view which holds that Community legislation can be equated with more or less the same thing as public policy (Radaelli 1998).

EU regulation is an interesting and challenging area of study precisely because it is not limited to correcting market failures as is the case in the United States. This wider role has given rise to the perception of regulation as a new form of governance (Majone 1994), and helps to explain where Community regulation over medicines has gone beyond simple market-correcting mechanisms.

3-2 The 'regulatory state'

Perhaps the most developed expression of this *sui generis* system of governance is the 'regulatory state' model. First set out by Giandomenico Majone, it has since been given extra depth by other European scholars including Helen Wallace, Alasdair Young and Francis McGowan. The regulatory state shows the development of Community regulation as something distinct from both the American system of statutory regulation and the European *dirigiste* state, though having clearly been influenced by both. It argues that because the EU lacks the means to undertake two of the main functions executed by the executive branch of nation-states – redistribution and stabilisation – it relies on (and seeks to consolidate) its regulatory competencies to establish its authority. Hence, the EU may not be a state *per se*, but via the European Commission it clearly does exercise one of the primary functions of government; and it does so to a greater degree than national governments given the lack of other state-like functions.

Perceived of in terms of a demand-supply configuration for regulatory policy, with the European Commission on the supply-side and organised interests (including member state governments) on the demand-side, the regulatory state model shows how three variables in particular are responsible for the growth of Community regulation. These are:

... the tightness and rigidity of the Community budget; the desire of the Commission to increase its influence by expanding its competencies; and the preference of multinational firms for dealing with a uniform set of rules rather than with [fifteen] different national regulations. (Majone 1994)

This view of how and why EU regulation has developed is applicable to the pharmaceutical industry on two fronts. First, with regard to the (supply) role played by the Commission in establishing the framework as currently exists. And second, the (demand) lobbying of the

Commission undertaken by medicine companies⁷³. This can be seen in the Commission's continuing pursuit of an 'industrial policy' for pharmaceuticals and its attempts to shore up support for addressing the pricing issue within a single market context (see Chapter 7). These can be seen as examples of its desire to increase its authority. That the European Medicines Evaluation Agency serves as little more than a quick route for the market access of their products is also a case-in-point. This is one of the main contentions made in Chapter 6, for the EMEA clearly benefits the industry by acting as a centralised approval procedure which bypasses having to make fifteen different national applications.

The perception of the EU as a regulatory state thus offers a plausible clarification of the on-going proliferation of Community regulation in all fields. First in terms of the extent to which its role goes beyond economic regulation, and second, through the willingness of member states to devolve responsibilities to the supranational level. Because of this, the Community's regulatory competencies continue to grow; although this does not deny that intergovernmental processes are at its heart. Nevertheless, the willingness of the member states to empower the Community in this way – a transfer of economic powers without a complimentary transfer of political powers as noted by Tsoukalis (1998) – means that the regulatory state is in essence a manner of de-regulation at national level. This is not only in instances where the member states feel that the EU may be better placed to oversee certain interests, but also where they are willing to accept EU regulation in order to shirk responsibility or shift the blame over politically sensitive matters.

With regard to the former, Majone (1996) cites the comparatively tenuous nature of traditional international regulatory arrangements between one or more governments as one reason that member states are willing to empower the Community. This is supported by Wilks' (1996) argument that because of chronic budgetary difficulties in the EU – thereby limiting the possibility of developing new spending programmes on a continuous basis – regulation in fact provides the best means by which the EU can make policy i.e. it is a relatively cheap way of making public policy. Unsurprisingly then, most of these new pieces of legislation pertain to the single market. As Héritier's earlier citation alludes to, this is either in terms of extending direct Community control over particular sectors (e.g. telecommunications and transport), or with regard to legislating over externalities which impact on business in Europe (e.g. environmental and working safety standards). As neo-functionalism would predict, it is to a considerable degree spill-over into social regulation.

Pertaining to the latter: "These are the circumstances where European measures are a useful scapegoat, a way of avoiding direct political responsibilities in difficult areas like cutting back industries with excess capacity... or structural readjustment of public finance".

⁷³ For a discussion of lobbying in the EU pharmaceutical sector, see Shechter (1998).

(Radaelli 1998, 5) With the Council of Ministers taking all final policy decisions, this helps unravel the paradox of national politicians complaining over excess bureaucracy being imposed by Brussels at the same time as they invite it in. And it of course reinforces the intergovernmentalist view that the member states are in charge of the integration process.

Negative versus positive integration: Which way for medicines?

Related to the broader theories of European integration and crucial to understanding the Commission's focus on industrial policy for medicines since the TEU, is the wider question of process. By setting 1969 as the date for attainment of a European common market, the 1957 Treaty of Rome invoked the two political dynamics of 'positive' and 'negative' integration. These are relevant to the discussion on Community pharmaceutical regulation as they support the earlier arguments regarding spill-over and intergovernmental bargaining over sensitive policy areas. Furthermore, they can also be tied into the old versus new regulatory policy division.

Negative integration involves the elimination of national barriers to the free movement of goods and services (old regulatory policy). Positive integration is concerned with "... the reconstruction of a system of economic regulation at the level of the larger economic unit." (Scharpf 1999, 45) This is the establishment of common policies, including social regulation, to define the conditions under which EU markets operate (new regulatory policy). The former involves liberalisation and the rescinding of national authority to the Community through tariff and quota reductions, and is therefore a more straightforward process given Treaty obligations (supranational). The latter requires the active harmonisation of national regulations, such as in the fields of consumer protection and environmental risk, and goes through the Council of Ministers (intergovernmental). The former applies to the industrial policy dimension of pharmaceutical regulation, and the latter to the healthcare dimension. Both processes were envisaged to run concomitantly towards achieving the common market, but the Luxembourg Compromise represented a setback. The requirement that unanimity be achieved in the Council meant that negative integration came to the fore. As arbiter over matters involving the single market this accorded the ECJ a prominent role in the integration process, and through a considerable amount of case law generated between 1970 and 1985, the Court has in fact been credited with giving rise to the SEA via negative integration (Stone Sweet & Caporaso 1998).

The Court has been involved in positive integration as well. A host of legal decisions in social policy fields has granted the Community a greater mandate than was perhaps envisaged in 1957. Expansive rulings in some cases have ensured the Court (and the Commission) a major say in certain areas, such as with respect to issues of gender equity

and social protection. This 'regulation-creating' ECJ role has been shown to result in changes on a national level which would otherwise have taken considerably longer to occur (Pierson 1996); thereby pushing integration. For instance, in many member states (particularly those of southern Europe) ECJ rulings in the field of environmental protection and 'green' policy for business have resulted in completely new legislation in the absence of earlier national regimes (Majone 1996). Where pharmaceutical policy is concerned, issues such as parallel imports and trademark exhaustion fall within this pro-active ECJ mandate. In these matters it was the Court which established Community policy, not the Commission or other EU institutions via spill-over, nor the member states rescinding authority of their own accord. In several important areas, therefore, the Community legal system has had a positive (integration) effect in establishing pharmaceutical policy.

Product versus process regulation: Healthcare versus industrial policy?

A further distinction of relevance to medicines to be drawn from Héritier's new and old regulatory policy is 'product' versus 'process' regulation. Product regulation involves the establishment of common standards on goods and services (negative integration) and characterised early Community legislation. Intergovernmental agreement can be expected in such areas because differing national requirements over product safety and quality would undermine the market harmonisation goals of the SEM⁷⁴. Despite derogations on the grounds of public health, public policy or national security amongst others⁷⁵, it is thus assumed that member states will reach agreement on product regulation because of their common interest in single market tariff elimination. This is not the case for process regulations which affect the more social and externally-impacting factors involved in regulating economic activity, and where a pro-active hand is required (positive integration) e.g. environmental and occupational safety requirements. Here the absence of a 'Euro' regime may allow member states to cut back on national standards to increase their own competitiveness. The incentive to raise standards individually or jointly is thus limited.

The rationale for member states to pursue harmonisation, therefore, is to avoid having to compete on an unequal footing with those countries with laxer standards, but is a classical prisoner's dilemma situation in the absence of binding EU legislation. In fact, it was really

⁷⁴ Articles 28 and 39 (ex 30 and 34) read: "Quantitative restrictions on imports and all measures having equivalent effect shall be prohibited between member States." and "Quantitative restrictions on exports and all measures having equivalent effect shall be prohibited between member States."

⁷⁵ Article 36 (now Article 30 of the Amsterdam Treaty) reads in part: "The provisions of Articles 28 [ex 30] and 29 [ex 34] shall not preclude prohibition or restrictions on imports, exports or goods in transit justified on the grounds of public morality, public policy or public security; the protection of health and life of humans, animals or plants; the protection of national treasures possessing artistic, historic or archaeological value; or the protection of industrial and commercial property. Such prohibitions or restrictions shall not, however, constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States."

only with the SEA that EU regulation in areas such as environmental policy became possible. Even then it was up to the Commission rather than the national governments themselves to ensure that a situation of social and ecological dumping in some member states did not take place (Scharpf 1996). Positive integration can thus be linked predominantly with progress in the harmonisation of product regulation, though it has had a much weaker impact on harmonising process regulation.

As pertains to pharmaceutical policy, product regulation has dominated the agenda. Most regulatory policy is 'old' having come about as spill-over from the single market programme. Only perhaps the Transparency Directive and the grounding of the EMEA – both which have a healthcare and/or social policy dimension – can be seen as process regulation. These two policies required considerably longer to be agreed, and involved detailed and protracted negotiations amongst the affected parties. The outstanding issues, including pricing and reimbursement, also relate to process regulation, and are those the member states are unwilling to devolve to the Commission. Fears over what a single medicines market may mean in terms of their own authority over healthcare matters and local industry prevents agreement on mandating the Commission a new or process regulation role. Again, this is in contrast to other industrial sectors where there has been more consensus on a broader Community function.

The regulatory state model thus establishes a framework which contextualises policy decisions generally, and those over pharmaceuticals specifically. A Commission relying on regulation to increase its authority is applicable to the pharmaceutical framework in light of the impasse over the single market. Policy is made wherever it can be achieved, resulting in much 'old' regulatory policy and the *ad hoc* framework. What it does not do, however, is to show why in specific cases Community regulation exists but does not in others. That said, the regulatory state model is one in which a more meso-level approach such as that offered by policy networks can be used. The relationship between a Commission supplying regulation and demand-side actors vying for influence means not only a blurring of the public and private, but also that groups of (competing) actors form over specific proposals. Conceiving of the Community as a 'regulatory state' therefore provides an understanding as to why the EU is bound to making the kind of policy it does.

As the focus of this study is not EU regulation itself, a more expansive treatment of the regulatory state model and the related distinctions between negative versus positive integration, new and old regulatory policy, and product and process regulation is not offered. This summary has simply served to show that by virtue of the single market, the EU is able and required to regulate in both an economic and social capacity. It also shows that under the SEM framework, member states lose much of their ability to regulate over

their own national markets and that the Court has had a major hand in pushing integration and promoting the consolidation of the regulatory state. The ECJ has been especially active in the pharmaceutical field given the gap in Community competencies.

3-3 Making pharmaceutical policy in the regulatory state

The discussion on the regulatory state makes clear several further points important to the study. First, it fits squarely within the multi-level governance view by offering insight into the unique dispersal of authority in the EU frame. It shows that "... 'state' capacity at the EU level is overdeveloped in the area of regulation and underdeveloped in terms of redistribution and stabilization functions." (Rosamond 2000, 154) This explains the nature of the Community's regulatory framework for medicines: heavy on single market industrial policy concerns, and light on substantive healthcare policy competencies.

Second, one dimension of the regulatory state holds that policy is made as a trade-off between the Commission on the supply-side and organised interests (including the member states) on the demand side⁷⁶. Majone's model accounts for the Commission's function as 'supplier' of regulation (supported by the ECJ), such that various demand-side actors are constantly trying to have their interests met by or in EU policy. While relevant to all policy fields it is especially so for pharmaceuticals. And not simply in terms of the Commission acting as regulator over both private and public interests, but also with regard to the healthcare versus industrial policy bargaining scenarios in which the Commission is involved. For the Commission has often found itself at odds with both industry and the member states, not to mention with the host of variegated interests in between e.g. wholesalers and distributors, pharmacists, doctors' and patients' groups etc. The case-studies provided later will elaborate on this.

With the emphasis on negative integration, it is not surprising that the Community's regulatory framework leans towards support of the industry. (Single market) policy is simply easier to agree and implement, and the Commission is generally seeking to increase its powers where and whenever possible. As a consequence, Lewis & Abraham (2001) point to a decided neo-liberal bias inherent in European pharmaceutical regulation. It has already been shown that the regulatory state is susceptible to influence, and the regulatory framework for medicines is thus heavily shaped by the interests of the industry and the research-oriented companies in particular. This is because of a similar bias in countries with a strong innovative industry (the UK, Germany and Sweden), and a

⁷⁶ The regulatory state model also captures the 'normative' and 'positive' theories of (economic) regulation. The former cites protection of consumer interests (from a host of potential market failures) as the rationale for state (in this case, Commission) intervention in the market. The latter regards the purpose of regulation as protecting the interests of the regulated industries themselves.

Commission which, above all else, is seeking to promote an 'efficiency regime' to "... meet the political objectives of a single European market and the commercial agendas of transnational pharmaceutical companies." (Lewis & Abraham 2001, 53)

Furthermore, despite the Commission being "... totally biased towards policy entrepreneurship" (Radaelli 1998, 4), the single-market subsidiarity clash precludes it taking wider harmonisation forward of its own accord. Where positive integration is to be achieved, therefore, it is posited that pharmaceutical policy is often driven by networks comprising the Commission and actors (including the member states) whose interests are from both the healthcare and industrial policy spheres. These form over specific policy proposals to see to what extent they can influence the final outcome⁷⁷. Support for this assertion is not difficult to find. Even if not specific to the pharmaceutical case, the unique system of EU regulation and governance leads to Héritier et al's suggestion that:

The EU, with its sectoralization, the functional differentiation and fragmentation of policies, as well as the dominance of corporate actors in a horizontal web of interorganizational relationships at the negotiating level, appears the most ideal area of application for policy network analysis. (Héritier et al 1996, 7)

This view has as much to do with the nature of the EU policy-making process as it does with a particular conception of policy networks. Although it appears to take a seemingly specific and exclusive definition of networks, the increasing body of theoretical and empirical literature on the EU as new form of policy-making (and the role of networks therein) would lend support to such a view.

Nonetheless, the study's concentration on the making of EU pharmaceutical policy as infringing on the goals of competing interests in the sector can be better understood within this frame. From the Commission itself, to the manufacturers, member state governments and consumers, Community pharmaceutical policies represent a formal regulatory influence on their activities and objectives. Whether it concerns package-labelling and market authorisation requirements or a future uniform pricing regime across Europe, supranational policy in this sector is – by definition – regulatory; Community competencies vis-à-vis pharmaceuticals relate to both 'old' and 'new' regulatory policy. And while it is clear that the framework which governs medicines in the EU has been predominately shaped by old regulatory policy, so too is it obvious that the healthcare dimension, as a member state competence, precludes all policy being made by the Commission. The former is driven by the single market and the latter is dependent on meso-level policy outcomes achieved amongst networks of actors. As such, the next chapter turns to policy

⁷⁷ The Court plays a pro-active (positive integration) role here as well.

networks themselves. It is necessary to understand what they are, how they operate, and where they are useful with regard to the policy-process for EU pharmaceutical policy.

3-4 Adjusting the lens

In concluding this chapter, the remainder of the study keeps with the dynamic, multi-level gaming view of EU policy-making outlined above. It is argued that the nature of current EU pharmaceutical policies, and the *ad hoc* framework which has resulted, stems in large part from the competing interests of the main stakeholders. As it is necessary to understand how policy has been made, the remainder of the discussion concentrates on Hix's 'politics of the EU policy-process' for pharmaceuticals, though bearing in mind the context provided by the wider European integration theories. This accommodates the fact that there is a plethora of inputs into European pharmaceutical policy – whether internal or external – and is able to contextualise the role of actors within such an environment. It is also compatible with both neo-functionalism and (liberal) intergovernmentalism as it recognises the role played by the European institutions and the member states.

The aim here was not to provide a coherent theory of EU pharmaceutical policy developments; assuming that this would actually be possible. Instead, it was to provide an initial theoretical perspective on how EU competencies have unfolded, by assessing the relevance and failing of the more accredited theories in view of the trade-off in policy interests which define the sector. The discussion has served to contextualise the development of the EU pharmaceutical framework and why, therefore, there remains a policy impasse over completion of the single market. Although a somewhat terse overview given the ever-evolving body of academic literature in the field, this initial look at integration and policy-making processes is an important element of the overall discussion. It shows to what extent macro-level influences can shape the EU's capacity to make policy for medicines, and equally, where this level of analysis falters. And it outlines the boundaries which frame the behaviour (and indeed, effectiveness) of the policy networks at the meso-level. This helps further the argument that politics and political factors have moulded the regulatory framework as currently exists.

CHAPTER 4

INTEGRATING THE MESO-LEVEL - NETWORKS AND THE 'POLITICS OF POLICY' FOR PHARMACEUTICALS IN THE EU

Introduction

The previous chapter teased out certain insights into EU pharmaceutical policy-making from European integration and policy-making perspectives, arguing that to go beyond these initial observations – and in order to test the study's main hypothesis – they needed to be supported with a more focused level of analysis. The policy network was advanced as a meso-level approach through which to better understand the politics involved. It is the purpose of this chapter to develop this line of analysis. The discussion concentrates on how the unique regulatory role of the Community creates a policy environment for medicines which influences policy outcomes. What this regulatory environment means for the sector's four primary stakeholders is also developed. Specifically, as networks do not act in a vacuum, Wilson's (1980) 'politics of policy' typology of regulatory decision-making is applied in order to set out a more complete conceptual framework than would be achieved by simply applying the 'macro' and 'meso' on their own.

1 Meso-Analysis: Focusing on actors

Because of the sector's inherent peculiarities, the complexity of the interests at stake, and the (often) competing interests of the stakeholders, a policy network framework has been chosen to help understand the dynamics at play in setting regulatory policy for pharmaceuticals. This acknowledges that, compared to other public policy theories, policy networks can more lucidly accommodate the argument that political and actor influences play a defining role in policy decisions. In order to justify this claim a brief examination of its more contemporary application proves a firm starting-point.

1-1 Contemporary policy network application: Structure, model or theory?

As mentioned at the outset of this study, there is no single view of policy networks. Moreover, there is no consensus over the approach's value. Nevertheless, policy networks continue to be used by students seeking a meso-level understanding of policy-making. The respective failures of pluralism and (neo-)corporatism as complete models – or at least their lack of significance in the face of evolving policy-making dynamics in western societies – have resulted in a host of actor-oriented public policy theories of which policy networks are just one. Networks offer a more fluid and relevant view of how actors interact

within different levels of the policy-process than either pluralism or neo-corporatism. Nevertheless, the literature on policy networks reflects aspects of both, as detailed in Börzel's (1997a,b) overviews of the literature. Posing the question as to whether policy networks are best seen as a structure, model or theory, she distinguishes two schools of usage: as a *model of interest-intermediation* or as a *mode of governance*. The division would appear a legacy of the pluralist-neo-corporatist debate, with the former conforming to the structural notions of pluralism and the latter relating to the more dynamic interpretation proffered by neo-corporatism.

In simple terms, the interest-intermediation view sees the policy network primarily as a generic representation of state-interest (bargaining) relations, while the governance view defines it in terms of political resource mobilisation in instances where such resources are shared or dispersed between public and private players. Given the latter interpretation it becomes immediately apparent that the division between the two is not always a clear one, and this is particularly so in empirical terms. Indeed, this division would appear to lie at the heart of contemporary discrepancies in conceptualisation and should be consulted in order to help clarify them⁷⁸. Without engaging the *minutiae* of policy networks, a *précis* of some of the more widely-cited conceptions makes Börzel's point.

In the language of Kenis & Schneider (1991), the policy network concept is an 'analytical toolbox' which helps define actor relationships and their consequences in issue-specific decision-making (25-29). Others who agree in principle with this, nevertheless see policy networks more as a diagrammatic model of 'interest group mediation' (Marsh 1995, 2) – one which helps fill the gaps left by pluralism and neo-corporatism. A further assessment is offered by those who view the policy network less as a tool for analysis and more as a tangible construct unto itself, as "... an arena for the mediation of interests of government and interest groups... [wherein] clusters of actors representing multiple organisations interact with one another and share information and resources". (Peterson 1995, 76) Citing these definitions is not to imply that the concept has an accredited understanding, for there is a plethora of further interpretation; even within schools.

Nevertheless, these represent examples of the more widely-cited theoretical perspectives to be found in the literature. They show is that the spectrum of views on both construct and applicability of policy networks covers inclusively all ground between an analytical and operational perception, to it simply being more of a structural/descriptive and summary-providing approach (governance and interest-intermediation schools). This has spawned

⁷⁸ The policy network as used by the interest-intermediation scholars is considerably modelled after the earlier (primarily American) iron triangle and 'sub-government' concepts. For the governance theorists meanwhile, the primary influence has been sociological network analysis.

criticism that the approach suffers from a "lack of substance" (Jordan 1990, 319), and is "...more a map of the policy process, than a fully fledged explanation of it... [one that is] ... inadequate in providing fully determined causal analysis." (Dowding 1995, 157-158) As a consequence, one of its main exponents has bemoaned the fact that the policy network is "... becoming ubiquitous... it is most commonly used as a metaphor... is infrequently used with precision... [and] it is rare for it to have any explanatory value." (Rhodes 1990, 293)

Yet the concept undoubtedly holds some currency, and not simply because of its recent popularity. Wherein does such value lie? Is the approach as critically evaluative in assessing policy outcomes as some would claim, or is its significance more in being a general '*model*' of interest mediation. Is it a viable *theory* for explaining sectoral policy outcomes in cases where there exists a tightly intertwined group of interests bound together in relationships of so-called 'antagonistic cooperation'? (Marin 1990) Or is this too specific an application for it to be used as a conceptual tool? Can policy networks be employed as an emergent form of governance in the EU, as argued by more contemporary scholars (e.g. Héritier et al 1996); or is the policy network better regarded as a manner of *depicting* and *comparing* inter-actor relationships towards the making of specific policy within transnational EU sub sectors (Josselin 1994, 295)?

The simple answer to these questions is that the student's focus of analysis will decide the choice of approach; each is valid in its own way. In the context of this study the interest-intermediation view is the more useful. For in using networks primarily as descriptor for studying policy-making in the sector, this could contribute to understanding outcomes as they manifest themselves in specific decisions and policies. In other words, it could help merge the (politics of) decision-making with the regulatory policies which result. Furthermore, given the lack of transparency in the pharmaceutical arena, there is a clear impetus for an actor-based clarification of the policy-process⁷⁹. Even a crude understanding of the policy-making architecture based on the use of networks would be germane to understanding the political forces shaping policy outcomes. This use of networks also goes some way towards confirming the study's hypothesis i.e. by showing how industry can dominate the policy networks which form over aspects of EU policy. The more fluid and active governance interpretation of policy networks, while interesting and relevant to the EU pharmaceutical sector, does not serve the aims of this study. This is not to decry its value – especially as the dividing-line between the two applications can be a thin one – but rather to keep within a manageable and relevant frame of analysis.

⁷⁹ Criticism of a lack of transparency is also levied against the EMEA. Based on the secretive nature of national-level pharmaceutical policy-making (particularly in pricing matters), European policy-makers are under pressure from both supply and demand-side actors to ensure that the same does not happen at supranational-level. This would undermine any legitimacy that the arguments in favour of EU-level regulation of the sector might espouse. See for instance Abbasi & Herxheimer (1998).

1-2 Using policy networks to depict the policy-process: Interest-intermediation reviewed

As the earlier and arguably more prominent of the two schools of policy networks, the interest-intermediation view offers the best indication of the theorists' disenchantment with the pluralist-corporatist debates. By employing the network as an alternative interpretation, they have for the most part limited its usage to the sectoral level where balancing the needs and resources of state and (private) civil interests is most apparent. This is the level where pluralism and corporatism would both seem to have failed. In this regard, scholars such as Wilks & Wright (1987), Rhodes (1988), Atkinson & Coleman (1989), and Jordan (1990) laid the initial lines for the development of further research by constructing various theoretical typologies of policy networks, and then applying them to particular empirical case-studies⁸⁰. Their typologies, however, differ, causing some to question the entire approach altogether⁸¹. Nonetheless, between them, their original categorisations of policy networks set the guidelines upon which not only other proponents of the interest-intermediation school were able to build, but also scholars from the governance school could adapt in grounding their own understandings.

It is beyond this study to critically evaluate these typologies, and thus only those elements relevant to the study's theoretical component are referred to. The discussion serves to show how, within a network configuration of interests, actor behaviour over a (regulatory) policy issue can influence policy outcomes.

Leitmotifs and relevance

A *précis* of some of the better-known interest-intermediation typologies of policy networks reveals three common threads relevant to EU pharmaceutical policy-making. First, the policy network is treated as an analytical tool which "... allows a more 'fine grain' analysis by taking into account sectoral and sub-sectoral differences, the role played by private and public actors, and formal as well as informal relationships between them." (Börzel 1997a, 10) This is a valuable level of analysis for looking at competing actors in a multi-level (governance) EU polity. Also, not only does the pharmaceutical industry span both sectoral and sub-sectoral levels, but the interplay between institutionalised interests and actors is considerable given the overlap between healthcare and industrial policy areas. The (corporatist) blurring of the public/private divide is here of especial importance given the issues at hand and with respect to the structure of the pharmaceutical industry and

⁸⁰ Another early contributor was Katzenstein (1978), who sought to use policy networks in the context of international relations theory.

⁸¹ As the typologies often differ "... according to the dimensions along which the different types of networks are distinguished" (Börzel 1997b, 08), this would support the earlier-posed idea that language is often the cause of discrepancies between theorists' usage.

influences upon the market. And all actors do their best to ensure that regulatory outcomes reflect their interests.

A second major *leitmotif* to be identified amongst several of the interest-intermediation scholars is that of the policy network being able to influence the policy process. The notion of resource dependencies leading to stable and established relationships over time is an assumption shared by most theorists in this field. Wilks & Wright (1987), for example, write that actors seek to 'balance' and 'optimise' their 'mutual relationships' via resource exchanges, and that these then constitute policy networks:

...the linking process, the outcome of those exchanges, within a policy community or between a number of policy communities... A policy network describes the general properties of the processes by which some of the members of one or more policy community interests in a structure of dependent relationships. (297)

This disaggregation to sub-sectoral policy networks leads them to conclude that the type of issue at hand defines the type of relationship and, therefore, that not all policy issues within a policy community will necessarily involve the same network. This too is an important consideration to be borne in mind through the remaining empirical sections of this study. For as already hinted at, the number of actors and resulting disparate interests which are at stake in the pharmaceutical sector mean that not all policy issues involve the same actors. The networks can and do change even if the main players are always present.

Based on the stability ascribed the interest-intermediation construct, it can be inferred that the policy network itself does influence the policy process – especially given that some actors develop a certain degree of clout within it. This inference, though debatable, is also relevant. For while "The EU decision-making process is fluid, open, and largely unpredictable" (Josselin 1996, 300), it does remain the case that EU level interests and institutions do, to a considerable degree, develop (resource) dependencies with each other in a relatively stable manner. Indeed, risk aversion for fear of failure compared to other actors or interests often precludes any attempts to be innovative in either pushing one's own agenda else forwarding a new policy idea. Instead, a type of established *status quo* prevails with actors more or less content in the stability of their existing relationships. This has led to the development and application of 'path-dependency' theory to the EU context.

Although path-dependency falls outside the discussion, as it generally asserts a type of 'institutionalisation' amongst actors (based on historical decisions which bind the actors together in a given infrastructure, thereby also setting their future preferences), it is applicable to pharmaceutical policy. The incomplete regulatory framework is the result of an impasse which cannot be broken by the main players within their current constellation of decision-making patterns and inter-relationships. These 'dependencies' are very strong

both as constructs unto themselves and in the stakeholders' relationships with other policy actors. The subsidiarity-free movement clash ensures that the nature of their relationships and future policy actions remain very much fixed – choices and behaviour within certain constraints. This, in turn, can be related to the 'joint decision trap' view of European integration and policy-making first developed by Scharpf (1988).

Briefly, Scharpf argued the development of institutionalised policy-making arrangements at EU level, resulting in 'sub-optimal' outcomes from the member states' perspective. This is based on the two-part dynamic of pro-European governments pushing for integration but not being willing to rescind their veto power, while less Europhile member states agree certain compromises, but mainly in order to maintain their influence within the European policy-process.

In noting the relevance of these perspective, the aim is not to offer a (new) institutionalist examination of EU pharmaceutical policy-making. Instead it is to understand the policy-process from a more complete perspective, albeit one which acknowledges an institutionalist framework. The focus is on the meso-level, and the study seeks to show how the regulatory environment – admittedly in part a result of path-dependency – can affect outcomes. The argument being that the regulatory issues associated with the pharmaceutical sector, in combination with the Community's unique – though in this case inadequate – regulatory functions, have an impact on what sort of outcomes can be agreed through the policy networks. There are major constraints facing policy-makers where pharmaceutical policy is concerned.

The final understanding to be gleaned for the interest-intermediation school is that policy networks are valuable in reaching difficult consensual policy decisions where other forms of interest mediation fail. Here the network is understood as a "... web of relatively stable and ongoing relationships which mobilize dispersed resources so that collective (or parallel) action can be concentrated toward the solution of a common policy problem." (Kenis & Schneider 1991, 36) This relates to path-dependency and can be used to support the idea of a new decision-making dynamic emerging in the EU. For the purposes here, however, it underscores the salience of actor (stakeholder) relationships in the policy-process within the regulatory state conception of the Community. It also fits squarely with the single market-subsidiarity clash. The Commission is unable to push any policy through without the support of the member states, with the latter's interests 'conditioned' as much by budgetary and public constraints as industry and private requirements. The degree of interdependence between the actors in the sector is therefore very high.

Policy networks and the EU policy-process: Scepticism?

It is recognised that use of the policy network within the realm of EU policy-making also has its detractors. Perhaps the main problem here is the terminology⁸². There is overlap with looser concepts such as the policy community and the issue network, but there is also overlap between the interest-intermediation and governance conceptions. In a critical article regarding the application of policy networks to EU policy-making processes, Kassim (1994) for example discusses 'policy networks' as something different from the 'network model'. The former grew out of the pluralist-corporatist debates in political science, and the latter finds its origins in international relations theory. This seems very much along similar lines to Börzel's distinction, although she refers to policy networks throughout. And while she claims that both are relevant to the study of the EU – the one to policy outcomes and the other to European governance – Kassim argues that neither is applicable.

He cites three grounds for this: 'elusive fluidity', a lack of attention attributed to institutions, and the 'boundary problem'. The first refers to the near impossible task of capturing the fragmentation of the EU policy-process under a single conceptualisation. Regarding the second, Kassim argues that both the policy network and network model fail to account for the institutional architecture through which EU policy is made. The final critique is that both views are predicated on being able to delimit networks, but that this is not really possible in the supranational context. These are valid concerns, and his conclusion that "... the search for a framework for analysing the policy making processes of the EU must continue" (Kassim 1994, 25) remains current. Others sharing this sceptical view include Mills & Saward (1994), Thatcher (1995), and Dowding (1994) who perhaps sums it up best when he suggests not to 'stretch a good idea too far'. Their scepticism is over policy networks as a new form of governance or, as seen with Kassim, as a complete framework *cum* theory.

Detailing their arguments is not the purpose here. It must suffice that they have been raised – especially as many other scholars feel that the governance view of networks does hold validity at EU level (given the multi-level gaming structure which characterises it). This is not to duck the issue, but rather to re-iterate that this study is uses networks as: a "... descriptor for policy making arrangements" in the policy process (Kenis & Schneider 1991, 32), not a mode or emerging theory of governance in the EU or elsewhere. In other

⁸² Dowding (1995) for example writes: "I will use the term 'policy network' as a generic category and 'policy communities' and 'issue networks' as subsets." (140) Jordan (1990) meanwhile essentially argues the opposite: "The policy community is thus a special type of *stable* network... the policy network is a statement of shared interests in a policy problem: a policy community exists where there are effective shared 'community' views on the problem." (327) Both are referring to the role and place of a specific level of interests in policy-making. But their differences have more to do with whether it is the policy network or the policy community which is the more overarching concept, than whether the approach itself is applicable.

words, an *apparatus* of structure and process, rather than a *theory* of process. It should also be noted that policy networks – as Börzel has shown and as this study understands them – do not aim to offer a complete framework. Perhaps some of the governance or process-oriented theorists come closest to proposing this, but even they do not hold up the approach as an authoritative model for understanding the EU policy-process. Within this study, the approach is simply accepted as a manner of conceptualising policy-making in the EU, and the interest-intermediation view is employed insofar as it fits with the multi-level governance view of Community policy-making not because it helps define it.

1-3 Employing policy networks – taking the approach forward

As they pertain to the EU pharmaceutical sector then, policy networks are treated as meso-level constructs with more formal relationships existing (in almost institutional terms) between the constituents. Identification of the major interests and actors (both domestic and supranational), as well as their relations and behaviour, falls within the remit of such an analysis. This involves assessing qualitative interactions amongst the networks' primary players and, where relevant, the ties between them and other actors or bodies in the EU. The study thus considers how networks work within the health and industrial policy communities of the pharmaceutical arena. The character of stakeholder relations within the sector is taken as interest-based towards achieving particular policy outcomes.

What appears to be lacking in the interest-oriented conception, however, is its linkage to wider contextual frameworks. For the most part the approach been used at a very specific level of analysis – the meso-level – and can perhaps be justly criticised as being either too context-specific, else too removed and unrelated to what goes on about the networks themselves. This has led some to deem the approach as overly-descriptive⁸³. It is a failing which has been noted by Marsh (1995) who, in support of the concept, has sought to show the relevance of networks to wider political science theories. Although the approach has been used effectively at the meso-level, it is his view that not only must it be integrated into micro-, but more importantly, macro-levels of analysis. His conclusion is not only that networks do fit within broader perspectives, but that the value of the approach could in fact be bolstered through its alignment with wider views⁸⁴.

For this study policy-making is the locus and the interest-intermediation approach is therefore valuable. That said, the reasons behind the development of the EU regulatory

⁸³ For instance Jordan (1990).

⁸⁴ Marsh demonstrates the concept's applicability within a macro-frame of analysis as pertains to theories of state-civil society relationships. Specifically, he undertakes an evaluation of the concept's relevance to 'elitism', 'pluralism' and 'marxism' as comprehensive political ideologies commensurate with his own conceptualisation of the need for macro-level analysis and application.

framework for medicines are not solely the result of what transpires in the networks. As the earlier discussion on liberal intergovernmentalism has shown for example, external factors play a major role in influencing actor behaviour with regard to their pursuit of specific policy outcomes. In particular, the EU's policy and legal frameworks ensure that discussion and outcomes – even at national level – are confined to specific arenas. Consequently, the study agrees with Marsh's underlying argument on the importance of context and integration with wider theories.

The discussion on the applicability of macro-theories of European integration to policy decisions in the sector – neo-functionalism and intergovernmentalism specifically – has already shown their relevance and failings in this regard. In the opening chapter, a case was made for tying the network approach to a wider theoretical perspective in order to look at how the nature of the issue at hand can influence the policy-process. The regulatory policy environment created by the subsidiarity-free movement clash represents this liaison. As a cost-benefit framework of regulatory policy-making which accounts for interest and actor bargaining over regulation issues, Wilson's (1980) 'politics of policy' regulatory typology is invoked. It is employed towards presenting a wider and more integrated manner of examining the development of EU pharmaceutical competencies than a simple application of meso-level analysis. Section 3 develops this level of analysis further, thereby reinforcing the network approach and giving rise to a broader theoretical context within which policy networks can be examined.

Rather than seeking to explain current understandings and usage, this section has simply opened the 'can of worms' that is policy networks. It has served to introduce the complex theoretical issues at hand, reviewing in particular the applicability of the interest-intermediation literature to the study. Above all, the discussion has made it clear that the adoption of policy networks to set out EU policy-making in the pharmaceutical sector is in keeping with a policy level approach. Wider theories do provide an interesting and important level of analysis but on their own they are too sweeping to explain outcomes. They offer a contextual understanding of the broader influences at work in shaping policy for the sector, and have shown the difficult environment in which policy is to be made. But they are not able to explain the more localised dynamics involved. Consequently, it is in order to supplement the insight provided by the wider theories that the study turns to networks and Wilson's 'politics of policy'. As this means understanding the perspectives and roles of the stakeholders in the policy-process, this is the next part of the discussion.

2 Constituent Interests and EU Pharmaceutical Policy

A delineation of all actors involved in the EU sector proves a complex task. First, there are so many implicated, and second because the health-industry duality means that their

interests tend to be quite specific and disparate. Deciding on which actors are or are not important in Community medicines regulation, particularly within the context of multi-level governance, thus presents a challenge and leaves open the possibility of omissions. It also means that assessing their relative influences proves difficult. As such, the study employs the terms 'stakeholder' and 'stakeholding' (used several times to this point). The use of the term stakeholder is to capture the main actors' vested interests and the nature of their involvement and interdependencies in a sector where traditional industrial relationships between consumer, producer and regulator do not feature.

2-1 Pharmaceutical stakeholders

By shedding the ideological and jingoistic accoutrement which some politicians have recently attached to the term, the discussion here simply accepts the concept as more "a matter of common sense" (Darling 1997) than a strict category of actor or actor behaviour. Although simplistic, this means that within the context of this being a study of sectoral policy-making (specifically, supranational regulation), those actors or groups of actors with enough of a vested interest to be able to affect the policy-making process – and having therefore obligations to each other as well as to the sector as a whole – are considered as stakeholders. There are therefore dependencies amongst the actors within the networks.

In most industries, the most obvious division to be made between stakeholders is between those actively involved in making policy and those who are either indirectly involved or are simply affected by such decisions. As was hinted at earlier, however, because of the nature of the actors' involvement, this is too facile a division to be made with respect to medicines policy. The EU pharmaceutical sector's constitution in stakeholder terms represents an unusually wide cross-range of interests and actors compared to other manufacturing sectors: from the (multinational) companies researching and making the drugs, through medical and scientific advisement bodies, consumer groups, governments and public regulatory bodies who assess medicines and their effects; to hospitals and the individual healthcare providers who prescribe them; to insurance agencies who pay for them; and ultimately to the patients themselves who consume them. Appendix 4-1 identifies several of the main national actors and their specific policy objectives in the pharmaceutical sector generally, while Appendix 4-2 presents a selected listing of the more salient individual actors and their vehicles for expression at EU level. Although simple indexes, they provide an idea of how many interests and actors are involved on both sides of the health-industry dichotomy. It is not difficult to imagine to what extent the pharmaceutical sector is characterised by a tight (often competing) intertwining of these actors in policy networks; such that the division between active and less active players becomes difficult to delineate.

The direct involvement of such a diverse range of interests reflects in large measure the public health and healthcare issues. Accordingly, all have at least a say in the policy-process, although, given their respective stakes, none find all policy decisions to their benefit. In looking at these players, a subdivision of the interests at stake leads to the four main supranational stakeholders already mentioned: consumer, industry, member state (government), and the Commission. These players and their interactions represent the focal point for the remainder of the study in light of the policy network frame of reference, and are deemed the primary stakeholders. Other actors or groups of aggregated interests also involved at EU level. Doctors' federations, non-EU industry associations, and international pharmaceutical standards groups such as the ICH may be seen as secondary stakeholders, but they are not examined in this study.

The stakeholder interpretation thus gives additional elucidation to the peculiarities of the sector, particularly with respect to the two-part fact that: a) at national and subnational level there are many more players involved in pharmaceuticals than other sectors (recalling the direct link to healthcare and (public) health policy); and b) at European level, given the plethora of national and subnational players, the EU's role is not entirely clear and remains complicated – which is not as much the case in other industrial sectors within the framework of the Internal Market. Importantly here, the concept of stakeholder-oriented actors fits in ideally with the use of policy networks. For the nature of the relationships it assumes is clearly the case in the pharmaceutical sector.

2-2 Interest and priorities *vis-à-vis* pharmaceutical regulation

In concentrating on the primary stakeholders, the actions of the Commission, the industry, and the member states are seen as the most important in policy-making terms. While consumers are the critical element – indeed it is their interests which underlie policy – as they are not involved in the decision-making process directly there is no vehicle for assessing their role beyond the positions expressed by patient or consumer organisations (generally from outside the policy-making arena). With regard to public health priorities, the member states do represent an element of the consumer view within their own aims. But in terms of any single consumer actor having a major say in the policy-process, there appears to be none. While the Commission claims to engage patient's perspective via dialogue with representative groups, it appears more a case of lip-service than a real commitment to involving them in a meaningful way.

The exclusion of consumers is a major failing of the EU medicines policy-process. It has been highlighted by numerous analysts, academics and scholars⁸⁵ for it is less the case at the national level where patients organisations and even doctors associations have at least some degree of say. Nonetheless, in order to understand what a single medicines market might mean in practice, the consumer (patient) perspective is paramount. So although patients are not involved in the decision-making *per se*, their positions and priorities require elaboration alongside those of the other main stakeholders. Indeed, as the discussion will show, consumer interests have featured, even if from the fringes.

Consumers: Medicines to bring public health benefits

Although not formally represented in the policy-making process, consumer interests are not entirely neglected. If a medicine is to sell it must work, and for it to work, it must pass the three hurdles of safety, quality and efficacy. These pertain not simply to 'consumer safety' (as in other sectors), but more specifically to public health. Still, consumers are the most marginalised of the sector's stakeholders primarily because, as a group, they have the least influence, compounded by the poorest access to information. Further, as noted in Chapter 2, their position within the market's demand structure means that they are unable to affect the market on their own. Their interest is simply in the best medicines irrespective of cost, and demand is via an intermediary. Indeed, one of challenges for both the industry and regulator in the future is going to lie in making the consumer more socially responsible and cost-conscious; for ultimately, as the end-user in what is a healthcare concern, the consumer's interests should play a bigger part in pharmaceutical policy decisions.

At the same time, consumers are becoming increasingly educated. Notwithstanding the amount of inaccurate, out-dated and unregulated information to be found, the Internet in particular has helped improve consumer awareness about diseases and medicines⁸⁶. Consequently, patients are increasingly organising "... on questions of access, on the use of particular treatments and on other causes." (Davis 1997, 20) A host of patient groups, disease-specific organisations and lobbying bodies have sprung up in recent years, and doctors are increasingly reporting that patients come with requests for specific treatments or medications (Spurgeon 1999). The development of these 'secondary' interests is in part due to the industry's growing willingness to provide information, but so too is it the result of greater awareness – both of industry activities and specific healthcare questions. And as doctors and other health providers are becoming more involved in the debates about cost-containment, especially cost-effective prescribing, consumers are no longer as uninformed

⁸⁵ For instance Orzack (1996), Abraham & Reed (2001) and Garattini & Bertele (2001).

⁸⁶ However, many health and health-related websites – including those providing disease and medicine information – are sponsored by the pharmaceutical industry. This raises questions as to the impartiality (and even accuracy) of the information provided.

as they were even five years ago. But it remains a paradox of the pharmaceutical arena that consumers have so little market power over a sector which deals in their health.

Regarding a future single medicines market, as there is so much uncertainty surrounding what form it would take and what benefits it might or might not bring, the consumer position is unclear. Access to the same products at the same price across the Community may seem a good idea, but questions regarding pricing and a lowest common denominator approach to quality qualify this. Patients in the UK and Sweden may for instance be envious of the comparatively low out-of-pocket expenditure on medication and health insurance of their southern Mediterranean neighbours, but the reverse may be the case in terms of access to newer, innovative preparations and simply more choice. Chances are that neither would be willing to compromise the benefits they currently enjoy under their national framework. What they are likely to agree on, however, is that any further movement on completing the market be based on public health requirements to the same degree as other, primarily industry, interests.

Industry: A regulatory environment conducive to business

As a collective stakeholder of its own, industry is often said to put profits ahead of public health and manufacturers are frequently accused of seeking increasingly exclusive patent rights while baulking at the prospect of increased competition. This, however, is not to say that the industry has no justifiable interests or concerns of its own. Notwithstanding that generic and research-oriented manufacturers have different priorities, balancing profits with escalating research costs, increasing government price controls to restrain healthcare budgets, and growing consumer demand (quantitative and qualitative), is no mean task. So while industry representatives may accept that their profits seem high relative to other industries, they argue that these are still not always in proportion to the costs which go into developing a product. According to the European Federation of Pharmaceutical Industry Associations (EFPIA), the EU research industry's trade body, these costs have been rising at a constant rate through the 1980s and 1990s (EFPIA 1998). And they stress that such returns are necessary to the production of high quality medication. Consequently, drug companies (research-oriented manufacturers especially) seek government incentives given the health importance of the work they are engaged in, and push for what they view as the 'fair', market-based (free) pricing of their products.

Fair prices are a subjective matter, generally dependent on whether one adopts a health budget or shareholder perspective. Nonetheless if, as industry claims: effective patent life times have decreased with the costs of discovering and developing NCEs increasing by over 50% between 1987 and 1990 alone (EFPIA 1995); only 1 or 2 of every 5,000-10,000

laboratory products synthesised are actually marketed as a drug (EUROSTAT 1998); and European companies are losing out to US manufacturers (Lawton 2001), then perhaps the industry does have a case regarding its future competitiveness. Indeed, Europe's 23.7% of the global market (by sales) is down from 28.9% in 1995 (EFPIA 1995), and the number of new chemical entities being discovered is going down relative to the US (EFPIA 2001b). Nevertheless, it should again be stressed that this data comes from the industry, even if it is also released as 'official' figures by the EU's statistical office EUROSTAT⁸⁷. They have been cited here to briefly indicate those arguments industry brings to the table.

Industry wants a regulatory environment which fosters and rewards innovation, where natural (as possible) market forces prevail, and in which the state (or EU) plays as minor a role as feasible. Here member state cost-containment measures which target the supply-side are often regarded as impediments to industry performance (EFPIA 1996), and a recent study revealed that a country's economic and regulatory environment impacts considerably on the drug manufacturers' competitiveness (Agrawal et al 1998). Still, as there is an appreciation that the relationship is one of co-dependence, the industry loudly proclaims that it is complying with, for example, demands for greater transparency in its operations e.g. the provision of information on clinical trials and testing (Sykes 1998). Whether the new regulatory system and conditions ultimately envisaged by the EU under a single market would meet industry's interests is not at all clear. And as is shown in the following chapters, the industry is concerned about what the future holds in this respect. If increased EU regulatory competencies in the sector will impinge on industry's behaviour (and affect profits), the industry may simply push to retain the *status quo* of a fragmented EU market. Simply put, the industry as a whole (i.e. both research and generic companies) wants to improve its global competitiveness – *vis-à-vis* the US industry in particular – and it wants to see EU regulatory policy designed to facilitate this.

European Commission: Pushing for a successful 'euro-industry'

Ostensibly the European Commission's responsibilities, as with those of the national governments, are as much to the consumer as they are to industry. As the only supranational stakeholder it also has an additional responsibility to the wider integration process. This means not only trying to balance industrial and health(care) questions, but equally, to reconcile economic and political interests towards fostering completion of the Internal Market⁸⁸. Thus, the Commission seeks to apply the free movement of goods

⁸⁷ For instance, this 1998 EUROSTAT citation on the number of products making it to market is a figure that EFPIA has long bandied around; EFPIA now cites that only one or two of every 10,000 substances synthesised in a laboratory will make it to market as a medicine (EFPIA 2001).

⁸⁸ One of the key issues on the Commission's pharmaceutical agenda is how best to adapt the current framework so as to integrate the healthcare markets of the accession countries.

requirements of Article 100 and to reduce intra-EU price differentials; both in order to diminish market fragmentation and to regulate towards a single pharmaceuticals market in some form. The Commission has identified its priorities as:

- Better medicines for all EU citizens, with fast access to innovations, better information and involvement in decisions affecting their health.
- Continued provision and funding of medicines by Member States and Insurance Funds with necessary safeguards on expenditure achieved with the minimum of legislation and regulation.
- Development of informed customer-supply negotiations on both prices and volumes, which provide a basis for enhanced competition.
- A steady stream of valuable innovative medicines from Industry and a thriving generic sector, both of which will make a supply side contribution to a genuinely competitive market.
- An attractive European investment environment in the biosciences and biotechnology for the R&D based Industry which will assume a prominent position for European Industry in world markets. (WG I 1997, 7)

In order to achieve any or all of these goals, the Commission mandate will require more formalised establishment in terms of specific competencies. As noted in Chapter 2 it is currently institutionally incapable of regulating the medicines sector appropriately and completely – given the proliferation of Community regulation, the Commission has in fact been shown to suffer from a management deficit more generally (Laffan 1997). It will have to develop further competencies which, notwithstanding the EMEA, build on the member states' own roles. Aspects of healthcare policy are necessary if the EU is to eventually preside over fifteen very different systems and traditions.

That said, as a completely harmonised market would mean equality of product (including branding and packaging), uniform (free) pricing, common reimbursement mechanisms, and equal access and supply of medicines in all member states, it would mean, first, a single market in healthcare⁸⁹. This does not exist and is clearly unattainable as things stand. The Commission recognises as much: "The problem is that the Community's health systems are not harmonised, and this is preventing completion of the standardisation process". (EUROSTAT 1998, 79) Complete market harmonisation is thus not necessarily the Commission's goal, at least not in the short to medium-term. Consequently, the Commission has set about trying to improve the competitiveness of the industry as a means to increasing its own competencies (related to the 'efficiency regime' referred to in the previous chapter) and towards pursuing some degree of price harmonisation. What this means in practice is outlined in Chapters 7 and 8.

⁸⁹ Recent ECJ rulings in cases such as C-158/96 – *Raymond Kohli v. Union des Casses de Maladie* and C-120/95 – *Nicholas Decker v. Caisse de Maladie des Employés Privés* (on the cross-border provision of medical services), or Joint Cases C-157/99 *Geraets-Smits v. Stichting Ziekenfonds* and *Peerbooms v. Stichting CZ Groep Zorgverzekeringen* (on the reimbursement of hospital costs incurred outside the country of origin) are, however, setting the stage for some harmonisation.

Member states: Protecting national interests

The third stakeholder – insofar as they can be lumped together – are the member states. Pinpointing a set of finite interests for fifteen EU governments requires some generalisation. Each has different priorities with respect to its own national industry, and each has a different healthcare system. Nevertheless, common ground can be found in that national authorities must ensure a certain quality of health and healthcare for the consumer through product safety and efficacy testing, along with maintaining control of medicines bills. They must equally make provisions for the industry in order to ensure both a high quality of product and national competitiveness. Governments' responsibilities are to industry, consumers, and the healthcare market, all within the context of the SEM.

This multi-role position is difficult in itself, but is hampered by the fact that governments' priorities for the pharmaceutical sector often have as much to do with electoral success as anything else. Keeping the voters happy is any government's primary concern. But how to do so when cutting costs through drug pricing controls may be a vote-winner on the one hand, but is seen as an impediment to a successful and contributing industry on the other? Failure to control expenditure leads to measures which are unpopular with consumers e.g. higher taxation or insurance contributions. Failure to meet the needs of industry i.e. a non-conducive regulatory environment, means a potential loss of jobs and, ultimately, a decreasing quality of healthcare. With the Commission potentially looking to take the lead in the sector, this puts an added strain on national authorities who must still ensure the sustainability and success of the local sector. For as highlighted in Chapter 2, current Commission and industry goals such as free movement and free pricing would undermine both. Furthermore, as some member states' industries would benefit from a single market at the expense of others', there is an added incentive to maintain the *status quo*.

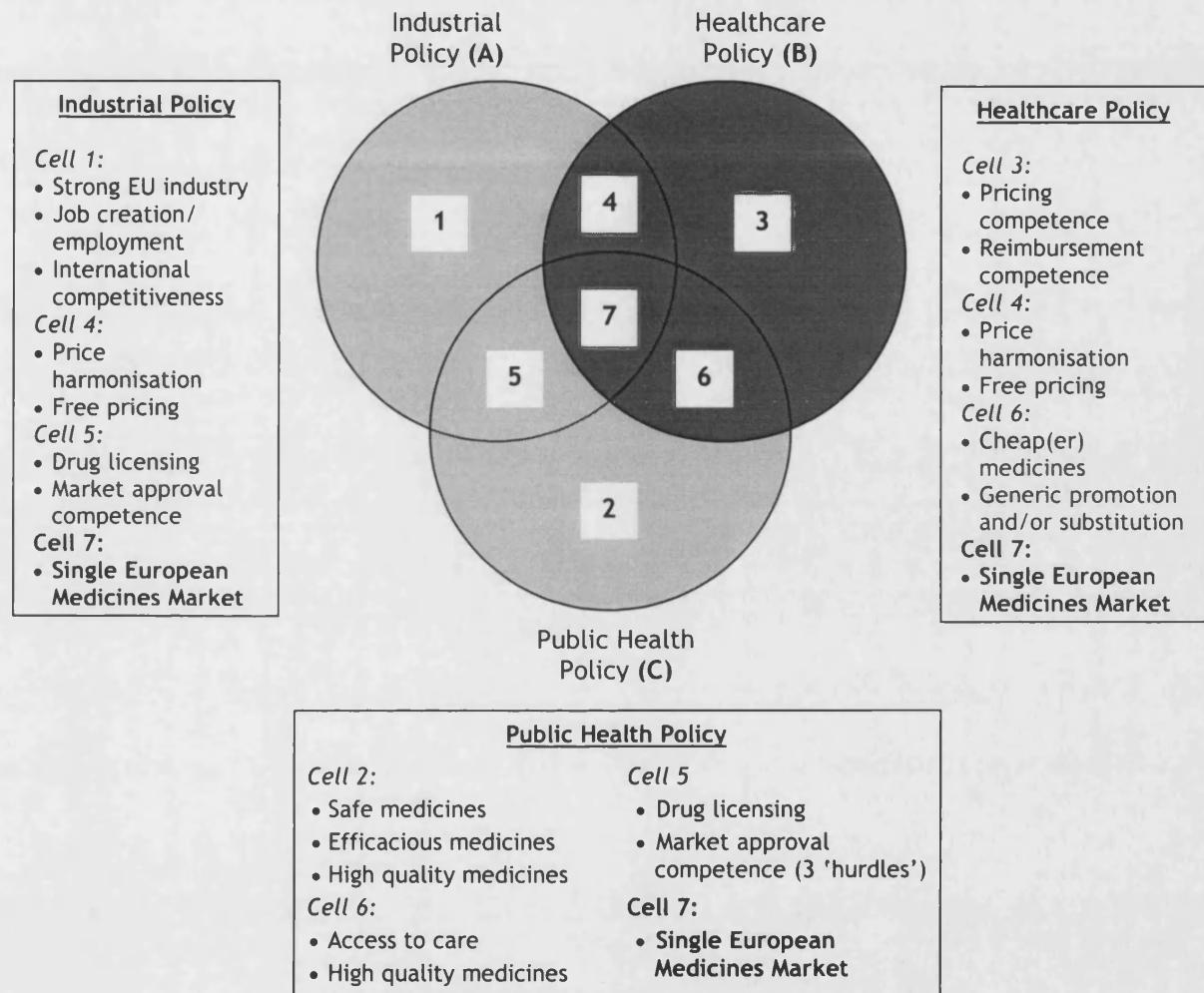
2-3 The EU policy clash

A more tangible understanding of what the clash means at EU level is now clear: A Commission interested mainly in promoting the free movement of goods (single market), improving the competitiveness of European industry (industrial policy), and some degree of price harmonisation (healthcare policy). The member states are pursuing similar, national industrial policy interests (supporting the industry and promoting employment), along with local healthcare and public health objectives (cost-containment and high quality of medicines). The emphasis is on retaining control of healthcare spending, and subsidiarity permits them this opt-out. The industry is lobbying for its interests to be met at national and supranational levels. Finally are the consumers. Although virtually excluded from the debate, the irony is that their interests are invoked by each of the other stakeholders to

justify their own positions. As a result, the lack of clarity over what sort of regulatory regime will actually develop means that policy-decisions (and the degree of consumer involvement in the process) will continue to be treated on an issue-specific basis.

Earlier it was shown how the dissonance between subsidiarity and free movement impedes the Commission (Figure 2-2). When the stakeholders' differing interests are added, the Commission's role is made even more difficult; especially as the EU's public health mandate is also limited (Holland & Mossialos 1999). This is represented in Figure 4-1.

Figure 4-1: Overlapping Policy Interests in EU Pharmaceutical Regulation



The figure captures the multiplicity and variety of interests involved in the policy overlap. Each circle (A,B,C) represents one of the wider policy spheres assumed in medicine regulation, while the numbered cells correspond to groups of specific policy goals. The 'healthcare policy' sphere (B) is the domain of the member states. Any policy interests that fall within it, even overlapping from another sphere, are subject to subsidiarity and member state approval i.e. Cells 4, 6 and 7. The 'public health' policy (C) and 'industrial policy' spheres (A) meanwhile, are areas in which the EU has at least some degree of competence and where, therefore, the EMEA, DG Enterprise and DG Sanco play a role.

The specific policy goals represented in the diagram are equally applicable to the national context in terms of domestic policy, but in the EU frame a single market would need to accommodate this structure 15 times over; each member state has specific requirements and expectations corresponding to these goals, and none will permit any Community incursion into its healthcare sovereignty.

Looking more closely at the figure, while the Commission may be interested in price convergence from an industrial or single market point of view, because this impacts on national healthcare systems there is no progress (Cell 4). The same applies for the EMEA in that its mandate represents an overlap between public health and industrial policy interests (Cell 5), but it has no pricing and reimbursement authority. Cell 6 shows that the issue of high quality medicines (and access), while clearly a public health matter and to some degree therefore a Community field, is nevertheless also a healthcare financing matter and beyond EU competence. Finally, the concept of a single medicines market is shown in Cell 7 to be an overlap of all three spheres, and one which is severely compromised given that not even Cells 4 and 6 show prospects of being devolved to the supranational level. The result of this is the Community's ability to only involve itself in industrial – and to a lesser extent – public health policy concerns. Though, as the figure shows, its competencies in the latter are also limited by the healthcare element.

With the differences in objectives of the primary stakeholders now clear, as well as the clash between free movement goals and the subsidiarity principle, it becomes necessary to see how they interact within the context of EU pharmaceutical policy. Understanding how policy networks form around policy proposals and in what way the regulatory environment impacts on the type of policy that can be agreed (in this case imposing constraints) is the next step. Industrial policies may dominate the EU regulatory framework for pharmaceuticals, but as some of these impact negatively on interests in the health(care) policy community, it is important to see how they have been reached. This is something macro-theories are unable to demonstrate.

3 The 'Politics of Policy': Recasting Community pharmaceutical regulation

The earlier discussion on the interest-intermediation application of policy networks made the point that networks do not operate in a vacuum. Instead, they take place within the constraints and boundaries of the policy environment. Nevertheless, much of the literature appears not to take this into account. Marsh (1995), however, has noted that: "Policy change is clearly not just a function of what occurs in the network: it is also strongly influenced by the economic, political and ideological context within which the network operates." (3) This is relevant to EU pharmaceutical policy, in that understanding the

regulatory environment will help to explain why some policies have been successfully carried out and others not. For although single market priorities resulted in the need to standardise package guidelines, advertising, and wholesale distribution among other issues, the sensitivity of healthcare matters have ensured that member states retain control over pricing and reimbursement concerns.

In order to address this and to understand how policy has been achieved given the clash represented in Figure 4-1, the discussion now turns to the 'politics of policy' approach formulated by Wilson (1980). It represents a framework of regulatory policy-making which characterises choices on the basis of perceived costs and benefits, arguing that the resultant cost-benefit configurations give rise to different modes of politicking. Having been effectively used to show at what level lobbying can prove effective (Hood 1994), it has also been applied to explain EU regulation more generally (Majone 1996). And its use here is to show how actors behave within the networks which form around (proposed) EU pharmaceutical policies. Understood as taking place within the broader perspectives outlined in Chapter 3, this offers a clearer picture of how policy is actually made. Moreover, it enables the study's main contention – that industry is the main beneficiary of the regulatory framework – to be tested in relation to the case-studies of later chapters.

3-1 Costs versus benefits: Four scenarios

As a student of regulation in the US, it is not surprising that Wilson's politics of regulation model was developed around the 'iron-triangle' conception of 1970s and 1980s American politics⁹⁰. And his conclusion that this regulatory view was valuable in explaining how industry interests could come to dominate policy discussions and, indeed, outcomes, represented a clearer elucidation of the earlier arguments made by other American scholars such Gabriel Kolko and George Stigler that regulation was designed by and operated for industry (regulatory capture). The ability of his framework to incorporate the trade-off between private and public interests within the policy-process, as opposed to seeing it as a by-product, is perhaps the main reason that scholars have since sought to apply it beyond the American context. It also firmly integrates business interests (and lobbying specifically) into policy-making, rather than treating them as an external influence – something which, as already noted, is prevalent in all areas of EU policy-making. The 'politics of policy' is thus particularly relevant to the EU in that traditional pluralist and neo-corporatist configurations do not adequately capture the dynamics at play in the Community's multi-level governance structure. It is, therefore, compatible with the policy

⁹⁰ The 'iron triangle' in American public policy theory referred to the relationship of interdependence between the state (or agency), a Congressional committee or subcommittee, and an interest group.

network approach which, as argued by Héritier et al (1996), is perhaps ideally suited to the 'sectoralised' EU frame.

Wilson's assertion, quite simply, is that "... policy proposals, especially those involving economic stakes, can be classified in terms of the perceived distribution of their costs and benefits" (Wilson 1980, 365); that is, the trade-off price of implementation to the involved parties. These costs can be either (or both) economic or non-economic, and the value they carry is changeable according to the political climate. It seems a common-sense and straightforward enough view, but its value is perhaps in the detail. Not only does Wilson qualify regulatory decision-making according to the distribution of costs and benefits (concentrated or diffuse), but he argues that for each of the four possible configurations this generates, there results a specific type of politicking via which outcomes are achieved. This goes some way towards supporting Lowi's (1969) argument of some years earlier that the policy arena often determines the nature of the political processes within it. Figure 4-2 offers a matrix representation of Wilson's four-dimensioned framework.

Figure 4-2: A Typology of the 'Politics of Policy'

		BENEFITS	
		<i>Diffuse</i>	<i>Concentrated</i>
COSTS	<i>Diffuse</i>	Majoritarian politics	Client politics
	<i>Concentrated</i>	Entrepreneurial politics	Interest-group politics

Source: Majone (1996), based on Wilson (1980).

The typology depicted in Figure 4-2 characterises the manner of politics via which different types of policy interest are resolved and, correspondingly, at what level this takes place. This is on the basis of what each player believes they have to gain or lose in a given policy scenario. From Wilson's perspective, as he was concerned primarily with economic regulation at the national level, the stakeholders were industry, the state and the general public, with the latter understood in terms of representing the wider 'common good'. As mentioned earlier, the EU the multi-level governance conception implies a host of further embedded actors, and policy-making in the pharmaceutical sector reflects this view quite clearly. However, as the study is concerned with the making of supranational policy, its looks only to the industry (particularly the research-based industry), the European Commission, the member states, and consumer interests (in whatever format or group represents their interests) as the main stakeholders. This allows for further inter-actor divisions where the policy issue at hand may provoke disparate reactions.

This model is relevant for two reasons. First, it shows how a more targeted decision-making framework ties in with the integration and regulatory theories already profiled. And second, it establishes the fact that policy networks operate within certain

constraints. The politics of policy matrix thus fixes a set of parameters within which networks can operate, as well as acting as the liaison between 'meso' and 'macro' environments. It is able to accommodate both.

Majoritarian politics

According to politics of policy framework, in instances where the costs and benefits of a proposed regulatory policy are both diffuse, as there is little incentive for those involved to collaborate, the likelihood of policy outcome is fairly slim. The question of who pays, or more specifically, who is willing to pay what for a share of the benefit, means that resolution will only take place where there is sufficient political will and popular support. Both sides will have to agree such that a policy outcome will only be achievable via *majoritarian politics*. In the EU context, where the issue is about extending supranational regulatory authority, this means that all the stakeholders – including the Commission and the member states – will have to consent to bearing some of the costs of a policy which will benefit the others as well; costs which are extremely high at least in the short-term. Majone (1996) has cited social policy as one such example. Indeed, the sluggishness of some member states in implementing the 1993 Working Time Directive⁹¹, for example, would seem to bear testament to this.

In light of the wide distribution of both costs and benefits, matters involving member state healthcare systems and the provision of health also fall into this category. The Commission may favour an increased Community role in health matters – though this needs centralising given that several Directorates-General affect matters pertaining to health policy (Merkel & Hübel 1999) – but the member states remain very much against in view of not simply the potential economic costs, but so too the political consequences. Relating this to EU pharmaceutical policy thus gives a potential view into why the healthcare policy dimension of drug regulation remains a national level concern.

Client politics

Over issues where costs may be diffuse but the benefits concentrated, as only a small group stands to derive the most gain, the conditions raise the possibility for *client politics* to emerge. There is considerable incentive for one or more of these small groups to collaborate in order to influence the policy-process in their favour. Their chances of success are potentially bolstered with the costs being so widely distributed that the per capita price becomes negligible. The likelihood of widespread opposition is therefore

⁹¹ Directive 93/104/EC.

diminished. This is the classic business lobbying profile which asks who regulation is intended to serve: business/industry interests or the wider public good. Accordingly, multinational companies and other business interests fit within this model. The potential dominance of industrial lobbies under this scenario is usually countered by the use of independent regulatory bodies. But where such agencies lack the clout necessary to enforce their views, Wilson suggests the 'producer-dominance model' (regulatory capture) can and does result. Industry may thus receive favourable treatment by government via subsidies or simply a laxer regulatory environment.

Industry lobbying over specific policies has been a trait of the EU pharmaceutical market since the SEM, and it has for the most part been successful in such endeavour. The first reason for this is the market's fragmentation. Second is the nature of the policy-making process; multi-level governance proposes multiple levels for lobbyists to target. In addition to its ability to organise, its success is also because the issues at stake tend to be similar across national boundaries and the multinational nature of the industry has enabled it to gain significant lobbying experience in a host of environments (Greenwood & Ronit 1994).

Entrepreneurial politics

The term *entrepreneurial politics* is used to characterise policy decisions involving a wide distribution of benefits though a more concentrated spread of costs. With only a small group responsible for bearing the burden of the proposed policy, it is unsurprising that they are often vociferous in registering their protest. At the same time, however, as the benefits are so widespread and diffuse, they are on their own insufficient to capture the imagination and mobilise actor support for the policy. This may be the result of a lack of knowledge, or it may simply reflect a general apathy in that the relative per capita gain does not warrant activism. With there being little incentive to support such legislation, some persuasion (of both sides) becomes necessary.

Wilson thus proposes that a 'policy entrepreneur' is needed to take the issue forward. This implies an actor able to galvanise public support and undermine any arguments the policy's opponents (those bearing the costs) may present. This the entrepreneur usually does by dramatising an issue or associating the benefits of the proposed (corrective) policy with values or the common good. For example, by revealing environmental mismanagement by multinational companies and associating them with things such as children's health, a skilled actor can engender support for sustainable environmental practices such that they become law. It is to be noted, however, that the entrepreneur may not be a completely objective party. More often than not it will have its own agenda.

At EU level, in light of its initiator role, the European Commission can often be seen to fulfil this entrepreneurial role. It is able and has a responsibility to galvanise support on a host of issues, primarily on the basis of the widespread Community benefits a policy could offer. Indeed, in the Commission's role has been characterised as exactly that of a 'policy entrepreneur' (Laffan 1997). As mentioned, environmental policy can be regarded as an area in which an entrepreneur is generally needed, and the Commission can and does play a role here. For although the benefits of stricter environmental standards are to be enjoyed by the member states' populations, the costs are concentrated; generally limited to private enterprise which is responsible for financing and implementing any requisite measures. When broken down into individual policy fields such as air or water pollution, the costs become even more concentrated requiring an entrepreneur. This is also the case where the costs of a given policy may disproportionately affect one member state, such as under the Common Agricultural Policy (CAP). As for medicines, given the difficulty in sourcing information on the industry and the informational asymmetries which characterise the market, it is clear that a policy entrepreneur (the Commission) is needed to bring the issues into the open and to educate people about potential ramifications.

Interest-group politics

Finally, a policy offering high benefits to only a small number of interests, though at the expense of an equally small number of others who will bear the costs, gives rise to *interest-group politics*. In an industrial setting government subsidies or other incentives will usually favour one segment of industry at the expense of others (this may even be with regard to single companies gaining some type of competitive advantage). As noted in the pharmaceutical sector, priorities differ between generic and research-based companies, with one side usually standing to gain from the other's loss i.e. stricter intellectual property rights. Accordingly, the motivation for both sides to organise in order to influence the policy-process becomes acute. Since the costs and benefits are seen as not really affecting the wider population, the question of the 'public good' is not normally raised.

The result is a multitude of groups representing a kaleidoscope of specific interests all campaigning to ensure their own welfare as much as pushing a particular proposal: the few on the basis of the benefit they stand to derive, the majority on the basis of the harm or cost they may have to bear. The gains and losses potentially implicated by such policies at European level means a variety of bargaining scenarios, more often than not involving member states competing against each other, and disagreement with European institutions. EU Structural Funds, where the emphasis is on the redistribution of (and competition for) financial support is an area where interest-group politics can develop. Given the interests at stake, and the stakeholding nature of actor relationships, this

dimension is clearly relevant to EU pharmaceutical regulation; discussions and bargaining between the main actors is a defining characteristic of the sector.

These are the four categories that Wilson sets out. Given the regulatory state conception of EU policy, wherein the Commission, the industry and the member states are all doing their best to preserve their own interests as much as they are trying to improve their respective lots, its relevance to the pharmaceutical sector is immediately clear.

3-2 The politics of policy and EU pharmaceutical policy

Wilson's framework is not perfect. It is very much a 'black or white' view grounded in the American rational actor tradition. There will be intermediate cases, and the high-low (concentrated-diffuse) measurement is inevitably a relative one. However, this does not diminish the conceptual value of the approach. After all, politics is not an exact science, and a degree of generalisation is usually necessary. Discussions over perceived costs and benefits can be made within reason. And as the study uses the framework in conjunction with other analytical perspectives – rather than claiming that on its own it offers all the answers – it can be seen that it is extremely useful in elucidating stakeholder interests within networks as they form over given policy proposals.

The application of Wilson's framework to selected policy issues in the EU pharmaceutical sector (past and present), will be offered in the case-study chapters (6, 7 and 8). These case-studies reflect not simply the relevance of the framework, but more the fact that supranational policy-making where medicines are concerned is an extremely sensitive affair with an appreciable effect on the stakeholders' interests. That various aspects of the EU regulatory framework correspond to different configurations within the Wilson approach reflects this complexity. While regulatory policy in more traditional industries might apply to only one or perhaps even two of the scenarios, it certainly does not involve all of them.

The first case-study looks at the successful industry lobby over intellectual property rights in the early 1990s and argues this as a case of client politics. The industry's claims that the patent protection rights accorded medicines were not sufficient to sustain the requisite research and development costs resulted in the Supplementary Protection Certificate legislation of 1992, which extended the protection period accorded new medicines. The second case-study concerns the establishment of the European Medicines Evaluation Agency. As mentioned earlier, the EMEA is a unique body, and is the office responsible for granting drugs EU market authorisation. The discussion will show that its establishment seems to have been a case of entrepreneurial politics within the network, though later discussions perhaps shifted the final decision towards client politicking. The third case-

study is the pricing and reimbursement debate. Commission initiatives to overcome this impasse are looked at, as are the reasons for why this area has remained such a sticking-point. This is seen as majoritarian politics given the continuing deadlock; with all sides having to agree, this explains why there is no progress.

An application of the politics of policy approach to the policy issues already raised (including the case-studies) thus generates the following matrix (Figure 4-3).

Figure 4-3: The 'Politics of Policy' as Applied to Selected Elements of the Community Medicines Framework

COSTS VERSUS BENEFITS			
Diffuse-Diffuse	Diffuse-Concentrated	Concentrated-Diffuse	Concentrated-Concentrated
Majoritarian	Client	Entrepreneurial	Interest-group
• Pricing • Reimbursement	• Patent protection • European Agency for the Evaluation of Medicinal Products	• Packaging, inserts and leaflets • A fully integrated single market for pharmaceuticals	
TYPE OF POLITICS			

Wilson's typology has four dimensions. The interest-group cell concerns a small group seeking to protect their interests in the face of benefits being accrued by another group. The respective win-loss trade-off and strength of bargaining which accompanies it means that policy is extremely difficult to agree, if at all. Consequently, Table 4-3 reflects the argument that a fully integrated EU medicines market corresponds to the interest-group politics scenario. Some of the reasons i.e. why a single market has not been achieved (most notably the winner-loser division which would emerge amongst the member states) have already been raised. As there is too much uncertainty for the stakeholders: what would a single market mean in practice, who will benefit more (which countries, which industries) and by how much, the interest-group scenario cannot really be tested empirically. There is no one policy which fits. Rather than compromising the applicability of the approach, not developing the fourth cell it in fact strengthens it. For the inability to attain a harmonised market reflects the impasse and extent of the constraints. There are many actors, representing a panoply of interests, all trying to ensure that they do not have to bear the very high costs in order for another party to benefit; not just the main stakeholders are involved. Chapter 8 provides a more detailed discussion.

Outlining Wilson's approach here was to introduce and show the utility of the matrix as a background to studying the Community's formulation of pharmaceutical regulatory policy. It adds another level of analysis with which policy networks can be integrated. And it can

be tied into both the multi-level governance perception of the EU as well as the regulatory state perspective on policy-making. Furthermore, it does not preclude the involvement of outside actors or external influences on the policy-process. The predominately clarifying (and positive integration) role of the ECJ has already been stressed, and there is no reason to suggest that this does not fit. As far as policy networks go, the politics of policy approach lays down some essential ground-rules which will affect the nature of outcomes irrespective of the degree of network activity. Wilson's model can supplement the interest-intermediation approach by showing how the nature of the issue at stake can impact on the manner in which policy is or is not developed.

Firstly, the cost-benefit configuration can determine whether networks will form and, to a degree, determines in what cases they might be successful. This is, however, where the framework's explanatory power stops. On its own it cannot reveal the nature of interactions within the styles of politics it distinguishes, nor can it account for instances where a policy issue changes i.e. where more interests and actors join the policy fray or where externalities force decisions. Network analysis provides insight into the former, while integration theories can account for the latter – the 'politics of policy' sits squarely in the middle. And it is precisely herein that its value is to be found. It acts as the liaison to link the 'macro' and 'meso' within the conception of the EU as a regulatory state subject to the dynamics of multi-level governance.

As noted earlier, the study does not offer a purely (new) institutionalist analysis. Path dependency within certain structural arrangements does characterise policy-making in the pharmaceutical sector, and here the use of Wilson's framework would seem to fit within this. As Rosamond notes (2000), "Rational choice institutionalism tends to define institutions as formal legalistic entities and sets of decision rules that impose obligations upon self-interested actors" (115), and this is clearly the broader environment which contextualises the study⁹². The discussion characterises the stakeholders' choices in large part on the basis of costs versus benefits, and subjects these to the formal decision-making dynamics of, for instance, EU voting rules within the Council of Ministers. And it is clear that this in turn will affect any policy outcome. That said, the study keeps within the politics of policy approach, focusing on policy networks and the meso-level. The analysis is very much oriented around what each stakeholder in a given network perceives it has to gain or lose over a specific policy proposal (and whether the *status quo* might in fact represent the best option). The study Wilson's matrix is thus used as an important contextual framework which provides important insights into the policy-process(es) of the case-studies which follow. Further, it enables a testing of the contention that the industry

⁹² Rosamond highlights the diversity in the institutionalist literature and posits 'historical', 'rational choice' and 'sociological' institutionalism as the main variants. See Rosamond (2000), 109-122.

dominates the networks such that the regulatory framework favours its interests. So although in some ways perhaps conforming to a new institutionalist framework, the study acknowledges this rather than seeking to detail or elucidate it in any way.

CHAPTER 5

'CLIENT POLITICS': THE SUPPLEMENTARY PROTECTION CERTIFICATE

Introduction

Intellectual property rights are generally regarded as central to the activities of highly research-intensive industries such as pharmaceuticals – the costs and length of time required to develop a new medicine are considerable. Moreover, the period from identification of the new molecule to the launching of the derived product represents a much longer registration and market approval process than is found in other sectors. What is less widely held, however, is what the appropriate robustness of this intellectual property protection should be when bearing in mind consumer interests, healthcare costs, (generic) competition and, in the EU, the principle of the free movement of goods.

Notwithstanding that pharmaceuticals fall under the auspices of the 1973 European Patent Convention (EPC), in legislation enacted in 1992 the Community seemed to deliver its own answer to the question of adequate robustness. The Supplementary Protection Certificate (SPC), was introduced to extend patent protection times for medicines in the Community. Manufacturers were granted a 5 year post-patent expiry extension⁹³, or 15 years total protection from the date of first *market authorisation* in the Community. This was as opposed to the 20 years from first *patent application* under the EPC. The SPC thus represented a derogation to both the European Patent Convention and the free movement of goods principles of Article 100.

This chapter examines how this piece of legislation came to pass, what the interests and roles of the stakeholders in the policy network which developed around the patent extension issue were, and how the policy-process fits within the politics of policy framework. Beginning with a brief overview of patents in Europe, the discussion turns to protection expressly for medicines. A brief outline of the arguments in favour and against patent-term extension of is then followed by an analysis of the political interactions behind the SPC. It is expected that such an analysis will not only show that actor (inter-institutional and even interpersonal) relationships and resource dependencies via a policy network configuration played a considerable role in this process, but will also indicate how industrial policy interests came to the fore. Specifically, the discussion argues that the Commission came to be influenced by the research industry on the basis of a client politics configuration (*vis-à-vis* the policy network's other stakeholders).

⁹³ Although industry commentators see the SPC as a patent-term *restoration*, this chapter uses the term (patent-term) *extension* given the limits it set on generic research during the extra period. Given these limits, other commentators regard the SPC as granting a period of 'marketing exclusivity'.

1 Protecting Intellectual Property

As with most other innovative and high technology-driven industries, pharmaceutical manufacturers place considerable emphasis on the role of intellectual property legislation as a means of securing rights and ensuring returns. A patent accords the holder the right to exclusive use of an invention (product or process), and provides legal grounds for preventing its unauthorised use. But for a medicines sector perhaps moreso than any other, the role of patents and the security they afford manufacturers is regarded as a 'make or break' issue given the costs involved. Moreover, industry representatives are often at pains to point to a causal link between a prospering European pharmaceutical sector where adequate intellectual property protection is in place, and better healthcare⁹⁴. As noted in Chapter 2, however, this proves a tenuous link even at the best of times.

1-1 Patents in Europe

Before looking at pharmaceutical patents, the general nature of European patent legislation requires brief mention. This underlines just to what extent the SPC is a unique piece of legislation. The origins of patent protection stem from the 1883 Paris Convention for the Protection of Industrial Property. It covered issues including trademarks, patents, tradenames, and even regulations pertaining to unfair competition. In Europe specifically, patent protection is legislated for under the European Patent Convention (EPC), established in 1973 in Munich, Germany. The EPC set down the principles of a Europe-wide patent for single applications for all industrial products/processes, which now applies to twenty European countries, not all of which are current EU member states.

The EPC grants the patent holder the same rights as would be accorded under a patent granted nationally. A single application is thus given multiple country accreditation by an international body, but is nevertheless subject to the national legislation of the individual countries. The term of coverage for all industrial patents is a standard 20 years from the date the application has been registered. Subject to several notable exceptions including certain biotechnology applications, medical (surgical) procedures and computer programmes, patents under the EPC are granted to new inventions which incur a significant 'inventive step' and which could be commercially exploited by parties other than the inventor. There are a host of internal definitions, clauses and conditions within this simplification, but they are too detailed for consideration here.

⁹⁴ For instance EFPIA (1995) and Gilmartin (1997).

Co-existing with the EPC is the Community Patent of the European Union. As the EPC covers several countries outside the EU, the European Community has long sought to establish its own patent system. The principle of a Community-wide patent was to provide an alternative (not a replacement) to individual national patents in the member countries. It represents an adaptation of the EPC, and was designed within the context of removing obstacles to the free movement of goods and services in the single market. Several of the more notable measures under the Community patent include:

- a single patent applicable in all EU member states;
- a process whereby an application approved in one member state becomes effective in the others following a so-called 'transitional period';
- national authorities retain the ability to invoke national legislation in the granting of compulsory licences;
- making available the option to pursue a single country patent to applicants; and
- protected products to be subject to the free movement of goods and services principle of the single market.

Originally agreed at the Luxembourg Convention on the Community Patent in 1975 and amended in December 1989⁹⁵, the Community Patent is still not in force; and its implementation remains high on the agenda for European policy-makers.

The benefits of a single EU patent include uniformity and Community validity with a central jurisdictional authority; the obsolescence of the current requirement that in order for a patent to be recognised in a country it must first be used there; and the removal of fees payable in each separate country for patent renewal. However, there are also drawbacks. These include that: a challenge or infringement in one member state becomes relevant to all and may result in an EU-wide revocation of the patent; companies with the same patent in several countries (on an individual basis) will no longer be allowed to let it lapse in one or two while maintaining it in others; and the administrative (including translation) and transaction costs may in fact be higher for the maintenance of a Community patent than for individual patents in each country. The aim in pursuing an EU patent system is to "...eliminate the distortion of competition, which may result from the territorial nature of national protection rights. It should also ensure the free movement of goods protected by patents". (EP 2001, 2) Once this legislation is finally enacted, it will have a considerable impact on pharmaceutical patents in the Community⁹⁶.

1-2 Pharmaceutical patents

For medicines, the purpose of patents is "... to stop competitors selling: the identical product, a similar formulation of the active ingredient, or a product incorporating a 'me-too'

⁹⁵ 'Agreement relating to Community patents'. OJ L401, 30.12.89: 1-27.

⁹⁶ For an outline of the European pharmaceutical industry's views on the Community Patent issue, see EFPIA (1997).

active ingredient for as long as possible." (Wright 1997, 19) Companies argue that particularly in less-developed countries "... patent infringements resulting from lax laws allow local generic companies to reap undeserved financial rewards. Multinational pharmaceutical companies lose revenue and market share..." (Ganorkar & Korth 2000, 77). As this costs them huge sums in legal costs, the patent-holding companies are keen on stricter intellectual property rights. Medicine patents are thus intended to lower the profitability of imitation by enhancing that of innovation. In principle such rationale are no different than in other sectors. But in practice, the intellectual property protection afforded drug producers is unlike that applicable to other industries.

Pharmaceutical patents apply to the discovery of new chemical entities and afford the holder the exclusive right to make and market drugs using that compound for the lifetime of the patent. In addition, multiple patents apply to any given medicinal product. These cover most notably: substance, compound, formulation, usage and process. *SmithKline Beecham's* antiulcerant drug *Tagamet*, for example, carries some 26 separate patents (EGA 2000a), precluding research into any of these areas. The breadth of this protection is a consequence of the costs and registration times for new drugs, as well as the knowledge-accumulation on which they are based (see Chapter 2). Not just the length of protection accorded patent-holders, therefore, but the fact that patents cover the discovery and any prospective application of a new chemical entity represents a situation not seen in more traditional manufacturing sectors. With this the case, why have pharmaceutical manufacturers in most major markets (the EU, the United States and Japan) sought, and been successful in securing, longer patent terms than are offered other products?

The reasons stem from the fact that pharmaceuticals are concomitantly an industrial good and healthcare commodity. Recalling that under the EPC patent-life is the length of time between the original application for a patent and the time the patent expires (20 years), the three hurdles of safety, efficacy and quality which must be overcome by new products seeking market authorisation, mean that a considerable amount of this protection period is lost before the product makes it to market. Consequently the phrase 'effective patent life' is used to denote the period of time a product is covered by a patent whilst on the market. The length of the pharmaceutical approval process not only compromises the duration of the effective patent-term, but the industry argues that "... since many persons and organisations other than the innovator are involved" (REMIT 1996, 20), patent protection should nonetheless apply during such assessment periods. And as approval and testing times are much shorter for more traditional industries, it does perhaps seem somewhat inequitable that products subject to such strict and important pre-marketing requirements receive briefer patent protection terms than products which are not.

As noted in previous chapters, rising R&D costs in the medicines sector have been commensurate with the amount of time it takes to develop a new product – the so-called ‘golden age’ of drug discovery of the 1950s and 1960s has long since passed. No longer do new compounds suggest themselves so readily, and the breakthroughs in areas such as histamines, steroids, and penicillin are not forthcoming (Sharp et al 1996, 3). Industry officials put cost of bringing a new drug to market at €500-560 million (EFPIA 2001a)⁹⁷ and argue that this expense alone justifies the need for patent protection which goes beyond that in other industries. In addition, the complexity of current genome research has led to claims that the cost of researching a single medicine is set to increase by more than 100% over the next few years⁹⁸. This represents a worrying direction for the companies, and reflects their strongest argument for patent-term extension. It is perhaps not surprising, therefore, that the Community has therefore legislated in this area.

That said, some see the industry’s claims as more of a smokescreen in the pursuit of higher profits and increased market shares. They question whether the medicines truly warrant exceptional patent-term coverage. New innovative medicines can, after all, achieve up to US\$1 million a day in global sales (Vogel 1998) and, despite increasing R&D costs, pharmaceuticals continue to be one of the most profitable of all industries (Scherer 1996). Furthermore, critics counter the industry’s complaints about unduly long registration times as a worst-case scenario, with many more drugs making it to market more quickly than before. As one commentator puts it, “... the industry in totality seems to have fared pretty well in spite of the encumbrance of ‘inadequate’ patent cover.” (Paltnoi 1998, 55)

Thus, pharmaceutical patents are generally viewed from two camps. The pro-industry view holds that stringent intellectual property rights on medicines act as an incentive to industry with regard to innovation⁹⁹, thereby promoting public health, healthcare and welfare:

It is imperative that the legitimate budgetary concerns of governments be reconciled with the needs of an innovative pharmaceutical industry, as in the long run, innovation and technological progress can supply a lasting contribution towards solving the problem of paying for healthcare... Innovation, with the stimuli of fair and healthy competition, can meet the healthcare expectations of the authorities and patients alike. Ultimately, only fair and healthy competition at various levels within healthcare systems will both contain costs and meet public health and patient needs and expectations. (EFPIA 1996, 11)

⁹⁷ Again, this is an industry figure, and one which includes a host of exogenous variables relating to R&D, risk and failure of other chemical entities and, furthermore, reflects the industry’s unwillingness to acknowledge that there is a ceiling in innovation capacity.

⁹⁸ EFPIA – ‘Did you know?’ (available at: www.efpia.org/2_indust/didyouknow.htm)

⁹⁹ A study undertaken by the US Office for Technology Assessment in 1981 concluded that “The evidence that is available neither supports nor refutes the position that innovation will increase significantly because of patent-term extension. Thus, the net effects of patent-term extension on pharmaceutical innovation cannot be ascertained.” (OTA 1981, 4)

Those who cast a more dubious eye over industry claims argue that extended patent-terms are sought simply to boost companies' profitability by insulating the holders from competition, and result in higher drugs bills and welfare losses. The former hails from an industrial policy position and the other primarily from the health(care) vantage-point. These competing perspectives, along with the uniqueness of pharmaceutical patents, should be borne in mind as the background to the ensuing discussion on the Community's decision to extend patent times in 1992.

The discussion has hinted at the rationale, and pros and cons for (extended) pharmaceutical patent protection. What is not as clear is whether long(er) protection periods represent a boost to healthcare and patients or not. Protecting innovative medicines may indeed help companies recoup their investments, and it may provide them with a tangible incentive to continue the search for new and better drugs, but as there is no definitive correlation between extended protection and (quality of) health, it is a question which remains unanswerable. The relationship is nevertheless an important one to bear in mind given the research industry's (ongoing) arguments for extending protection periods. As regards the European Community's 1992 extension of patent-terms for medicines under the SPC, it is therefore perhaps surprising that the Commission should ultimately deliver a proposal so clearly in favour of the research industry.

1-3 The Community Supplementary Protection Certificate

The Supplementary Protection Certificate became effective on 2 January 1993 and applied to drugs granted market authorisation after 1 January 1985¹⁰⁰. A synopsis of its main terms reveals just to what extent the SPC represented a major boost to Europe's research-driven companies. First, it extended the effective patent life on new and innovative medicines by 5 years¹⁰¹. The Certificate provided a longer period of coverage than previously available – a maximum 15 years 'effective monopoly' from the date of the medicine's first market authorisation within the Community. This prolongs the profit-life of covered products as it is during the period of marketing exclusivity that drug sales are generally at their highest (IMS Health 2001). Second, it prevented 'unauthorised third parties' (generic companies) from engaging in R&D prior to patent expiry.

Generic manufacturers had previously been able to begin their own testing and research from the date of the original patent submission, potentially releasing their copy on the very

¹⁰⁰ The SPC came into force on 01.07.93 for Austria, Finland, Norway and Sweden, and on 01.01.98 for Greece, Portugal and Spain.

¹⁰¹ The time difference (years) between the date of patent application and first market authorisation minus 5 years decides the length of the SPC period. If the product was approved within five years of patent application, then it does not qualify for the SPC. A period between 5-10 years qualifies for a certificate, and anything longer than or equal to 10 years receives a maximum five years extra SPC coverage.

day the patent on the original had expired. By preventing generic research during patent coverage, longer shelf-life for the branded products was ensured. The legislation ostensibly shields the research industry further from the more traditional levels of competition seen in other sectors. More importantly, the total coverage period of 15 years was more generous than what was available in the US and Japan at the time – as will be seen, the Commission had originally proposed a 10 year SPC with up to 30 years coverage – helping boost the research industry's position in the global market.

An example of the degree to which the research companies benefit from the SPC comes from *Eli Lilly*'s antidepressant *Prozac*. In the UK *Prozac* came to market in 1986 and the patent expired in early 1995 (around 9 years effective patent life). The company applied for the extra coverage which was granted until the end of 1999. According to IMS Health (2001) data, *Prozac* achieved approximately 80% of its total sales between 1990-1999 in the last 5 years alone i.e. during the extension period granted by the SPC. This was the situation in the UK; *Eli Lilly* had SPCs on *Prozac* in 8 other Community countries (any company seeking an SPC is required to submit an individual national application for each market). With *Prozac* achieving UK sales in the vicinity of £100 million a year, the overall benefits to the company on this one product alone have been substantial. Two years after the enactment of the SPC, one analyst commented that "The pharmaceutical industry, owners of patents covering successful commercial products, have been trying to get the highest profit from the EC Regulation and National Laws." (de Pastors 1995, 192)

How was it, therefore, that Regulation (EEC) 1768/92 and extended patent protection was agreed by the Community, especially as it is clear that the research companies alone stood to gain from any extension? First, there is no verifiable link between more drugs and better healthcare (it depends on what is being researched and licensed – see Chapter 6) but there is a correlation with increased drug prices. And second, "Although the additional patent protection period clearly helps the innovative industry, it may not necessarily encourage innovation; it may simply create inertia and a disincentive for rapid innovation and transition to a new product cycle." (Kanavos & Mossialos 1999, 324). So given that patents on medicines clearly impact on national healthcare financing – and bearing in mind the EU's lack of competence in healthcare policy – how did the SPC come to pass?

2 Extending Medicine Patents in the European Community: Initial dialogue

Because of the issues already outlined, the passing of the legislation was not an easy affair. The policy network which emerged consisted of the major stakeholders: the Commission, industry (research and generic), the member states and consumers, all with their own views and interests on the matter. Consequently the Commission was subject to

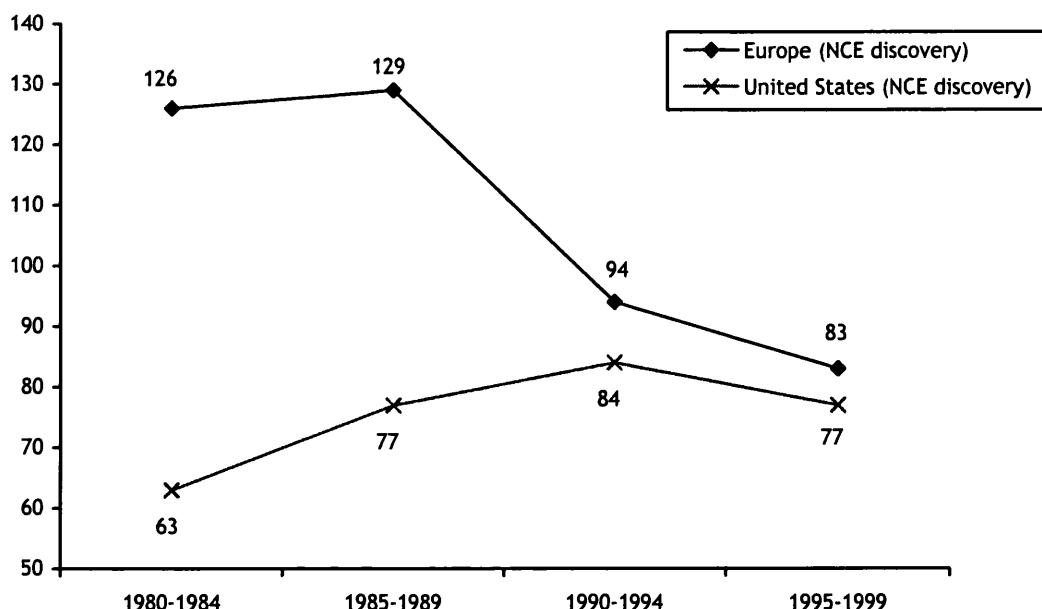
intense lobbying and detailed representations by these and other actors, particularly after publication of the Commission's proposal document. The preliminary draft proposal of September 1989 was soon followed by the official Proposal in April 1990 (CEC 1990a). After some revisions, based also on the Parliament's reading (EP 1991a), the Council Common Position was published in February 1992 (CEC 1992a) before the final text was agreed and adopted by Regulation (EEC) 1768/92 in July 1992 (CEC 1992b). It was a decision openly in favour of the research industry though, as the discussion will show, prior to the amendments the Commission's proposals had actually gone even further. An examination of the interests expressed by the stakeholders during the policy-process reveals to what extent the Commission was influenced with regard to the content of the new Regulation, why in the final legislation the Commission's proposals were diluted and, ultimately, why the client politics scenario is therefore invoked to characterise its passing.

2-1 'Industrial policy' and the research industry lobby: The case for an SPC scheme

In light of ever-decreasing effective patent life terms since the 1973 EPC, not to mention having already seen both the US (1984) and Japan (1988) introduce new and extended patent protection measures for pharmaceuticals, the need for effective protection was slowly being recognised by the European industry during the 1980s. Manufacturers felt that because of growing research and development costs, the lengthening of pre-market testing periods, and extended registration times, they were not earning sufficient returns on their products to warrant their expenditure. The industry claimed that as the number of new chemical entities being discovered was diminishing, the length of the discovery and approval processes (and hence their own costs) were increasing, compromising European competitiveness *vis-à-vis* the US and Japan. Figure 5-1 (overleaf) shows that NCE discovery in Europe dropped in the mid-1980s commensurate to the US closing the gap (see also Appendix 5-1). As mentioned in Chapter 2, however, the issue of R&D is not quite so clear-cut: companies may be spending more, but it is difficult to ascertain just how much of this is pure R&D expenditure.

The industry claimed that stricter licensing procedures in the member states and growing pressures to look into as yet untreatable conditions such as human immunodeficiency virus (HIV) and cancer were behind these trends. They claimed that lengthier patent protection would allow them to recoup their costs and reinvest them in research and development for new preparations. A 1996 report commissioned by the European Commission estimated that R&D intensities in the main drug-producing countries rose from between 7-8% to 10-12% between the 1970s and 1990s, with the main causes being increased regulatory requirements combined with the difficulty of testing drugs for chronic long-term diseases, and diminishing returns to drug discovery (Sharp et al 1996).

Figure 5-1: Number of NCEs Discovered - Europe versus United States, 1980-1999*



Source: EFPIA (2001b), OECD Health Data (2001).

* For 2001, of the 36 NCEs launched on the world market, 13 are European in origin while 18 are American.

The fear expressed by many national politicians and commentators was that Europe was losing its hitherto dominance in the sector, and that research-bases would be re-located to the US where innovation was better rewarded. The statements by Lords Butterfield and Hacking during an April 1991 House of Lords debate makes the point:

Lord Butterfield: I am for British industry and I am for the pharmaceutical industry. I have a nightmare in which the West Germans, the French, the Americans and the Japanese run our pharmaceutical industry off its legs. (as cited in Hansard 1991a, 1326)

Lord Hacking: What then should the government be doing? They should certainly not be dithering. Perhaps I may gently suggest that they should adopt the posture of supporting their industries. They should support their research-based industries; they should support skilled scientists who work in such industries and, above all, they should encourage investment in the United Kingdom. (1320)

It was with similar justification, and to attract foreign direct investment, that both the French and Italian governments unilaterally introduced national 'supplementary protection' legislation in 1991 for their respective industries (France proposed 17 years effective protection and Italy 18). However, as it was obvious that such national approaches would have ramifications for the single market, the need for a Community-wide policy was recognised (with the adoption of the Regulation all such national measures were to be abandoned). But rather than emanating from the Commission itself, the impetus for the prolongation of patent protection on medicinal products in fact originated from the industry.

The European Federation of Pharmaceutical Industries and Associations (EFPIA), the self-styled 'voice' of the research-based industry since 1978, took up the baton. At the time of the SPC, the association represented eleven of the twelve member state organisations (excluding Luxembourg) along with those of five European Free Trade Area (EFTA) countries: Austria, Finland, Norway, Sweden and Switzerland. EFPIA's job was to ensure that the industry's interests were heard in the European arena, and this it did through the organisation of meetings, the drafting of reports and position papers and the running of information seminars. More importantly, the association was the industry's official representative in negotiations with the European institutions. EFPIA was created specifically "... to bargain with the EC's institutions over the precise forms of regulation and self-regulation compatible for example with the Community's drug information policy, harmonization, pricing and patent law." (Middlemas 1995, 468) This led to it being targeted by individual firms seeking to lobby in Brussels (Abraham & Lewis 2000), and in 1997 it was restructured to account for this. Membership is now held not just by the 15 member state organisations (plus those of Switzerland and Turkey), but also by 40 of the world's largest research-driven firms. Organisationally EFPIA consists of four policy committees: Economic and Social Policy; External Trade Policy; Scientific, Technical and Regulatory Policy; and Intellectual Property Policy, which are responsible for issuing the association's recommendations and positions on relevant issues.

From as early as 1988 EFPIA and its members were lobbying the Commission over patent-term extension (SCRIP 1287), and the association published its vision for the sector in a booklet entitled 'Completing the Internal Market for Pharmaceuticals' (EFPIA 1988). As patent extension was an issue which affected the European industry as a whole, EFPIA saw it as a matter which could be most effectively handled in a centralised Community manner, rather than on a member state basis. In lobbying the Commission, however, EFPIA's initial contact did not go well. In mid-1997 Nelly Baudrihaye, EFPIA's Director-General, met with Berthold Schwab, Head of Unit for Intellectual and Industrial Property in the Competition Directorate-General (DGIV), to discuss the issue. She found that he did not see this as a matter for the Commission (Shechter 1998). As noted in Chapter 2, pharmaceutical policy was the domain of the industrial Affairs DG, and the Commission could (can), therefore, only act where industrial policy issues are at stake. Mr Schwab recognised that patents on medicines impact on national healthcare financing and did not see how DGIV, far less the Commission itself, could take the issue forward. The industry's calls for a Community response to the question of inadequate protection were thus rejected at the first hurdle. This was to change dramatically.

The industry regrouped, altered tack, and aimed to sell the idea from an industrial policy stance. EFPIA set about making a unified and well-presented case, centring its arguments

around the idea that current patent protection terms were beginning to starve innovation, and that this could potentially have negative effects on the Community's industrial competitiveness. They turned their attentions from Mr Schwab to DGIII (Industrial Affairs), and pinpointed Fernand Sauer, then head of its Unit for Pharmaceuticals and Cosmetics (DGIII/E/F), aiming to convince him of the merits of their case¹⁰². In the course of their discussions with Mr Sauer it seems a deal was struck: for Commission support on the patent issue, the industry would trade in their objections to Commission proposals on Community pricing rules – they would at least be willing to engage in dialogue over the matter. At the time DGIII/E/F was trying to secure support for Community rules on medicine pricing transparency (what was to later become Directive 89/105/EEC), which the industry had until then regarded as an unfair interference in their affairs (see Chapter 7).

Discussions about Community rules on the transparency of drug prices were at a fairly advanced stage at this time, and Shechter (1998) has stated that "He [Mr Sauer] then promised a trade-off – if the industry accepted the Price Transparency Directive, the Commission would take the initiative with regard to the SPC issue." (83) When asked about the Commission's stance on the SPC in a 1993 interview, needless to say Mr Sauer made no mention of this. Furthermore, his answer: "We are neutral" (as cited in Koberstein 1993, 32) seems unlikely in light of the clear pro-research industry recommendations made by the Commission in the 1990 proposal (see Section 3-1)¹⁰³. Irrespective, this concession or trade-off by EFPIA's members appears to have been a successful one. DGIII helped to make the industry's case within the Commission and Mr Schwab amongst others came on board. With influential 'insiders' not just sympathetic to their cause but actually embracing it, EFPIA then set about lobbying the other Community bodies and sought also to curry the support of the national associations.

2-2 Creating the Commission's proposal document

With DGIII and the Commission in support and pushing the policy – and the industry making its case to the other European institutions as well – discussions between EFPIA and the Commission turned to the specifics of an official proposal. How was the Commission going to sell this industrial policy slant to the European Parliament and Council, and on what grounds; especially when its own initial reaction (under DGIV) had been negative? It was going to need 'proof' and thus EFPIA was requested to provide substantial evidence as to their claims of patent time erosion.

¹⁰² Interestingly, Fernand Sauer went on to become the first Executive Director of the EMEA before returning to the Commission in December 2000 as Director of the Public Health Unit (Directorate 'G') in DG Sanco.

¹⁰³ Later in the same interview Mr Sauer refers to the SPC as "clearly a message in favour of innovation" (34). This can surely be interpreted as reflecting a conscious decision by the Commission to side with the research-oriented industry.

A veritable 'blitz' campaign of data, fact and detail on all aspects of the industry and indeed the economic costs associated with patent protection was launched. Amongst other things, the companies cited the 6 year registration and approval process in some member states (CEC 1993a) – which, when substituted from the 20 year protection accorded by the EPC, resulted in a much diminished effective patent life compared to other products – as a major impediment to their operations. In Germany the effective period was around 8 years at the time of the discussions, while in the UK the effective period of protection on some drugs was cited as only 6 years by the Association of British Pharmaceutical Industry (APBI) in a memorandum to the House of Lords (Hansard 1991a). The EFPIA members pointed to the revised patent legislation in America and Japan to support their case. Europe was not only losing out they argued, but patent-term restoration in the other two countries could be linked to their closing the competitiveness gap (see Appendix 5-2). This could be measured in terms of total sales, employment, R&D spending and, as Figure 5-1 hinted at, the number of new discoveries being made. Closer to home, EFPIA was also able to use France and Italy's earlier pursuit of patent restoration measures for their own industries as further indication of the pressing nature of their claims.

A special group was set up within EFPIA to deal with the Commission's request for evidence. It was charged with drafting a report to demonstrate diminishing patent periods for several hundred products across a host of therapeutic categories. The British trade body, the Association of British Pharmaceutical Industry (ABPI), played a leading role as the UK industry had already been extremely vociferous on the matter at home; highlighting declining exports and growing imports in Europe compared to the US, and criticising the UK government's lack of initiative to address this (e.g. SCRIP 1291, HoL 1991a). The end product of the group's work was a 'study' entitled 'Memorandum on the Need of the European Pharmaceutical Industry for Restoration of Effective Patent Term for Pharmaceuticals' (EFPIA 1988). The report spanned the period 1960-1986 and was presented to the Commission in early 1988. The Commission apparently needed no further convincing and, in April of 1990, it presented its 'Proposal for a Council Regulation Concerning the Creation of a Supplementary Protection Certificate for Medicinal Products' (CEC 1990a) to the European Parliament, the Council of Ministers and the Economic and Social Committee for their consideration.

After the initial hiccup regarding DGIV's lack of interest, things had very much gone EFPIA's way. The Commission had adopted an industrial policy (rather than competition-oriented) view on the issue and drew up a proposal which more than met the industry's demands – as already noted, the Commission's proposals were considerably stronger than those ultimately agreed. Indication of the Commission's commitment comes from the Proposal's suggestions for a 10 year SPC with 30 years maximum patent coverage. This

was notably more generous than the periods agreed in other countries following their own lobbies over patent-term extension issues. Both the 1984 Hatch-Waxman Act in the US and its 1988 legislative equivalent in Japan allowed for (up to) a 5 year extension and maximum 25 years protection. And whereas these pieces of legislation contained provisions for generic competition – the Hatch-Waxman Act included a ‘fast track’ procedure for generics, and the Japanese legislation was agreed in a climate of healthcare cost-containment – in the case of the SPC the Commission essentially sought to stifle it.

Generic companies were to be prevented from engaging in research during patent coverage on the branded product. This should be compared with the US where it has been claimed that “The robust generic industry owes its very existence to the [Hatch-Waxman] act...” (Mossinghoff 1999, 54) and was noted in the Opinion of the Parliament’s Economic and Monetary Affairs and Industrial Policy Committee on the issue: “... what is striking, of course, is that this competition-boosting aspect of the US legislation is totally absent from the Commission’s proposal.” (EP 1990a, 20) In light of the implications such a blatant one-sided position carried, it is not surprising that an opposition lobby emerged during Parliament’s discussions over the Commission’s submission.

3 Adopting the Proposals

Until now the Commission and EFPIA had been working together behind closed doors (Shechter 1998); none of the other stakeholders had been involved. But with the proposals leaving the Commission for a wider readership, the other policy actors were to get their say. For as part of the Parliament’s reading procedures it is required to consult numerous committees and outside groups. Equally, as the ministers in the Council must deliver a response which reflects the position of all member states, they too must consult with a broader constituency. As might have been expected with the Commission’s proposals now under scrutiny from a broader range of actors, the more sceptical position outlined at the outset of the chapter was voiced. With more actors now part of the policy-process, most notably the generic industry, the national governments, and consumers/patients, a policy network emerged around the SPC issue. Needless to say, as these latter stakeholders were to bear the costs of the research industry’s gains – with no immediately apparent benefits to themselves beyond the anecdotal evidence given to the Commission by EFPIA – they were understandably critical.

3-1 Debate and amendments

With the Council as the real decision-making authority the agreement of the ministers was crucial if EFPIA were to have their way – the Proposal was assigned to the Internal Market

Council. However, several of the member governments had concerns with the Commission's proposals. Their primary interest was in controlling healthcare costs and it was felt that patent extensions could delay the introduction of cheaper generics, thereby keeping drug prices high. Of course not all member states had identical interests within this broad objective. While those with generic industries (or no real indigenous industry *per se*) such as Greece, Portugal and Spain opposed the proposals outright, countries such as the United Kingdom and Germany which have major research-based industries were reluctant on other grounds¹⁰⁴. As cost-containment was a political priority at home, their reservations had to do with the potential effects any changes to patent times might have had on pharmaceutical prices. UK Minister for Industry and Enterprise, Douglas Hogg, noted that: "In its *Fiche Financière*, the Commission suggests that the proposal would have no effect on the EC budget. While this may be so, there are implications for the prices of and expenditure on drugs, which the Government are currently considering." (as cited in HoL 1991a, II-11) Nevertheless, both the UK and German governments supported the revised proposals in the end.

In light of this EFPIA would have to convince the Parliament. As outlined in Chapter 2, the co-operation procedure allowed the Parliament a second reading of proposed legislation. As the Commission had based the SPC legislation on Article 100(a) – free movement, single market concerns – it was subject to co-decision. This meant that should the Parliament reject the legislation, the Council would only be able to enact it via unanimity. And with Greece, Portugal and Spain going to vote against in the Council, EFPIA needed Parliamentary support. But much to its chagrin some forceful opposition was voiced during the MEPs' consideration of the proposals.

In May 1990 the document was assigned to the Committee on Legal Affairs and Citizens Rights. The Committee on the Environment, Public Health and Consumer Protection, the Committee on Energy, Research and Technology, and the Committee on Economic and Monetary Affairs and Industrial Policy were also asked for their opinions. In delivering its view, the latter committee in particular expressed reservations, questioning many of the Commission's assertions. Most notable of these pertained to the risks of R&D relocation, the discouragement of generic competition, and the supposed benefits to the European patient (EP 1990a). Indeed, as one commentator noted from the outset:

... no company will give a commitment today to close down an R&D laboratory if patent-term restoration does not happen in Europe, any more than it will formally undertake to open a new one if patent-term restoration does come into effect. Nor can any firm or group of firms guarantee to discover more, or fewer, new medicines as a direct result of the outcome of this debate. (Albedo 1990, 16)

¹⁰⁴ Germany also has the largest generic industry in Europe.

The Committee was in essence challenging the basis for the research industry's claims.

The European Economic and Social Committee (ESC) – which is always granted a reading of proposed legislation – raised some crucial questions in its own Opinion (ESC 1991a). Handled by the Section for Industry, Commerce, Crafts and Services, the ESC Opinion opened by questioning the legal basis for the Commission's action: "This proposal, which is based on Article 100A of the EEC Treaty, falls within the framework of a Community health policy or, more specifically, of an Internal Market for medicinal products." (point 1.1) This was exactly the point Mr Schwab had raised in his first meeting with the EFPIA Director-General when he expressed the view that was not a matter the Commission could deal with. Although the ESC agreed with the Commission on the effects of patent-term erosion and the need to remain competitive with the United States and Japan, pointing out that "A fair solution would be to align on US and Japanese patent protection laws so as to safeguard the competitive position of the Community's pharmaceuticals industry worldwide" (point 3.3), it adopted a health(care) policy line throughout its Opinion.

For instance, noting the specific claims of the Commission (research industry) about unduly long registration times, it pointed out that these were "... administrative procedures which are recognized as necessary precautions for the marketing of medicinal products. Furthermore, the effect of brand loyalty over longer periods should not be underestimated in the case of many products." (point 1.4) The Committee also voiced its concerns on the potential impact on the generic industry. It accepted the 10 year extension under the SPC as necessary in order to compete with the US and Japan, but it stressed that:

The interests of generics producers, who have an influence on price competition in a number of market segments must also be borne in mind. In this connection, a balance must be maintained between the interests of this industry and pharmaceutical research... The Committee urges the Commission to verify whether the direct interests of generic producers will be damaged. (point 3.4.1)

Furthermore, it asked the Commission to take into account the price increases which would result from extended patent periods. Despite such intense scrutiny of the proposals, however, the Committee gave its approval, with 81 members voting in favour with 5 abstentions. The irony in its doing so, was that, unlike the Commission, its main interests had to do with the benefit to the European patient and healthcare policy in general. As part of the rationale given for approval, the Opinion reads:

The Committee recognizes that, in the interests of health protection, the marketing of medicinal products in the Community must be subject to stringent quality and therapeutic requirements... Patent protection for innovation in the Community pharmaceutical industry can also be said to contribute to health protection. (point 3.1)

However, as the ESC is only a consultative body within the legislative process, its calls for clarification were not taken on board by the Commission.

The Committee on Legal Affairs and Citizens' Rights, to which the legislation was assigned, gave its approval to the document in its Opinion of 29 November 1990 (EP 1990b). However, it argued that the SPC be extended to include patents on plant protection research as well. The argument being that plant protection research is also central to improving public health by helping ensure supplies of good quality food, and that plant protection products as an R&D intensive industry would also cease to be produced in the Community without patent-term extension. This of course was not what EFPIA had in mind, and the Council in fact dropped the motion in its February 1992 Common Position. What should be noted, however, is that the Committee was agreeing the legislation principally on the grounds of health policy concerns.

3-2 EPC compatibility and agreement

Concurrently, an important parallel debate was taking place regarding the legality of the SPC proposals with the terms of the European Patent Convention. Article 63(1) of the EPC stipulated the 20 year patent term from date of patent filing, and the question was how to bypass this. This point was in fact tabled by one MEP as a written question to the Commission asking: "The Commission will shortly submit a proposal to the Council concerning the introduction of a patent protection for new medicines; what legal basis will the Commission use for this?" (CEC 191/91) Any changes to the Convention required the approval of three-quarters of its signatories (fourteen countries at the time), more than a quarter of which were not Community member states. An exception for only the EC countries was thus not likely. In addition, simply tacking on an extra 5 years to the EPC period would affect patents on all industrial products and would not result in the derogation the pharmaceutical industry was seeking for itself.

Following pressure by the EC member states and the Commission, a diplomatic meeting was called in 1991 to discuss the issue. The result was agreement on an addition to Article 63. This enabled any EPC contracting state to extend the terms of the European patent immediately following its expiry. This was, however, only applicable where the subject-matter of the patent "... is a product or process of manufacturing a product or a use of a product, which has to undergo an administration authorisation procedure required by law before it can be put on the market in that state." (as cited in SCRI 1993, 94) It was a compromise which suited all parties and the Commission was now free to advocate the SPC without fear of contravening the EPC.

With EPC compatibility secured, Parliament agreed the legislation on second reading subject to certain revisions in the Council common position. The first was that some member states were granted different implementation dates. A transition period was permitted for those countries which had opposed the legislation outright. Greece, Portugal and Spain were given until January 1998 to implement the SPC in order to protect their local (generic) industries. The second was that the date of first authorisation for drugs after which an SPC could be granted would be different in some member states. The legislation covered medicines authorised as of 1 January 1985, but Germany was allowed until January 1988 on account of its introduction of a new reference price system which would have been affected by the legislation. Denmark too was permitted until 1988, while in Belgium and Italy the corresponding date was in fact pushed backwards rather than forwards, to 1 January 1982, in order that more drugs would qualify. The third amendment was a reduced SPC term. The Commission's 10 years were cut to 5.

EFPIA, needless to say, was disappointed with the latter revision in particular. John Griffin, Director of the ABPI, was reported to have given a 'guarded welcome' to the decision, saying that the association would "... obviously have preferred the Commission's 'imaginative and constructive' original draft regulation." (as cited in MARKETLETTER 1992a, 17) Still, the SPC was an obvious 'win' for the research industry, and one which demonstrated its strength within the policy network.

3-3 Health(care) policy interests and opposition

Generic manufacturers had been dead-set against the proposals. No longer able to begin their own testing and research from the time of patent submission for the original product, they would have to wait until patent expiry, thereby further delaying the release of their own medicines. And while EFPIA's members viewed this as rectifying what they perceived to be an unfair competitive advantage, generic manufacturers saw it as threatening their very *raison d'être* – they too faced growing research periods and rising costs. The generic producers sought to bring this to the Commission's attention, and in their representations, their position was boosted by data showing that patent expiry did not mean an automatic end to a medicine's market life as the research-based industry was claiming (Anon 1990). They also tried to have the SPC limited to only the first drug in a new class of compounds, as was the case under the data exclusivity rules of the US Hatch-Waxman Act.

The generic industry thus sought support from outside Europe, particularly from their US counterparts. For with much of the generic industry's output being sold to American drug-makers as bulk pharmaceuticals, the SPC would negatively impact on the US industry (and healthcare system) as well. When asked about the imminence of the SPC legislation in

Europe, the view expressed by Dee Fensterer, President of the US Generic Pharmaceutical Industry Association, was: "It's the same crazy battle we had here in the US in the early 80s, with the Pharmaceutical Manufacturers Association saying that US patent life was only about eight or nine years. And, of course, that was a horrendous lie." (as cited in Bahner 1993) Indeed, some commentators were sceptical of EFPIA's 'proof':

... it must be admitted that, at present, there are insufficient data to support the generalisations, particularly with respect to Europe. The more closely one examines this putative evidence, the more one wonders if the data couldn't give rise to queries regarding the size of the samples in the studies and the comprehensiveness of the raw data... Above all, the most striking feature of the current industry argument is the rather general tone of the statement that patent-term restoration will have a beneficial influence on the range and quality of products in the future. This still has the ring of assertion rather than demonstration. (Albedo 1990, 15-16)

Unsurprisingly, patient and consumer groups rallied against the proposals during and after the policy-process. They expressed concerns surrounding the length of protection under discussion and, consequently, the speed of access to new products and potential for higher prices. In early 1991 the *Bureau Européen des Unions de Consommateurs* (BEUC, the European Consumer's Organisation) issued statement claiming the proposals represented 'a blank cheque' for industry (BEUC 1991). In a memorandum circulated later the same year, the UK's National Consumer Council (NCC) spelled this out in more detail: "... even if the erosion of patent life has been as large as the industry claims... The expiry of patent protection does not mean an end of the drug's role in the market, or the return on the patentee's investment." (as cited in HoL 1991a, 23) More importantly perhaps, the NCC made the point that "Increasing patent life passes the cost to consumers, or taxpayers. The balance on interests on patents is innovation, but not at any cost." (24)

The Consumers in the European Community Group (CECG)¹⁰⁵ made similar representations. It argued that lengthy patents, as they limit the speed of access to new therapies, were more of a public health matter than a simple industrial policy concern. On this basis, and fearing higher prices, they felt that the Commission ought not to have taken a decision so easily. In a letter to the UK House of Lords, they wrote that "... we believe that extending patent protection will undoubtedly restrict the production of generic drugs – which are cheaper than branded drugs – and therefore we oppose the Commission's proposals." (as cited in HoL 1991a, II-9) This view was not limited to the consumer organisations. At least one industry analyst warned against a "price explosion", arguing that the only safeguard against it "... is the acceptance, indeed encouragement, of

¹⁰⁵ The CECG is an umbrella group of UK organisations concerned with the effects of Community policies on British consumers.

legitimate generic competition for products whose patent (and in future, Supplementary Protection Certificates) had expired." (Redwood 1992, 22)

Opposition continued even after the proposals were agreed. The CECG now argued that:

...increased protection should apply only to new molecular entities which represent a genuine therapeutic gain. CECG sees no reason why virtual copies of old medicines should receive extra protection and the production of cheaper generics be impelled. (CECG 1993, 28)

This had been one of the generic industry's main points, one which the Parliament had also endorsed during its first reading. It had sought the inclusion of a provision limiting the certificate to products which are "... already protected by a patent and which provides for the effective treatment or diagnosis of a condition which has not hitherto been adequately treated or diagnosed by a medicinal product already on the market." (Article 1 new) The fear was that extended protection across the board would act as an incentive for industry to research products which were more profitable than they were therapeutically valuable. And that it would have been more equitable to the generics industry to have the SPC limited to only the first drug in new class of compounds, rather than including everything which might follow as well. As the Commission ignored this, thereafter both the generics industry, via its trade association, the European Generic Medicines Association (EGA), and the BEUC called on the Commission to codify generic substitution as a *quid pro quo* for the extended patent-terms granted the research industry under the SPC (SCRIP 1993). Not only was this rejected by the research lobby at the time, but with no competence in healthcare policy, it was (and still is) something beyond the Commission's remit.

Within this generalised opposition, there existed further differences in opinion and more specific interests *vis-à-vis* the Commission's proposals. Nevertheless, the one thing all had in common was the potential negative effects the SPC would have on healthcare policy and/or welfare. The problem, however, was that they either came too late, else were simply not strong enough.

Prior to the single market for example, there was no official European representation for generic producers. The EGA was only formed in early 1992, the very year the SPC legislation was passed; indeed, in part as a result of the SPC (Shechter 1998). Institutional opposition from generics companies as a unified group within the policy-process was therefore heard only after the Council Common Position was released in February. Consumer interests via the CECG, the BEUC and the Parliament were also tabled late in the game. But, as highlighted in the previous chapter, compared to the other stakeholders they in any event carry comparatively little sway in the EU policy arena.

4 Conclusions

It is clear from the discussion that the path to agreement of the SPC was a complicated one. The major stakeholders were not in agreement as not all would find their interests served by the legislation. The policy network which developed was one in which the actors were scrambling to protect (if not maximise) their own interests, allowing the application of Wilson's politics of policy framework. More specifically, it can be seen that even if the research industry did not get all that it had wanted, EFPIA had been spectacularly successful; not simply in putting the issue of patent-term extension on the Community agenda, but also in convincing the Commission to support and help push it through. This allows several conclusions to be drawn in support of the contention that the Supplementary Protection Certificate policy-process was a case of client politics.

4-1 Costs versus benefits

First it is clear that the cost-benefit configuration to the stakeholders' interests is applicable. Patent-term extension was a policy issue which involved concentrated benefits for a small group, with diffuse costs to be borne by a much wider constituency. The SPC, like any longer marketing exclusivity period for innovative products, was going to benefit the research-driven industry at the expense of the sector's other actors. For patent-holding companies not only does longer intellectual property coverage help make up the effective patent-life lost by the approval process, but it serves to keep their drugs at a higher price for longer, maximising their returns – *Prozac* was shown to be an example. Such concentrated benefits induce co-operation between otherwise competing firms in pursuit of a common goal which would benefit them all. The gains to be made by collaborating outweigh those to be made individually by not. And this can be seen in the cohesion achieved by the companies during EFPIA's lobby.

The costs of the SPC meanwhile were to be fairly widely distributed amongst a larger group of actors. These included the generic companies, patients, and those interested primarily in controlling healthcare costs; most notably the member states. Beyond granting the research industry an extra 5 years extra coverage, the SPC actually sought to constrain the generic industry by preventing any R&D until after patent expiry. This may also harm patients' interests by preventing cheaper products being made available, else inhibiting new, innovative and more efficacious treatments being made available more quickly i.e. older products remaining on the market for longer. Not only does patent-term extension not offer a guarantee of better healthcare, but it is generally accepted to result in higher drugs prices; higher prices tend to disproportionately affect the elderly and those suffering from long-term or chronic maladies i.e. those most vulnerable and potentially

least able to pay. And it is especially with regard to research into chronic disease and illnesses associated with ageing that the industry feels that patents should be used as an incentive (Goldberg 2000).

Another potential cost (to the consumer) is that with extended patent terms, companies are likely to seek protection for those products which are most profitable. This is only natural, but the issue is that these products are not necessarily in therapeutic areas which serve society's greatest needs. As shown earlier, this was formally noted by the consumer groups, the generics industry and the Parliament in their respective representations to the Commission. Along with higher prices and patents on drugs for chronic illnesses, this carries healthcare financing repercussions for national governments (and insurance funds) who pay for medicines, making cost-containment goals *vis-à-vis* the national drugs' bill more difficult. It was for these reasons that Greece, Portugal and Spain opposed the SPC legislation in the Council, while Germany and the UK were, at least initially, hesitant.

This meant that industry had to act strategically. In the words of one commentator (who at the time questioned many of the research industry's claims) it was to "... tread a difficult tightrope in simultaneously demonstrating its desperate need without scaring off support with fears of the likely costs." (Albedo 1990, 19) As shown, these 'cost's saw other actors express their objections to the proposed regulatory intervention. And although the need for the beneficiary(ies) to 'act strategically' clearly fits with the client politics scenario, the extent of the opposition expressed by those bearing the costs (even if late), does not. The typology assumes that the costs to the non-benefiting actors are so diffuse and insufficient as to not warrant opposition; hence it is only the beneficiary who lobbies. That said, several mitigating factors resulting from the SPC for the opposition actors can be identified, such that the costs to each were eventually made more palatable.

For instance, while generic manufacturers were justifiably up in arms over the restrictions to be imposed on their activities, they admit that the research industry needs incentives to continue to invest. For without someone else doing the discovering, the generic industry has no market. At the time of the discussions, when asked about the response of the UK generics industry, Edward Leigh, Secretary of State for Trade and Industry, responded:

The representations received from the manufacturers of generic medicines have covered a range of views. None has given unqualified support to the Commission's proposal; indeed, some have not favoured any supplementary protection. Most, however, have recognised the case for some supplementary protection, but have advocated a shorter period. (Hansard 1991b, 19)

This was echoed in a recent discussion paper by European Generics Association:

The EGA believes that pharmaceutical innovation is critically important to both European healthcare and industrial policies. Innovative pharmaceutical companies should be allowed to enjoy premium prices and market exclusivity under patent periods to reward them for the high cost of developing genuine [sic] innovative medicines. (EGA 2001, 12)

The CECG may have objected to the Commission's proposal document but it too will have been aware that a happy industry is an innovative one, and that innovation is key to future cures. In a 1993 report following the SPC legislation, they wrote that: "Consumers have always accepted that, where a drug is genuinely innovative and required substantial research effort and investment by the manufacturer, it is right that there should be a stronger element of protection." (CECG 1993, 28) In addition, the financial impact of longer patent protection on patients themselves is minimal as they generally do not bear the true costs of the medicines they consume. It can be presumed that the potential for more and better products – and the potential long-term benefit to the European patient – was also in the minds of the Parliament and Council when they agreed the legislation. During the ESC's deliberations at least, the benefit to the consumer/patient was raised.

Regarding the mitigating influences on the costs to the member states, there appear several. First, increased patent protection helps to ensure a successful national sector where a research-driven industry is present and, theoretically, could help in the provision of better quality products within the healthcare system even where it is not. As well, if patents do promote innovation and research into new drugs, they may help to foster pricing competition among comparative products. They may also generate research into new drugs for chronic and long-term illnesses (areas in which governments are keen to make savings). These latter points are debatable, but a successful 'Euro-industry' is definitely in the interests of all member state governments. And as the SPC was expected to improve the research climate compared to Europe's competitors it is perhaps not surprising that the majority eventually adopted a 'pro' stance subject to the different implementation dates already mentioned. Furthermore, what all countries were aware of was that all these discussions were taking place within the context of developing the Single European Market. The differing transition periods notwithstanding, the SPC would in the long-term standardise medicine patent-terms and times across the Community, thereby helping to promote the free movement of goods and services.

Finally, a successful industry is also in the interests of the Commission given its pre-occupation with promoting European industry. Extended patent protection on medicines boosts this. At the same time, however, it may be argued that the SPC legislation – in allowing different implementation times – complicates the pursuit of the single market as the Commission's other main goal. But perhaps the two cancel each other out. Or at least one can assume this from the Commission's push for the SPC legislation throughout the

policy-process and its trade-off over the transparency proposals. For the latter represented more of a problem within the single market framework than the former.

4-2 Collective action and capture

Another relevant element of the client politics scenario is that the concentrated costs can bring the likely beneficiaries together. And further, that a relatively small number of these interests (actors) can, if sufficiently well-organised, come to dominate the policy agenda to their obvious gain. This is especially the case where a weak regulator is present, resulting in the 'producer-dominance model' or regulatory capture.

Addressing these points with respect to the SPC legislation, the research companies banded together under EFPIA's lead. This group included not just the major European companies of Germany and the UK but, ironically given the arguments for boosting the competitiveness of European industry, many of the American multinational drug producers with operations in Europe as well. The US firms were concurrently represented by their own umbrella group, the Pharmaceutical Manufacturers of America (PMA) – now the Pharmaceutical Research and Manufacturers of America (PhRMA) – which had an office in Brussels. This led to close collaboration between the two trade organisations over the SPC issue within the framework of the so-called 'Dolder Group' (named after the Dolder Grand Hotel in Zürich, where representatives of the two groups held regular, informal meetings) (Scherer 2000).

Such collaboration between otherwise competing companies has long been a feature of the pharmaceutical industry, reflecting its truly global nature. More importantly, it led to a single face being presented to the Commission and resulted in a Proposal document which could have been drafted by EFPIA's members. It echoed the industry's argued link between stricter patents to further innovation, more drugs and, as a by-product, greater pricing competition amongst medicines designed for similar purposes. Intellectual property rights were not only deemed necessary to the delivery of new, high quality, innovative and efficacious drugs, but they were justified as important in the context of global market competition. The small but well-organised EFPIA lobby had influenced the policy agenda to its benefit.

Wilson asserts that within this cost-benefit scenario the 'producer-dominance model' can result where a weak regulator is present. As the regulator in the SPC policy-process, the Commission may not have been weak – in fact the opposite is perhaps the case – but it clearly was steered by the industry lobby. It was mentioned earlier that information plays a crucial role in the pharmaceutical sector. Not only is independent information difficult to

come by, but with the Commission's limited resources, it would have been an almost impossible task had the Commission tried on its own to procure such sensitive data as on patent-term expiry for medicines, and R&D expenditures. Thus the Commission virtually unquestioningly accepted and acted upon the data and information put to it by EFPIA in its 1988 memorandum. Through the strategic use of information, therefore, the industry was able to convince the Commission as to the merits of its case. According to the UK's NCC at the time of the initial proposals, "... the drugs industry has so far won the battle for the hearts and minds of many policy makers in Europe by default." (as cited in HoL 1991a, 24)

Just as important in the Commission's capture, however, was the fact that the industry's interests coincided with the Commission's wider agenda – the promotion of European industry and progress towards the single market. These are reflected in the Commission's Proposal where the sixth and fourth recitals read respectively:

Whereas a uniform solution at Community level should be provided for, thereby preventing the heterogeneous development of national laws leading to further disparities which would be likely to create obstacles to the free movement of medicinal products within the Community and thus directly to affect the establishment and functioning of the internal market.

Whereas medicinal products that are the result of long, costly research will not continue to be developed in the Community unless they are covered by favourable rules that provide for sufficient protection to encourage such research. (CEC 1990a)

Given the Commission's priorities then, in its eyes the SPC legislation represented the stone with which it could kill two birds. That the Commission not only endorsed EFPIA's position but effectively campaigned on its behalf shows to what extent this agenda coincided with the industry's more specific demands. Indeed, the unmitigated support of the Commission went a long way to convincing key individuals in the EU frame as to the merits of patent-term extension (Shechter 1998). And though the final Regulation may not have been all that the industry had hoped for, the Commission's original Proposal had tried to meet all its demands. In Section 1-3 it was asked why the Commission delivered a Proposal so blatantly favouring the research industry. The answer is now clear. The SPC was a case of client politics in which the Commission as regulator was 'captured'.

4-3 Final remarks

Perhaps the most important factor behind the SPC legislation was the regulatory context in which it took place. The creation of the Single European Market by 1992 was the pre-occupation in all areas of Community affairs. For the research-oriented industry, therefore, the timing of their lobby was very good. The Commission was not simply interested in promoting European industry, but it was more focused on removing market impediments

across the board and, as the Cecchini Report had noted some years earlier, pharmaceuticals were an area in which comparatively little progress had been made.

More than that, however, the Commission was seeking to maximise its own sphere of influence. Recalling Majone's (1994) point that the proliferation of Community regulation can in part be put down to the Commission's attempts to increase its influence by expanding its competencies (Chapter 3), the SPC is a case in point. Irrespective of healthcare considerations, it took the view that medicine patents fall into the industrial policy side of pharmaceutical regulation. For it was only by making this an industrial policy issue that the Commission could have competence. Thus, not only was the Commission's position during negotiations handled by DGIII, but the Commission in fact took a pro-active stance in selling the matter as an industrial concern to other Community institutions. Here it perhaps again worth stressing that the Commission's move to enact the SPC as a Regulation was a strategic move. Regulations are uniformly binding pieces of legislation across the Community and would over-ride any national level measures, thereby giving the Community (the Commission) exclusive competence.

Early on, therefore, the Commission displayed its hand. By proposing the SPC as a Regulation, in addition to sanctioning the research industry's arguments, the Commission demonstrated the strength of its conviction on the issue: this was an industrial policy matter; the Commission and DGIII in particular had competence¹⁰⁶; and all the member states would be obliged to implement the legislation in full. Given the prominence of the Commission's role one might be tempted to see this as a case of entrepreneurial politics. But despite the Commission's own interests in seeing a strong industry and internal market for medicines, it is clear that the impetus actually came from the industry. The fact that the final Regulation reflects so blatantly the industry's agenda shows just to what extent it was able to influence the Commission's thinking in a client-oriented manner. So although not a distinction to be found in Wilson's approach, it would appear that the Commission thus acted more as policy 'manager' than 'entrepreneur' (Laffan 1997).

Finally, the industry's successful campaign over the SPC shows two other details relevant to the remainder of the study. First, the dilution of the original Proposal was the result of the interplay and exertion of pressures by cross-cutting interests amongst the stakeholders in a policy network configuration. Although initially sidelined, once the proposals were sent to the Parliament and Council, the other stakeholders were able to voice their interests.

¹⁰⁶ In 1992 Spain challenged the use of Article 100(a) for the SPC legislation. Its position – recalling that Spain voted against the Regulation – was that patent-terms on medicines were not a single market issue; something that the ESC had also raised (see Section 3-2-1). In its 13 July 1995 judgement, however, the ECJ dismissed the case, finding in favour of the Commission (Case C-350/92 *Kingdom of Spain v. Council of the European Union*. ECR I-1985).

And secondly, that the policy network which developed around the SPC was constrained from the outset. Beyond having initially been excluded from the policy arena, patients, national governments and the generics industry did not have too much to lose (or at least the costs were diffuse and carried something in compensation). Accordingly, they did not (were unable to) oppose the legislation as intently as they perhaps could have. In other words, the issue at hand, in involving concentrated benefits and diffuse costs, essentially dictated the outcome from the outset – client politics would result.

CHAPTER 6

'ENTREPRENEURIAL POLITICS': THE EUROPEAN AGENCY FOR THE EVALUATION OF MEDICINAL PRODUCTS

Introduction

Based in London and responsible for granting EU market approval to new medicinal preparations, the European Agency for the Evaluation of Medicinal Products (EMEA) celebrated its seventh birthday on 26 January 2002. Established via Regulation (EEC) 2309/93, the agency occupies a unique place in the EU frame. Rather than gathering and disseminating information or issuing generic opinions in the manner of other EU agencies, by delivering specific recommendations which result in Community decisions that are binding on the member states, the EMEA exercises a quasi-regulatory role¹⁰⁷. It is perhaps something of an irony that such a body exists for the pharmaceutical sector, an area of EU policy for which there is neither a single market nor a coherent Community strategy; wherein the Commission has but limited competence; where the EU's legal (Treaty) and policy (free movement) frameworks clash; and where the member states have very different interests which they collectively defend in reference to the principle of subsidiarity. At the same time, it is precisely because of this that an agency exists.

The idea of a centralised authority emerged in the mid-1980s. The Community authorisation regime was not proving popular and it was becoming clear that a more efficient and binding system was required. Yet the explanations offered by the Commission for creating the EMEA at the time of the agency's launch in 1995 had less to do with single market designs than they did with public health protection. In the press-release accompanying the agency's inauguration, the Commission proclaimed: "The creation of the European Medicines Evaluation Agency is firstly a benefit for the European patient." (CEC IP 1995) This does not sit with the preparatory work behind its establishment. In the words of one commentator, "But five years ago no one thought of seriously selling the idea as a patient benefit." (Albedo 1995a, 10) That the Commission changed its tune suggests pressure from other actors within the policy network which developed around the proposals.

In light of this, the aims of this chapter are threefold. First, to show that the rationale for the establishment of the agency had less to do with patients' interests than they did

¹⁰⁷ Under the 'Meroni Doctrine' – resulting from the 1958 judgement of the ECJ in Case C-36/56 – *Meroni v. ECSC High Authority* – European law prevents the Commission from delegating decision-making to any other party. But as the Commission is reliant on the EMEA to a much higher degree than the other EU agencies (see Section 1), the agency's role can be seen as (quasi-)regulatory.

Community industrial policy goals. Second, to demonstrate that, as a result, the agency serves the interests of the pharmaceutical industry – both in practice and by design. And thirdly, to provide evidence for the contention that the regulatory policy represented by the creation of the agency was a case of entrepreneurial politics with the Commission acting as entrepreneur in the policy network.

In pursuing these aims, the discussion first sketches the agency's functions and purpose. This serves to differentiate it from other EU regulatory agencies. Next, an outline of the stakeholders' positions on a Community pharmaceutical agency at the time of the original discussions is provided, before detailing how, given the differing views which prevailed, the final Regulation establishing the EMEA was agreed. This is followed by an examination of the criticisms which surround its work and examples of its industry leaning. Here several points of comparison are made with the US Food and Drug Administration which, as part of a wider remit, decides on new drug authorisations¹⁰⁸. Although this helps to underline just to what extent industry is the prime beneficiary of the EMEA regime, this does not *de facto* imply an endorsement of the FDA model.

1 The EMEA: Reassessing Community authorisation

The significance of the EMEA should not be under-stated, neither in respect of its unique (quasi-regulatory) function in the EU generally, nor in terms of what it means for the pharmaceutical sector specifically. The discussion in Chapter 4 referred to different regulatory traditions in Europe and the United States: Europe with a strong state role, the US with minimal state intervention relying instead on the use of expert agencies where the market fails. As this derogation of responsibility to independent regulatory bodies is frequently based on the government's lack of expertise in the area, such agencies are often granted judicial and executive powers by which to enforce the implementation of their decisions. Although most of the EU member states still rely primarily on public bodies for addressing the market, the American model has impacted on the way regulation is carried out at the supranational level. For there are now 10 such independent Community agencies; that is, bodies outside the central administration of the Commission.

1-1 The EU agency 'model'

In addition to the EMEA, the 10 EU agencies are: the Community Plant Variety Office; the European Centre for the Development of Vocational Training; the European Foundation for the Improvement of Living and Working Conditions; the European Environment Agency;

¹⁰⁸ The FDA carries regulatory responsibility for a wide range of consumer products beyond medicines. Its Center for Drug Evaluation and Research (CDER) is responsible for pharmaceuticals.

the European Monitoring Centre for Drugs and Drug Addiction; the European Training Foundation; the Office for Harmonisation of the Internal Market; the European Agency for Safety and Health at Work; and the Translation Centre for Bodies of the European Union.

The use of independent regulatory bodies represents a break with the more statist traditions prevalent in much of Europe after world war two, especially in those member states with a (neo-)corporatist or *dirigiste* history such as Austria and France. The Community 'model' is not commensurate with that in the US, but "... is based on the quantitative expansion of EC jurisdiction, and might be seen at the same time as a qualitative change within EC policy-making through both horizontal and vertical co-ordination and co-operation." (Kreher 1997, 241) Consequently, there are increasing calls for the development of further independent offices in other areas of Community policy, including for instance in telecommunications and maritime safety, and a European Food (Safety) Authority is hoped to be up and running by mid-2002. This increased use of independent agencies is an element of Majone's (1994) earlier-cited 'regulatory state' characterisation of the EU polity.

Without comparing in detail the ten agencies, it should be noted that there is no single cast. They are structured, staffed and financed differently (see Appendix 6-1), and in terms of their function, they operate across the three EU pillars. For instance, the drug addiction monitoring agency works in the fields of health protection and safety; the harmonisation agency with regard to competition and free movement; the EMEA's functions combine free movement and public health aims (with emphasis on the former); while the environment agency's powers developed out of existing Community environmental goals (Chitti 2000). All the agencies, as Majone (1997) notes, regulate on the basis of information i.e. influencing/affecting behaviour indirectly "... either by changing the structure of incentives of the different policy actors, or by supplying the same actors with suitable information." (265) While the agencies differ along a host of dimensions, where they are similar is that they "... owe their existence to a kind of paradox. On the one hand, increased uniformity is certainly needed; on the other hand, gradual centralization is politically inconceivable, and probably undesirable." (Dehousse 1997, 259) Their broadly-shared 'regulation by information' mandate is an attempt to account for this.

Nevertheless, the EMEA is something of an anomaly amongst the agencies; that which reflects the peculiarity of the pharmaceutical sector. Unlike the other agencies, instead of regulating by gathering and then sharing information – towards co-ordinating networks of actors (Dehousse 1997) – it has information provided to it (by the pharmaceutical companies) and which it guards in drawing up opinions on market authorisation for new

medicines. Rather than linking actors through information within the regulatory process, as the chapter shows, the agency uses information to exclude them.

1-2 The Community medicines agency: A unique institution

The EMEA's establishment elicited headlines such as 'A drug Tsar is born' (Anon 1994) and 'A real European milestone' (Albedo 1995b). Such applause was because, unlike previous attempts to create a unified approval procedure for new medicines, the authorisations issued by the EMEA are binding and valid throughout the Community. A single process was to relieve the duplication of effort by (then 12) different national regulatory procedures, thereby easing bureaucratic and administrative pressures on manufacturers and national administrations alike. It was also to speed the time required to bring new medicines to market; a review process which, as noted in previous chapters, is unique in terms of the time and detail required. By streamlining the regulatory environment in this way, not only has the agency contributed to the Commission's free movement goals, but it helps to make the EU a more attractive place to do business.

The agency can also help national regulatory authorities by filling knowledge gaps; none can on its own keep up with all the latest advances in the technology of drug development. Though its own core staff is small – the secretariat consists of about 200 people providing technical and administrative support to the scientific committees and working parties – the EMEA brings together the expertise of some 2,400 experts from across the EU, including from Norway and Iceland (as part of the European Economic Area both are subject to the original 1965 Directive on medicines). Thus, it is national experts working on the agency's behalf who carry out the assessments.

The emphasis may be on speeding approval times, but the safety, efficacy and quality criteria for authorisation as set down in the 1965 Directive have been retained, and the EMEA has a role in pharmacovigilance (via the issuing of updates and alerts relevant to specific products or compounds). The Commission stressed that the new agency "... allows for a quicker and simpler access [for medicines] to the single market, with the guarantee of an evaluation of the highest scientific standard." (CEC IP 1995) And though it is the Commission rather than the agency which delivers the final ruling on market authorisation, as "...the Commission has to take into account the expertise produced within this agency before it can take a decision" (Kreher 1997, 237) – not to mention that its opinions are almost always accepted – the EMEA's role is not only more imperative, but the agency is closer to an independent regulatory office than any of the other agencies.

1-3 New licensing procedures

Charged primarily with the task of fostering market access for new medicines, two new systems were put at the EMEA's disposal¹⁰⁹. Subsuming the CPMP (concertation) and multi-state (mutual recognition) procedures outlined in Chapter 3, these are the 'centralised' and 'decentralised' procedures. Again, both are based on the Community's safety, efficacy and quality criteria as laid down in Directive 65/65/EEC. In addition, as communicating information towards demystifying the drug approval process has been a self-declared priority from the outset, the agency maintains a website (www.emea.eu.int) which posts material relevant to its work.

A detailed review of the centralised and decentralised authorisation procedures is beyond the scope of this study and can be found elsewhere¹¹⁰. Hence, only the main features and steps are highlighted in following. The aim is to consider how the EMEA works, what it can and cannot do, and what its focus in practice has been. Such an overview serves to qualify the Commission's claim of it having been designed as a benefit first to the European patient, helping set the stage for later elaborating why the policy-process leading to its establishment can be characterised as one of entrepreneurial politics.

Centralised procedure

The centralised route is an updated concertation (multi-state) procedure with approval now by majority vote (Appendix 6-2). Mandatory for all products derived from biotechnology, it is also optional for those conventional products with an innovative or high technology element. According to Vogel (1998), "Biotechnology was targeted because of its potential for economic growth and, because since it is such a new field, individual states have not yet created their own testing infrastructures." (6) Companies send an application to the agency (in a standard format, the drug dossier) which refers it to the Committee for Proprietary Medicinal Products (CPMP) for review. Itself revised under Regulation (EEC) 2309/93, the CPMP is the body assigned the task of preparing the agency's opinions on medicines for human consumption (under the decentralised procedure as well).

As the body responsible for deciding on behalf of the EMEA, the probity of the CPMP must be ensured. The committee is comprised of scientific experts from each of the member states who are nominated by their national administrations, and they are required to put

¹⁰⁹ Accompanying the new procedures was 'The Rules Governing Medicinal Products in the European Community', a 6 volume publication (now 9 volumes) which sets out common guidelines in areas such as pharmacovigilance and clinical testing requirements.

¹¹⁰ For example Kingham et al (1994), Jeffreys (1995) and Cameron McKenna (2000).

aside any national sympathies or private interests¹¹¹. By keeping national politics and industry ties out of the mix, the intent is to guarantee scientific decision-making of the highest quality¹¹². The CPMP evaluation is undertaken by experts drawn from a list provided by the member states, and the committee has 210 days to carry this out.

Towards ensuring an objective report, two assessment teams are appointed to produce concurrent independent reviews (*rapporteur* and *co-rapporteur*). The committee evaluation – consisting of the committee's opinion, the assessment report, the Summary of Product Characteristics (SPCs)¹¹³ and the text for labelling and the packaging insert – is passed to the Commission, the member states and the applicant, along with a recommendation, and the Commission is required to prepare a draft decision on authorisation within 30 days. During this period both the member states and the applicant may raise concerns or query the CPMP opinion. Should a member state appeal against the decision, they must do so in writing within 28 days and only on the basis of "... important new questions of a scientific or technical nature which have not been addressed in the opinion of the Agency" (CEC 1993b); the committee is then required to take this into account in drawing up a new opinion. Barring unnecessary delay, the process from application to final national decision was designed to take a maximum of 310 days. According to the December 2001 update on use of the centralised procedure, authorisation has been granted for 183 products via this route (EMEA 2001a). And with the majority of the 150 approvals issued by late 2000 having been completed within a timeframe of 240 days, the agency has been *fêted* as a major success by Fernand Sauer, its first Executive-Director (Sauer 2000).

Decentralised procedure

The decentralised procedure is a revamped version of mutual recognition and was revised to improve the member states' faith in each others' assessments (Appendix 6-3). It applies only to conventional products and involves the company making an application for marketing approval to one of the national agencies. Designated the 'Reference Member State' (RMS), this is the market targeted for initial product launch. Should approval be granted – the documentation includes a detailed assessment report, approval of the company's submitted SPCs, and the proposed text of the accompanying labelling and

¹¹¹ This failed to prevent a scandal emerging around Dilio Poggiolini, former chairperson of the CPMP, who was accused of accepting up to US\$180 million in 'gifts' from pharmaceutical companies during his 30 years at the Italian Ministry of Health.

¹¹² However, the grounds for selecting and appointing these representatives differ by member state, and not all are necessarily completely free of industry connections. Since the 'Poggiolini Affair', a declaration of interests is required, and a code of conduct applies for all CPMP members.

¹¹³ The SPCs – created via Directive 93/570/EEC – is part of the marketing authorisation and represents the scientific text which contains all of the important information on the product. The information leaflet is derived from the SPCs (see Section 3-1).

patient information leaflet – additional member state authorities are expected to recognise the authorisation. These become 'Concerned Member States' (CMSs). A right of appeal exists should a CMS refuse the authorisation, with a formal arbitration procedure going through the CPMP. In such cases the committee issues a verdict on extending marketing access to the CMS(s), which is then reviewed by the Commission before it delivers a final decision. As was the case with its predecessor, however, the member states' commitment to the decentralised procedure has been sketchy. Brian Ager, Director-General of the European Federation of Pharmaceutical Industries and Associations (EFPIA), is quite frank about this: "Countries simply balk. Suppose you're a German regulator and someone comes along with a product approved in Greece or, once the EU is enlarged, Estonia – how are you going to react?" (as cited in Ross 2000a, 65) The CMSs thus continue to simultaneously assess applications themselves.

While not an FDA, the EMEA serves a combination of public health policy and industrial policy goals, as well as fulfilling economic (market-related) and social policy interests – "The EU's goal [in establishing the agency] was to transform the relationship between national regulatory authorities and those of the Union, thus finally creating a common market for pharmaceutical products." (Vogel 1998, 5) None of the other agencies can make a similar claim about the policy field in which it operates. Recalling the Community's history of regulatory competence in the pharmaceutical sector from Chapter 3, the institution of a centralised agency is undoubtedly the most important achievement to-date. However, despite the satisfaction expressed by the previous Executive-Director, the EMEA and its authorisation procedures have not been free from criticism.

Before looking at such criticism, it is first necessary to understand 'how we got here' and what the involvement of the stakeholders was in creating the agency. Beginning with the consultations of the late 1980s, the next part of the discussion lays out the path to adoption of the final Regulation in July 1993. The focus is on the stakeholders' positions during the run-up to its establishment rather than the intricacies of the legislative process. This provides insight into actors' interests and what weight they carried in the policy network. Further, it supports the contention that the EMEA came about as the result of entrepreneurial politics according to the Wilson framework.

2 Establishing the EMEA: Putting a new face on medicines control in the EU

Notwithstanding more recent pronouncements regarding the 'European patient', the main rationale cited by the Commission during the deliberations over the potential for a European agency was the need to speed market access for new medicines. There were several reasons for this. First, drug registration was slowing down in most European

countries – according to the Commission's background document on the agency, authorities in Germany needed up to six years to review a product in the early 1990s (CEC 1993a). A surge in the number of products and applications, a growing industry, and increasingly technical and complex scientific issues were contributors to this trend. Second, the CPMP and mutual recognition procedures were deemed slow and inefficient, and were not facilitating the process as had been envisaged. Third, the '1992' deadline was imminent, and it was clear that the pharmaceutical sector was not ready. This latter point was the most important from the Commission's perspective, as the failings of the Community authorisation procedures represented a setback in its aims to promote the single market. Thus, it was in a 1988 report on the work of the CPMP that the Commission first raised the possibility of a single, unifying regulatory office for medicines (COM 1988).

2-1 The Commission agenda

The 1988 report is significant on several fronts. Having asked the member states and so-called 'interested parties' "... as to the form which any definitive system for the free movement of medicines might take (mutual recognition, a centralized Community system or an intermediate approach)" (COM 1988, 23), it laid the basis for the Commission's later formal proposal for an agency. As the interested parties consisted of industry and consumers, the Commission essentially established the policy network from the beginning. Furthermore, as the report was issued by the Industrial Affairs Directorate-General without consultation with the Social Affairs Directorate-General, the nature of the relationships within the network were also established; consumer interests were somewhat marginalised from the outset. Indeed, the report concentrates primarily on the need to improve the system from an industrial rather than patient health standpoint.

But perhaps the most important element of the document is that it reveals the Commission's agenda. The report reflects on the failings of the multi-state route, pointing out that the number of applications discussed by the committee was:

... very few in comparison to the hundreds of applications made separately each year in each Member State... [and] it is unfortunate that, to date, every dossier has systematically been the subject of reasoned objections, in spite of the obligation on Member States to take due consideration of the initial authorization, save in exceptional cases. (COM 1988, 6 and 11)

More precisely, during the eight years of the CPMP procedure (1978-1986) only 41 dossiers were considered and all were referred back to the committee. Mutual recognition was proving equally inefficient, and as the member states consistently raised objections to authorisations granted by other national authorities the industry's pursuit of single market applications had continued unabated. With multiple national approval systems having

been identified as an impediment to completion of the single pharmaceuticals market in the Cecchini study, the report concludes that:

In accordance with Article 15 of Directive 75/319/EEC as amended, and also within the legislative programme set out in the White Paper on the Internal Market, in light of experience, the Commission must, before 1 November 1989, submit to the Council a proposal containing appropriate measures leading towards the abolition of any remaining barriers to the free movement of medicinal products within the Community. (COM 1988, 23)

The Commission regarded an authoritative Community system as necessary to address the failings of the two procedures; to promote multiple market applications by the industry; and to overcome disparate national approval procedures (thereby eliminating varying authorisation times), all which hampered the development of a single medicines market. Underlying this was "... the assumption that many national regulatory standards are really disguised barriers to trade: their primary purpose or effect is to protect domestic producers from international competition." (Vogel 1998, 16) There is, therefore, an element of 'spill-over' in the establishment of the agency. But a neo-functional explanation of how and why an agency emerged is a somewhat superficial one which fails to acknowledge the direct role played by the Commission. For DGIII found that its priorities did not gel with the views of the other stakeholders in the policy network, and that it would have to push hard if its agenda was to be implemented.

2-2 Stakeholders' interests – costs versus benefits

In order to understand the positions of the other stakeholders during the policy-process leading to Regulation 2309/93, a brief outline of several of the more important issues under consideration helps to establish the backdrop. Table 6-1 (overleaf) generalises the actors' concerns during the late 1980s when it was still unclear as to what form, if any, a new authority might take. For while all were agreed on the necessity of quicker approvals, they did so for different reasons and therefore had different hopes and fears.

From the table's admittedly simplistic division between the then (perceived) pros and cons of what an agency might have brought, the potential costs and benefits to the stakeholders – and hence their representations during subsequent negotiations – can be contextualised. Each had different interests and each would be affected. The Commission's April 1989 compilation of responses document (CEC 1989) revealed the extent of this lack of consensus (including the depth of scepticism), and these views were to harden as discussions developed around more concrete proposals.

Table 6-1: Perceived Pros and Cons of a Potential European Medicines Agency (prior to the EMEA)

STAKEHOLDER	PRO (BENEFIT)	CONTRA (COST)
INDUSTRY	<ul style="list-style-type: none"> • a standard application format and single approval mechanism could ease companies' administrative difficulties <i>vis-à-vis</i> 12 disparate national procedures (in several different languages) and save costs • a system geared towards speeding the approval process may serve as a boost to industry generally, and help to promote small-to-medium sized companies specifically • quicker approvals (via a new body) would limit the erosion of the effective patent life for new drugs 	<ul style="list-style-type: none"> • one EC system (via a centralised office) might mean higher levels of scrutiny across Europe, thereby undermining their ability to 'pick and choose' amongst national authorities according to perceived ease of assessment criteria • the potential for an overly politicised body staffed by bureaucrats, wherein decisions on marketing authorisation are taken on political rather than scientific grounds
MEMBER STATES	<ul style="list-style-type: none"> • a Community body would not have to preclude the continuation of a complimentary system of single country applications • might promote collaboration with other member state scientists and regulatory offices, and foster the exchange of knowledge • political, scientific and legal liability to be shifted from the national to the supranational level (Commission) 	<ul style="list-style-type: none"> • a loss of sovereignty - not just in political terms but with regard to: <ul style="list-style-type: none"> i. the ability to decide on which drugs are appropriate for their populations ii. healthcare financing autonomy, and control of the drugs bill • a centralised mechanism for all companies irrespective of origin may harm local industry • loss of national responsibility for the health protection of its citizens; how would an EU agency be held accountable, and who is then liable?
PATIENTS	<ul style="list-style-type: none"> • national approval procedures (often) relate to other political or economic goals, and can mean delays in the introduction of new medicines to the detriment of patients - an EU agency would not have such wider responsibilities • an EC system could overcome disparate member state approval procedures, eliminating differences between member states in approval times for the same products 	<ul style="list-style-type: none"> • the potential for a 'lowest common denominator' approach to safety and efficacy guidelines i.e. those member states with strict approval procedures having to dilute them given a European 'efficiency regime' approach • resulting in a body in which they might have less say (compared to the national level) and one susceptible to regulatory capture because of a reliance on (European) industry fees for its financing

The drug companies seemed to think that they stood to lose the most from a single European office not directly geared towards industrial policy interests. It was felt that a single centralised procedure (via an agency) was unlikely to be able to adequately match their growing expenditure on new drugs with more efficient approvals. In the 1989 document EFPIA said that its members were firmly "... against a fully centralized system with decisions being made by a European body." The association suggested that not only would the workload prove too great – and therefore approvals too slow – but there was a danger that any Community agency would be a political construct leaving important scientific decisions in the hands of bureaucrats rather than appropriately-trained experts. The worry was that authorisations might be politically determined. EFPIA thus insisted that mutual recognition be made binding, arguing that companies should not be disadvantaged under a revised (centralised) Community regime because of political imperatives. The fear

was of a 'Euro-FDA'¹¹⁴, and John Griffin, Director of the Association of British Pharmaceutical Industry (ABPI), referred to the Commission's early vision for an agency as a 'recipe for disaster' (as cited in MARKETLETTER 1989). Because of these fears (and the potential costs to be assumed) EFPIA even suggested that it be consulted and involved in all preparatory work for future Community legislation in the area.

Although sharing an interest in preserving sovereignty and controlling healthcare expenditure generally, the 1989 document showed that the member states' views were not uniform. While some (such as Ireland and Luxembourg) reflected on the merits of a single supranational license issued by a Community office, others (most notably France) favoured a revised mutual recognition procedure with national authorities at the heart of the system. And the UK's qualified support for an agency in principle can be compared to Germany's outright opposition to any such body. The differing member states' views would later prove problematic in agreeing the legislation.

The consumer position was, and would remain, the most straightforward (even if the least heeded). Responding to the 1988 consultation, the European Consumers' Organisation (BEUC) echoed the other stakeholders' dissatisfaction with existing arrangements. Its primary concern, however, was the persistence of different safety standards in the member states (Anon 1988). For instance, while the drug *Halcion* – designed to treat sleeping disorders – was withdrawn from the UK market in 1993 on safety grounds, it continued to be marketed in other member states¹¹⁵. The BEUC thus endorsed the creation of a binding Community agency providing that it would harmonise safety and quality standards upwards. Its stance was that "... from a consumer point of view it is doubtful that they [the existing procedures] represent the safest methods for authorising new drugs", and that patients would be best served by a pan-European office with stringent approval standards, rather than continuing with twelve national regimes exercising different criteria.

Notwithstanding the stakeholders' opinions, the Commission was not to be deterred. DGIII was wary of the 1992 programme and, after stressing in the 1989 document that a "major transfer of executive competence" was necessary to complete the single market, in November 1990 the 'Proposal for a Regulation laying down Community Procedures for the Authorization and Supervision of Medicinal Products for Human and Veterinary Use and

¹¹⁴ This was a reference to the US FDA which was seen by both European and American industry officials to be overly-bureaucratic and slow in reaching decisions on market authorisations. See for instance Matthews & Wilson (1998).

¹¹⁵ The UK's grounds for first suspension and then withdrawal of *Halcion* in October 1991 had to do with certain side-effects. The CPMP's response was to commission two position papers (released in October and December 1991), both of which concluded that the drug was safe if used in strict accordance with the labelling information – this despite internal recommendations for its withdrawal throughout the Community.

'Establishing a European Agency for the Evaluation of Medicinal Products' (CEC 1990b) was submitted. This was presented to the Council as part of a package of four 'future system' instruments representing broader plans for the free movement of medicines (COM 1990). But the discrepancy in the stakeholders' positions meant that it would only be in July 1993, after several important amendments, that the final text of Regulation (EEC) 2309/93 was agreed (and yet another two years before the EMEA became a reality).

2-3 The route to approval

The Commission's proposals made clear its goals. An agency would be established to co-ordinate two new authorisation routes: a centralised procedure applicable to biotechnology and certain high technology products, and a decentralised procedure for the majority of other products (based on mutual recognition). Initially optional, the decentralised route was to be mandatory after 1996. Member states' objections to authorisations granted under the former were to be permissible only for "objectively defined reasons of public order or public policy", while under the latter, the Committee for Proprietary Medicinal Products would arbitrate where bilateral agreement failed. The aim was to deliver Community authorisations subject to efficacy, quality and safety criteria within a timeframe of around 300 days. Given the clear internal market orientation of these proposals, the Commission put it to the member states that Article 100(a) of the Treaty – designed to facilitate completion of the single market through harmonising national laws – was the appropriate legal basis for establishing the system.

The German government rejected the applicability of Article 100(a). In addition, it claimed that subsidiarity precluded the Commission taking decisions on drug authorisations, and was, therefore, only willing to countenance a small 'technical secretariat'. According to Robert Hankin (then of DGIII), in his testimony to the UK House of Lords Select Committee on the European Communities, this was because of "... the German concept of federalism and the view that the role of the Community should be limited to decisions of principle while decisions on individual products are the responsibility of the individual Member States." (as cited in HoL 1991b, 56) Other governments, including those of Ireland and Luxembourg had no difficulties with the proposals, and accepted the use of Article 100(a).

More subtle views were revealed in the member states' answers to the Commission's December 1990 request in the Council for written responses to the future system plan. Denmark, Italy, the Netherlands and Spain were in favour of an administrative agency (retaining the member states' technical competence), while France preferred to continue with a strengthened mutual recognition principle. The French position was essentially that

of its industry, and was set out by Yves Juillet of the French industry association, the *Syndicat National de l'Industrie Pharmaceutique* (SNIP) at a 1988 conference¹¹⁶:

It is the view of SNIP that the operation of the future European system, harmonized with the two alternative procedures [the proposed centralised and decentralised routes] which may be used at the choice of the manufacturer, *should remain* in line with texts and procedures which already exist, with no break in the structures that are already set up... with the only changes being:

- that States which make remarks or objections would have to justify their position
- that the European Committee in charge of judging the validity of these refusals would issue a ruling which the Member States would have to respect.

(Juillet 1989, 262-263)

In favour of an agency, the UK position was nevertheless that if it were to rule on 'scientific issues' (i.e. drug approvals), then Article 100(a) was inappropriate for its establishment and that Article 235 was required instead. Article 235 – which allows the Council to take decisions on fostering the common market where existing Treaty provisions are insufficient for the Commission to do so – had already been invoked to create other Community agencies. That said, the UK government's official response was that

... ministers wish to reserve their position on the acceptability of any particular proposals until they can satisfy themselves that the proposals are capable of meeting satisfactorily the objectives set and of maintaining acceptable standards of protection of public health." (as cited in HoL 1991b, II-18)

In other words it wanted further consultation with its industry, as the ABPI had already made clear that was dead-set against a centralised European agency (Griffin 1990).

What the ABPI was after, as set out in its 1988 policy document 'ABPI's Blueprint for Europe', was a single authorisation regime characterised by unambiguous data requirements and overseen by an independent authority, separate from the CPMP, which would reach decisions within 210 days (Abraham & Lewis 2000). All biotechnology products would be automatically scrutinised by this new authority, but companies would retain the right to choose whether to submit all other products to this regime or continue with mutual recognition. In the case of the latter, the Community authority would be empowered to make binding decisions. This is very much the system which emerged, albeit based on an agency with a revamped CPMP at its heart.

Not just the British, but the Belgian, Italian and Spanish governments all saw Article 235 as necessary if the agency were to be delegated any scientific powers. Even if opposed to

¹¹⁶ At the same conference, Trevor Jones, head of the UK's Medicines Control Agency, argued that "... what is required for the future is an efficient, authoritative central agency which operates to a high standard of scientific and clinical understanding with a minimum of timescales." (Jones 1989, 255)

the agency, the German authorities also agreed that this provided a more appropriate basis. The French view was more nuanced: were Article 100(a) used for the creation of the agency, then the centralised procedure would have to be based on Article 235. So despite both the European Parliament and the Economic and Social Committee (ESC) having earlier endorsed the use of Article 100(a), it was decided at the Internal Market Council meeting in December that Article 235 would provide the appropriate legal basis¹¹⁷. As this meant the consultation procedure and unanimity in the Council, it may seem an odd decision given Germany's clear opposition and France's scepticism. Since consultation only allows the Parliament a single reading, the choice of Article 235 was to ensure that the MEPs did not have much say. The Parliament's Committee on the Environment, Public Health and Consumer Protection, which had been assigned the text, had already suggested numerous amendments with which the Commission was unhappy (EP 1991b).

As a forum where wider interests are heard, particularly those from consumer groups, the Parliament focused largely on the only tangential attention paid to consumer and public health requirements in the proposals. It suggested that 'medicinal products belonging to specific pharmacological categories of particular social significance' be added to the biotechnology and high technology designation of the centralised procedure (Article 18(4)). This was to ensure that products designed to treat diseases or conditions of especial concern would qualify for the quicker, multiple market route. Unlike the Commission, the Parliament envisaged a sparing use of the centralised procedure.

In its consideration the ESC also suggested that public health protection feature more prominently (ESC 1991b). Recognising that "The importance of the Agency lies in the remit and role which will be assigned to it" (Point 1.2), the Committee asked whether the division between types of product qualifying for the two procedures "... protects the interests of either the 'passive consumer' (i.e. patients) or the 'active consumer' (the doctor who prescribes the drug and is thus the real promoter of its consumption." (3.7.3) The point being that drug approvals carry a social element not adequately addressed in the proposals. Prepared by the Protection of the Environment, Public Health and Consumer Affairs section, the ESC report stressed that transparency needed to be a central element of the new agency, with the names of the national experts carrying out reviews on its behalf being made public. As this did not happen – ostensibly in order to protect the experts' safety (see Section 3-2) – the ESC's further calls for the agency to "... avoid interference from industry and intervention by the national authorities which would be incompatible with assessment duties" (4.2) were also disregarded.

¹¹⁷ A switch from Article 100(a) to 235 would also prove the case for the Community Plant Variety Office.

The industry did not impassively watch these debates unfold. There was a great deal to gain from a revised regime, but it saw the Commission's plans as going in the wrong direction. EFPIA took the view that as the CPMP procedure had not worked the first time, there was no reason to believe that an agency would make it any better. It criticised the Commission's call for further centralisation, reiterating its members' frustration at the lack of any real (i.e. binding) mutual recognition in practice. According to Orzack et al (1992):

... industry objected to the bureaucratic prolongation of approval processes, feared the creation of a centralised agency empowered to render final decisions that would override national regulations, called for effective mutual recognition of national decisions, desired quicker action from existing agencies, and hoped for close links between industry and regulatory bodies. (860)

More specifically, it expressed its fear that the culture of mistrust between the member states would continue, leading to overwhelming use of the centralised procedure and resulting in the national authorities trying to outdo one another in terms of who could set the strictest approval criteria.

Beyond representations to the Commission and the national governments, industry representatives voiced their concerns more publicly. For instance, in clearly playing to the audience, John Griffin asked in a letter to the *British Medical Journal* at the time of the proposals: "Is patient safety being put at risk in the decision making process offered by the Commission?" (Griffin 1990, 1537) He argued that CPMP members were not always medically or pharmaceutically trained, and that the committee ought to be comprised of recognised scientists to ensure rigorous assessments. This health protection line belied the industry's underlying interest in ensuring that the appeal/review process would not go back to the same officials who rejected the authorisation in the first place. A further example is the point made by William Currie (1990):

There is little to support haste in the creation of such a European Institution. We must remember that currently the time to achieve market authorization in the Member States of the EC is not greater than that taken in other geographic areas and that comparable statistics reviewed periodically by the Pharmaceutical Manufacturers Association (PMA) of the US often show the European national performance in a favorable light. (388)

Representing an American company, Dr Currie's agenda was slightly different from that of his European counterparts i.e. expressing a preference for the European *status quo* over the US system. But what is interesting is that his assertion contradicts EFPIA's position in its 1988 memorandum to the Commission on the need for extending patent protection periods. The argument then was that improved protection was necessary because of slower registration times in Europe (recall Chapter 5). Ultimately, industry was wary of a Community equivalent to the FDA and was prepared to try all lines of argumentation.

Nevertheless, the companies acknowledged that some type of Community authority was necessary if the regime was to be improved, and if they were to glean any benefits from the SEM. With the Commission pushing for an agency, EFPIA sought to ensure that authorisation decisions would serve industry's interests and be based on a wider perspective than that generated solely by political considerations. It thus insisted on manufacturers' freedom of choice between mutual recognition or the centralised procedure. The former – subject to the addition of certain procedural 'safeguards' in terms of ensuring that national authorities were bound to recognise each others' approvals – was to remain the heart of the 'future system', with the latter based on a fortified CPMP with the authority to enforce its decisions (especially regarding appeals). EFPIA was also adamant about companies retaining the right to choose the *rapporteur* in applications.

Although this is very much the current system (and that proposed by SNIP), the problem at the time according to Dulio Poggiolini, Chairperson of the CPMP, was that:

An improvement in the legal situation of the CPMP will only be possible if the Council of Ministers is charged with making the opinions of the CPMP mandatory and operational... The acceptance of EEC opinions on marketing authorizations of new medicines implies a renouncing of sovereignty and sovereignty includes political and legal aspects. (Poggiolini 1989, 243)

With the impending single market, sovereignty was a concern for the member states generally. But the potential 'free movement of medicines' represented a particularly difficult prospect at a time when national governments were struggling to control health budgets; Community approval of expensive medicines could mean higher drug bills. Further, any loss of sovereignty was seen as potentially damaging to local industry, and public health concerns too would be affected.

Indeed, the BEUC expressed serious concerns about the potential public health implications of the proposals. Having accused the Commission of being "... more concerned about promoting the recognition of other countries' medicines, despite differing safety standards... Proposals for opening up the market take precedence over those which have to do with the quality of health care" (as cited in Orzack 1996, 20), so too was it sceptical of industry's vision. Irrespective of whether the member states would show more faith in each other's work, or of a binding mutual recognition route, the BEUC was against both the industry having a choice of procedure and national agencies competing against each other. The worry was that this would:

... create the strong possibility of a Community licensing system containing double standards... medicines assessed by a newly created, highly scientific central body may be scrutinised more critically than those submitted to a less resourced and sophisticated national agency. (Currie 1989, 771)

Were this the case, industry could be expected to overwhelmingly turn to the latter. The BEUC envisaged a policing rather than policy-making role for the national authorities towards attaining higher Community-wide standards.

The Consumer's Consultative Commission (CCC)¹¹⁸ also insisted on a stronger public health protection element to any new authority. It argued the agency should be able to assess medicines according to 'specific therapeutic advantages' *vis-à-vis* products already on the market (CCC 1991). This echoed the Parliament's call for products of 'particular social significance' to be granted centralised approval¹¹⁹. To facilitate this, the CCC sought consumer representation in the CPMP, suggesting that its independence "... is not guaranteed, for research in the area of pharmaceutical products is largely funded by the industry." The Commission ignored this, as well as most of Parliament's submissions¹²⁰. DGIII's single-mindedness is reflected in a May 1991 unpublished correspondence from Fernand Sauer, when still in charge of the Pharmaceuticals and Cosmetics Unit, to Ricardo Perissich, Industrial Affairs Commissioner:

Thus at the present time it appears that the current proposals do provide a good basis for negotiation within the Council, and no fundamental review is required. Consideration needs to be given to the extent to which the Commission can accept 'Communautaire' amendments from Parliament, bearing in mind that such amendments may provoke a counter reaction from Member States. (Sauer 1991)

It would appear Mr Sauer had foreseen that public health concerns would be raised by the Parliament and was suggesting, if not recommending, that any prospective Parliamentary amendments be disregarded for fear of the policy being rejected by the member states. Patients were obviously not the Commission's nor the member states' prime concern.

2-4 Final obstacles

Returning to the legislative process, just two months after the ESC's July 1991 report the Commission agreed an amended proposal for the agency based on Article 235. But Denmark now expressed reservations. Its national authorisation criteria were seen as stricter than most of the other member states', and it was concerned that unanimity under Article 235 meant no possibility of opting out. Although the details of the centralised

¹¹⁸ The CCC is a consultative body of the Commission which represents consumer interests before the Commission; its views are not binding.

¹¹⁹ This 'need' criterion in approving new drugs is not part of the agency's mandate (see Section 4-1).

¹²⁰ One amendment adopted by the Commission was for limits to be imposed on the member states' power to temporarily suspend authorisation. Based on reservations about governments' protectionist motives, the Parliament argued that suspension should be permitted only after assessment of the harm likely to be accrued during the wait for a Commission decision i.e. unless there were justifiable public health reasons for not waiting, the product could not be withdrawn until the Commission had assessed the reasons. This was accepted by the Commission, for the unilateral right of the member states to withdraw products was seen as undermining its internal market goals.

procedure were still under discussion within the member states (in consultation with their industries), once Danish opposition faded it looked more-or-less a 'done deal'. However, at the 10 November 1992 Internal Market Council another obstacle emerged when Belgium and Spain raised the issue of 'headquartering' the new agency.

At Belgian and Spanish insistence, a Council Declaration stating that the agency would only begin operations eighteen months after its headquarters had been decided was agreed. It had been expected that the decision on the EMEA's location would – along with the new environment agency and internal market harmonisation office (and drug addiction monitoring centre, training foundation and police force which were still 'homeless') – be decided via raffle at the December 1992 Edinburgh summit meeting. But under the Declaration, the location of the EMEA would have to be decided by the leaders of the member state governments. And now that it was clearer how the agency and a centralised procedure would work, Denmark, Ireland, the Netherlands, Spain and the UK launched campaigns to host it. Eventually a decision of the heads of state and governments on 29 October 1993 agreed London as the EMEA seat.

The reason for the bidding war was the perceived industrial policy gains to be accrued. When asked why the UK government had fought to have the agency in London, Virginia Bottomley, then minister of health, stated unequivocally that it had done so because:

The British pharmaceutical industry will have the advantage of easy access to the agency, which will be working in its language and will offer its products quicker access to the European single market, all of which means that there will be increased inward investment in the UK, more exports and more jobs. (Hansard 1995)

Unsurprisingly, the ABPI had spearheaded the UK's campaign (Jackson 1993). And with Prime Minister John Major stating that "I and the British government support the pharmaceutical industry's initiative in proposing that the Agency should find its permanent home here." (SCRIP 1820), it clearly did so with full governmental backing.

What proved to be the final sticking-point emerged over the fees to be paid to the agency. Several member states objected to the proposed cost of applications as too high compared to those charged by national authorities. It was feared that the result would be increased overall expenditure on drug regulation and a loss of national fee revenue to the member states. And while some governments sought Commission oversight of EMEA financing via a subsidy from the Community, the UK favoured an agency funded solely by fees as was the case for its own Medicines Control Agency (MCA).

This dragged out the opening of the EMEA's doors by another few months, especially as the Parliament had a vested interest here. Any Community budgetary plans would have to be granted Parliamentary approval and MEPs wanted to retain some control over agency financing (Gardner 1996). The end result was a 'half-and-half' agreement under Regulation (EEC) 297/95, but not before the Parliament and Council reduced the amount of the subsidy in late 1995, with financing to be reviewed after three years. Since revision of the 'fee schedule' under Regulation (EEC) 2743/98 of 14 December 1998 – the main changes being the addition of an annual fee for each medicinal product already authorised, a fee for scientific advice rendered prior to application submission, and an administrative fee for supplying documents or certificates – the agency is now financed mainly through fees much to many people's unhappiness (see Section 3-2).

Differing industrial policy goals, and to a lesser degree public health concerns, were implicit in the member states' disparate reactions and positions throughout the policy-process, and all shared an uncertainty about the Commission's vision. Initially, most feared that their own regulatory authorities might slowly be squeezed out and that a streamlined authorisation procedure could mean rationalisation of local industry. This has not really happened in practice, though some agencies are more used than others. And by working with the companies the agency in fact helps to promote the European industry. Ultimately then, it seems that for the member states the costs to be borne were less significant than the gains – the amended proposals were endorsed in the Council on 23 July 1993¹²¹.

2-5 The Commission's new line

Following Council's adoption, the Commission sought to distance itself from its position of industrial policy first and health policy second, and set about presenting the agency as a patient benefit. Dr Bangemann, successor to Mr Perissich, and known for his strong commitment to a single pharmaceuticals market (see Chapter 7), immediately adopted this new health protection line. Gone were his earlier references to "... quicker access for new medicines to the enlarged Single Market" (Bangemann 1991) and the agency's role in fostering "... consolidation of the internal market" (CEC IP 1994). Now he stressed that by improving market authorisation procedures, the new structure "... generates consumer protection thanks to severe test criteria." (as cited in Albedo 1995b)

More recently, in an information booklet on the EU pharmaceutical sector published by DG Enterprise, the agency is claimed to have been established "... partly in response to demands from consumers' organisations, particularly the BEUC and the European

¹²¹ Parliament conducted a second reading, but its amendments (26 May 1993) were again disregarded.

Parliament.” (CEC 2000, 7) The discussion has already shown that this was not the case. The BEUC may have endorsed the principle as first raised by DGIII, but it had a completely different vision, and most of the Parliament’s amendments were ignored. What is true is that the decision to draw up and publish the EPARs was the result of consumer and Parliamentary pressure for transparency, and it was at the Parliament’s insistence that two members of the EMEA management board are nominated by the Parliament to increase accountability – the other members comprise two representatives of each member state, and two from the Commission¹²². As stated at the outset of the chapter, ‘no one thought of seriously selling the idea as a patient benefit’, and there is in fact no proof that patients have benefited from the revised approval procedures under the EMEA¹²³.

The Commission’s change in how it came to promote the agency reflects the criticism it drew both before and after the deal was done, especially as the policy network involved no consumer representation during the policy-making process (Mossialos & Abel-Smith 1997). (After the initial consultation, the discussion has shown that formal patient/consumer interests were not solicited.) The Commission sought to deflect criticism by insisting that the patient had always been the prime concern. Indeed, one of the characteristics of Wilson’s policy entrepreneur is that (irrespective of an agenda of its own) it often aims to associate the proposed regulatory intervention with broader social concerns or widely-held values. Despite the Commission’s new sell, it is clear that DGIII’s single market pre-occupation, along with industry pressure, had been the driving force. Further evidence of this comes from the agency’s operation in practice. Particularly the degree to which it works with, rather than independent from, the industry.

3 Persistent Criticisms

As a unique body it should not be surprising that the EMEA has its share of detractors. But what is perhaps surprising given the Commission’s insistence that the agency is designed primarily for European patients, is that its critics are primarily those with patients’ interests in mind. Dissatisfaction relates mainly to the nature of the system and the resultant loss of responsibility at the national level. Criticism has generally taken two, albeit related, faces. The first has to do with a perceived lack of transparency in the agency’s work. Not only is the CPMP secretive in its deliberations on product assessment – the minutes of which are not publicly available – but neither consumers nor patients have the access they perhaps should. Stemming from this, the second critique asks whether the agency’s operations (and even its remit) are therefore geared more towards the needs of industry (i.e. the applicant) than the patient. The criticism being that the EMEA’s emphasis is on improving

¹²² The Commission representatives are from DG Enterprise and the Agriculture DG.

¹²³ For instance Cameron McKenna (2000) or Edmonds et al (2000).

time-to-market (TTM) for new drugs rather than protecting public health *per se*. Bringing new medicines and treatments to market more quickly does serve a public health function, but the question is whether speeding TTM as an end in itself is sufficient to meet patients' interests as the Commission seems to assume. These are charges which reverberate especially sharply with those interested in the public health side of medicines regulation¹²⁴, and they relate to the earlier discussion on how and why the agency was established.

3-1 Transparent, accessible?

The lack of transparency criticism is one which the agency has fought since its inception with but limited success. Primarily through the maintenance of an oft-updated website, the EMEA has striven to make its activities open and accessible. The site posts an array of material, ranging from the usual 'Who we are/what we do' and 'Frequently-Asked Questions', through summaries of meetings and assessments of its operations. It also provides a listing of all legislation pertinent to medicines in the Community. More importantly, it publishes two sets of document. First is the Summary of Product Characteristics (SPCs) for new drugs. These provide detail about individual drugs so that interested parties – primarily doctors and national regulatory officials – can obtain objective information about clinical effectiveness. Second are the European Public Assessment Reports (EPARs). These are detailed assessments of new applications for all positive opinions granted under the centralised procedure. Publishing such information is intended to demonstrate the agency's self-declared open approach. But the nature and value of what is published has been questioned, and accusations of non-transparency therefore persist. One of the most openly critical voices has been that of the International Society of Drug Bulletins (ISDB). Founded in 1986 with the aim of promoting "the international exchange of information of good quality on drugs and therapeutics, to encourage and to assist the development of professionally independent drug bulletins in all countries and facilitate cooperation among bulletins"¹²⁵, it has consistently questioned the extent of the EMEA's commitment to transparency.

According to the ISDB, the material provided by the agency on its website, along with the way it is presented, is opaque, often inconsistent, and even unhelpful (ISDB 2001). In a 1998 report assessing nine EPARs, the society characterises them as "hazy and irrelevant." (ISDB 1998) This is a sentiment echoed by the BEUC, which recently expressed its view that, at around 30 pages, the EPAR:

... requires a high level of technical knowledge about pharmaceuticals and is therefore adequate for professional use. Consumer organisations usually have

¹²⁴ For instance Dukes (1996), Abraham & Lewis (1998) and Garattini & Bertele (2001).

¹²⁵ Mission statement available at the ISDB website: www.isdbweb.org.

very limited financial resources and it is hard to get experts with this kind of knowledge willing to work for small money. For the ordinary consumer/citizens the publication is not useful. It is too technical and very difficult to find your way around in for an unskilled person. (BEUC 2000, 3)

The ISDB report concludes that the major problem with the EPARs, however, is the "... lack of a clear and consistent policy on the reporting of the clinical trial data which influenced the decision on whether or not to license a new drug." More recently, the group has accused the EMEA of employing obscure and coded language in the presentation of these reports; that which diminishes the reliability of their content (ISDB 2001).

The SPCs have also been criticised, and not just by the ISDB. Critics identify two main failings. Doctors do not have the ease of access they might i.e. they are expected to look up the SPCs on the EMEA website themselves (assuming they have the means and time). It has, therefore, been suggested that the national regulatory agencies be able to supply their local doctors with hardcopies of the summaries (Garattini & Bertele 2001). More importantly, in the SPCs the drugs are described without reference to comparable preparations, let alone those designed to treat similar conditions. This hinders doctors' ability to make comparative assessments for prescribing purposes, raising questions about the value of the summaries as they are now drafted.

Beyond containing unclear information, a further concern is that the manufacturers are involved in writing the SPCs and EPARs (although the CPMP has final say over the text of the latter). Not only may this result in documents of variable quality¹²⁶, but it may compromise their objectivity or accuracy. For instance, even though the direct-to-consumer advertising of medicines is prohibited in the EU¹²⁷, it has been alleged that:

In practice, drug companies have failed to fulfil their duty to inform via the patient leaflets and SPC. By completely blurring the dividing line between information and promotion, they have developed highly effective promotional tools and methods that ignore the very special nature and utilisation of the "merchandise" they produce. (Bardelay 2001, 4)

Another example comes from a question tabled by MEP Nel van Dijk in 1996 (CEC 814/96). He asked why the package leaflet for the drug *Fareston* – designed to treat breast cancer – does not actually carry the word 'cancer', using the word 'tumour' instead. As 'cancer' features in both the EPAR and SPCs and is not interchangeable with 'tumour',

¹²⁶ This variability prevails despite the harmonisation of SPCs under the centralised procedure. And while the majority of medicines circulating in Europe pre-date the procedure and thus already carry differing SPCs, the EMEA could make more of an effort to ensure that all drug reporting is more objective and to a high standard.

¹²⁷ Directive 92/28/EEC.

he claimed that this was misleading to patients¹²⁸. The Commission's response was that the leaflet text was in accordance with Article 7(2) of the labelling of medicinal products Directive¹²⁹, which states that "The competent authorities [CPMP] may decide that certain therapeutic indications shall not be mentioned in the package leaflet, where the dissemination of such information might have serious disadvantages for the patient." While the applicability of the Article may be questionable given that cancer is such a widely-reported issue, the Commission did concede that steps needed to be taken to ensure a higher degree of comprehension for patients. And it should be noted that the Commission's response was given by Martin Bangemann, then Industrial Affairs Commissioner, rather than Social Affairs Commissioner Pádraig Flynn.

Not just the ISDB, but consumer groups too have demanded clearer presentation of material and have sought improved access to the EMEA's work. The BEUC has long complained about the lack of patient representation in the CPMP, registering its dissatisfaction as early as 1986 that consumer groups were not formally included in discussions on drug approval under the multi-state procedure, while industry's views were in fact solicited (Orzack 1996). In France for instance, both industry and consumer representatives are both permitted to make observations during scientific deliberations (Vos 1999). Relating their attempts to access from the agency what they felt was 'general information' that the average patient might be interested in, two British academics write:

... despite European Commission and EMEA support of greater freedom of information, the European procedures for medicines regulation remain opaque to public scrutiny. We found it impossible to get basic information from the EMEA about mutual recognition applications, such as names of products, RMSs [Referring Member States] and CMSs [Concerned Member States]. The EMEA referred us to the Mutual Recognition Facilitation Group of the national regulatory authorities; the chairman of that group, Dr D Lyons, told us in a letter dated Sept. 5, 1996, that 'only the applicant, the RMS and CMSs need know' such details. Moreover, there is no public right of access to CPMP meetings or minutes. (Abraham & Lewis 1998, 481)

According to the authors' more recent work, this situation has hardly improved (Abraham & Lewis 2000). While issues of commercial and industrial secrecy must be respected, this exclusion of the public from even basic information does not inspire confidence where public health is concerned.

The agency admits the importance for increased transparency and access. Not only does it hold yearly audit meetings of its performance to which numerous non-governmental

¹²⁸ Ellen t'Hoen of HAI Europe also queried the Fareston package leaflet. In a letter to Fernand Sauer she makes the point that "The use of Fareston (toremifene) is restricted to the treatment of breast cancer and is not indicated for benign tumours." (t'Hoen 1996)

¹²⁹ Directive 92/27/EEC.

groups including the ISDB and BEUC are invited, but another series of annual meetings discusses specifically how the agency can work towards increased openness, and again a range of interested parties take part. At one such meeting in June 1998, the ISDB put the findings of its study on the 9 EPARs to Rolf Bass, head of the agency's Evaluation of Medicines for Human Use unit. Acknowledging the need for improvement, he said that the agency's website would soon be carrying a full index of trials to accompany the EPARs, as well as the complete list of documentation generated in each drug approval case (HAI 1998). This was understood to include even restricted documents which, while remaining so, would at least acknowledge their existence.

In addition, and as a follow-up, Professor Bass issued a letter to Ellen t'Hoen of the ISDB in December 1998 responding in detail to the group's 1998 study (Bass 1998). Based on consultation with the CPMP, Prof Bass addressed the ISDB's complaints on a product-by-product basis, generally acknowledging 'shortcomings' and 'inconsistencies'. However, he refuted that the EPARs did not provide sufficient scientific data, arguing that "in accordance with current legislation", only "... commercially confidential information e.g. pharmaceutical development details" were not included. Further, he claimed that the reports were a "readable and digestible volume of text" based on the full study reports. And again, assurances were given with regard to improving the quality of the reports, particularly in relation to common standards under the International Conference on Harmonization with the US and Japan. In a follow-up report two years later, however, the ISDB complains that these assurances have yet to be met (ISDB 2000).

Still, the publication of the EPARs and SPCs, and the maintenance of a website is, as even the critics admit, a laudable step. Few national agencies are so forthcoming (Abbasi & Herxheimer 1998). But given that much of this information is quite specialised, and assuming that transparency really is an EMEA priority, a more realistic attempt should be made to facilitate public understanding of the authorisation process – this includes providing the types (and names) of drugs under consideration. Ultimately, a website, irrespective of how often it is updated, is simply not sufficient when the material posted remains selective and/or inaccessible to a broad readership. The charges of a lack of transparency or inaccessibility are not likely to dissipate soon.

3-2 Favouring the industry?

Such failings have led to the second main line of criticism: wider questions about what the agency's function really is. Despite regulating for the safety, quality and efficacy of new medicines, many commentators remain unconvinced that public health is the first priority as the Commission, agency representatives and industry all consistently stress. And here

they point to the degree of co-operation extended to the companies – co-operation which is unlike the industry's relationship with the FDA in the US.

For example, the applicant is allowed to nominate one of the two *rappoteurs* in the assessment. The result is that they usually choose someone from one of the larger, better resourced and 'quicker' agencies (see Section 4-3)¹³⁰. Even before choosing the *rappoteur*, a company is permitted to seek scientific advice from the agency four to six years in advance of the application. This is to ensure that its clinical research protocols comply with the types of questions the EMEA is likely to ask about the product come the evaluation (Ross 2000a). Highlighting this function is not to suggest that anything untoward takes place, but it more than likely results in companies 'tweaking' their documentation so that the drug stands a better chance of a positive opinion. By contrast, the FDA is often involved in the whole development plan for a new medicine, which is aimed more at ensuring the product meets approval standards than simply fulfilling licensing requirements.

A more worrying issue is the access to the agency's evaluation work which the industry currently enjoys. Silvio Garattini, one of the two Italian CPMP members, has asked why the applicant companies are privy to the committee's consultation documentation (which includes preliminary votes) prior to the final decision (Garattini & Bertele 2001). This gives manufacturers an initial 'feel' with regard to how the authorisation is going, and allows them to either withdraw the product before assessment, else accept a preliminary negative decision at an early stage in order to have time to prepare an appeal. Between 1999 and 2001 there were some 30 withdrawals prior to the CPMP opinion (EMEA 2002)¹³¹. The details of negative decisions or those in progress before a company's withdrawal of the application are not published alongside the positive decisions. Withholding this information and not divulging the reasons for withdrawal (nor the names and types of drugs withdrawn) is clearly not an attempt to serve patient interests as much as it is an attempt to placate the industry. As noted by the ISDB, "... it is not by working hand in hand with drug companies to produce documents stamped 'controlled' that drug agencies can make themselves most useful and credible."¹³² This also compares badly with the US where, according to Gerald Deighton, formerly head of the FDA's freedom of information office, public access is permitted to around 90% of the FDA's records (as cited in NCC 1993). Although secrecy and opaqueness are features of the national regulatory process as well (Dukes 1996), the

¹³⁰ The *rappoteurs*, indeed none of the 2,300 experts at the agency's disposal, are named on the agency's website. According to Abraham & Lewis (2000, 107), this is "... largely at the behest of the UK which cites 'personal safety' reasons"; though what these reasons are remains unclear.

¹³¹ Concerns about the rising number of pre-CPMP opinion withdrawals saw the 1999 establishment of the Working Group on Withdrawn Applications.

¹³² ISDB Newsletter 1999; 13(1): 5.

EMEA leaning towards industry does remain in stark contrast to the member states' own regimes at home which reflect much more of a health protection mandate. It should, however, be noted that prior to 1995 when there was no centralised Community agency, information about the specifics of the review process and applications under consideration was even less available than now.

The reason that the companies are involved in the EMEA's operations to such an extent (including in the drafting of the SPCs and EPARs which are essentially matters of public health) is because the products are theirs and it is assumed that they therefore know its indications best. Another perspective is that company fees represent an increasingly large share of EMEA receipts¹³³. Applicant fees accounted for about 71% of total EMEA receipts in 2000 (EMEA 2000a), continuing an upwards trend: 39% in 1996, 48% in 1997, 53% in 1998 and 70% in 1999¹³⁴. The agency, the Commission and the industry refute any link between the fees paid and the agency's work; indeed, most national authorities are financed mainly by industry in this way (and the fees paid to the EMEA are split between the agency and the member states). Still, some commentators maintain that this reliance on the industry does mean that the companies are bound to have a considerable say in how the EMEA operates and that TTM is going to be the priority (e.g. Abraham & Lewis 2000). Evidence for this comes from the FDA where, following the enactment of the Prescription Drug User Fee Act (PDUFA) in 1992¹³⁵, it was found that approval times for new chemical entities declined by 51% (TUFTS 2000).

Such collaboration with the companies makes it clear that the relationship with industry is a close one. In a recent interview, Brian Ager concedes as much: "The essential fact is, though, that what we have is not a case of the regulator versus those regulated when it comes to improving performance. It's a partnership..." (as cited in Ross 2000a, 62) Even the American interviewer expresses his surprise at this admission: "That's a far more cooperative system than anything we have in the US... It strikes me that the EMEA has really made a tremendous effort to form a partnership with industry." The emphasis on TTM around which this relationship revolves has even seen the US government's General Accounting Office (GAO) raises the question as to whether "... the new European drug approval processes may provide some alternative approaches for improving the timelines of FDA's drug approval." (GAO 1996, 1); something which American industry representatives have themselves not missed (e.g. Miller 1999). It thus seems widely

¹³³ The distribution of EMEA fee revenue is 30% to staff costs, 30% to *rapporteur* and *co-rapporteur*, 30% to 'special activities' as agreed by the management board, and up to 10% for 'sampling and testing costs for centrally authorised medicines' (EMEA 2000a, 13).

¹³⁴ Commission financing was designed to be phased out after 5 years, and represented 24% of EMEA receipts in 2000 (EMEA 2000a).

¹³⁵ The PDUFA is a scheme whereby the pharmaceutical and biotechnology industry pays 'user fees' to the FDA in exchange for the setting of performance standards aimed at reducing approval times.

recognised that the industry enjoys (undue) access and participation in the work of the EMEA. Having considered the criticisms pertaining to the agency's pro-industry design, it is now necessary to look at how the EMEA's work reflects this leaning. This is particularly in relation to both the member state authorities and the US FDA, for which the *Thalidomide* tragedy had provided the impetus.

4 Working as "Firstly a Benefit for the European Patient"?

How does all this square with the Commission's insistence that the agency was designed to benefit patients? In its recent information document on the EU pharmaceutical market, DG Enterprise stresses the EMEA's more efficient approvals ensure quicker access to new innovative medicines, thereby contributing to improved health protection (CEC 2000). Again, the causality may be tenable, but "to contribute to the protection of public health" is the thrust of the EMEA's mission statement according to its annual Work Programmes. This it does by:

- Mobilising scientific resources from throughout the European Union to provide high quality evaluation of medicinal products, to advise on research and development programmes and to provide useful and clear information to users and health professionals.
- Developing efficient and transparency procedures to allow timely access by users to innovative medicines through a single European marketing authorisation.
- Controlling the safety of medicines for humans and animals, in particular through a pharmacovigilance network and the establishment of safe limits in for residues in food producing animals. (EMEA 2000b, 2)

Without putting too much stock into the specific wording, it is perhaps interesting to note that in respect of public health the mission statement has evolved (been diluted?) since the founding Regulation, which called on the protection of public health "... by mobilising the best scientific resources within the European Union [emphasis mine].” The goal to “promote health care through the effective regulation of pharmaceuticals within the single European market” has also been dropped. Notwithstanding that the agency to a degree fails in at least the first two aims, does such a mandate warrant claims of a benefit firstly to the European patient?

4-1 A public health mandate?

The answer for many analysts is no. As different countries have nuanced standards in terms of approval requirements, the single authorisation process raises the possibility of standards being laxer at EU level. This is especially as the decentralised procedure leads to competition between the national agencies, with only the largest and best-resourced really benefiting (the RMS receives the largest share of the applicant's fee). By inducing competition between national agencies, the procedure may result in a race to the bottom

rather than to the top i.e. who can turn applications over most quickly rather than who has the strictest standards. Fernand Sauer may claim that "They [national agencies] really enjoy working together, and instead of worrying about sovereignty issues, they now feel a degree of competition to prove that they are able to do the work in the required timeframe" (as cited in Ross 2000b, 56), but others have expressed concerns and the need to ensure that "... the rush of competition does not overwhelm the fundamental responsibility for safety and efficacy in drugs." (Gardner 1996, 62)

Indeed, it has been suggested that member state authorities are often less enamoured with this type of competition than Mr Sauer, and that it does lead to the bar being set lower. Abraham and Lewis (2000) for instance find that some German and Swedish regulatory officials concede to having accepted products approved via the agency which, under their own national safety standards, they would not otherwise have granted authorisation (147-171). Technology is changing not only the development process, but so too the assessment procedure, and though some states are more advanced than others or have higher standards, the EMEA regime does not account for this.

The degree of health protection afforded via the centralised procedure has also been questioned. In a letter to Mr Sauer asking about the marketing approval of certain anti-depressant medications in 1997, Charles Medawar of Social Audit Ltd¹³⁶ suggests that "... the scientific evidence on which the [national] authorisations have relied is so flawed as to leave open the possibility that even basic assumptions about safety and efficacy (and therefore benefit and risk) may be quite wrong." (Medawar 1997) Amongst other reasons, he suggests this is due to the lack of transparency, no consumer or patient involvement in the regulatory process, and inherent conflicts of interest between regulatory authorities and industry. He puts it to Mr Sauer that: "... these are serious shortcomings also in the EMEA/CPMP system." This letter sparked a three year exchange of correspondence between, primarily, Mr Medawar, Fernand Sauer, Rolf Bass, and Patrick Deboyser (then Head of DGI/III/E/F) and is too lengthy for examination¹³⁷. Its mention here, however, is to reflect to what extent the agency has a public health protection role.

Another area where the EMEA has no say, is in pursuing the 'need' element in drug registration i.e. helping to see that those drugs for which a clear need is established are granted approval. Although this is because the 1965 Directive stipulates safety, quality and efficacy as the only criteria permissible for approval, according to CPMP member

¹³⁶ Social Audit Ltd is the publishing arm of the Public Interest Research Centre (PIRC). PIRC is an independent UK charity which aims broadly to represent the 'public interest' in pharmaceutical medicine, and is financed largely by the Joseph Rowntree Charitable Trust.

¹³⁷ The full chain of correspondence is available on the Social Audit Ltd website at: www.socialaudit.org.uk.

Silvio Garattini, the EMEA ought to be given the power to "... acquire the rights on drugs abandoned by the industry because of the lack of commercial interest despite their clinical importance." (Garattini & Bertele 2000, 441) The companies (and member states) would never agree to this, but were the agency able to pursue/complete the development of such products and then perhaps sell the licenses to companies interested in marketing them as generics, its commitment to health protection could be strengthened. By comparison, the FDA grants 'priority review status' to those products it deems to represent a potential significant therapeutic advance¹³⁸. With patient and consumer groups not involved in the CPMP's evaluation work, need is not a consideration in any form. The agency simply considers those products the industry brings before it¹³⁹.

4-2 Qualifying innovation

Related to this is the lack of a official EMEA definition of 'innovation'. Unlike the strict safety, efficacy and quality standards in place since 1965, criteria for the evaluation of therapeutic value have not been laid down in similar manner. The agency instead enjoys the discretion to decide whether a product constitutes a significant innovative gain or not. Along with no mandate to assess 'need', this means an inability to prioritise products for approval, and results in a clash between industry and patients' interests.

Since innovative products qualify for the quicker and wider market access of the centralised approval, the companies favour a definition which allows more of their products to qualify. Consumer groups meanwhile would prefer a stricter elaboration towards ensuring that only truly therapeutically superior products are granted centralised access. Industry representatives claim that stricter innovation criteria at EU level would have repercussions on reimbursement decisions in the member states (Mossialos & Abel-Smith 1997). But as this is not likely – national authorities do not employ innovation as a reimbursement criteria for their own markets – the industry's argument is something of a smokescreen. Patient groups have therefore criticised this discretionary element of the agency's remit, and a study commissioned by the DG Enterprise found that:

... only 37% of patient associations feel the availability of innovative products is satisfactory or very satisfactory, and their concerns are increasing as Governments seek to control the rising expenditure on health caused by

¹³⁸ The FDA also has an Office of Orphan Drug Products which actively encourages the development of medicines for rare diseases via the provision of grants.

¹³⁹ Although not part of the centralised process and not bound by EMEA decisions, as a member of the EEA, and thus subject to Directive 65/65/EEC, Norway had to drop its own need clause in 1994. The Norwegian national centre for medicines control, the *Statens Legemiddelkontrol* (SLK), had used the need clause since 1938 to limit the number of medicines available on the market. Serving public health needs had been its priority in this regard (Norris 1998).

demographic change and scientific developments. (Cameron McKenna 2000, 51)¹⁴⁰

Even earlier, MEP Adriana Ceci referred to the Community's "discretionary structures" as potentially promoting the "corrupt acceptance" of new medicines (as cited in STOA 1993). Indeed, looking at the FDA's criteria for priority review, the EMEA's innovation criteria – while more technical in language – are vague by comparison; dependant very much on the 'opinion' of the agency (Table 6-2).

Table 6-2: FDA 'Priority Review' Versus EMEA 'Innovation' Criteria (centralised procedure)

FDA (US)	EMEA (EU)
<p>The drug, if approved, would be a significant improvement compared to marketed products [approved (if such is required), including non- "drug" products/therapies] in the treatment, diagnosis, or prevention of a disease. Improvements can be demonstrated by, for example:</p> <ul style="list-style-type: none"> (1) evidence of increased effectiveness in treatment, prevention, or diagnosis of disease; (2) elimination or substantial reduction of a treatment-limiting drug reaction; (3) documented enhancement of patient compliance; or (4) evidence of safety and effectiveness of a new subpopulation. 	<ul style="list-style-type: none"> • Medicinal products developed by other biotechnological processes which, in opinion of the agency, constitute a significant innovation. • Medicinal products administered by means of new delivery systems which, in the opinion of the agency, constitute a significant innovation. • Medicinal products based on radio-isotopes which, in the opinion of the agency, are of significant therapeutic interest. • New medicinal products derived from human blood or human plasma. • Medicinal products the manufacture of which employs processes which, in the opinion of the agency, demonstrate a significant technical advance such as two-dimensional electrophoresis under micro-gravity. • Medicinal products intended for administration to human beings, containing a new active substance which, on the day of entry into force of the regulation, were not authorised by any Member State for use in a medicinal product intended for human use.

Sources: FDA Manual of Policies and Procedures (CDER) and List 'B', Annex, Regulation (EEC) 2309/93.

This has meant that a significant proportion of products approved via the centralised procedure may not be strictly innovative in terms of therapeutic gain. According to a review of the 129 products granted centralised approval by the end of 1999, about half were copies or 'me-too' drugs (Garattini & Bertele 2000). This discretionary interpretation of innovation is a benefit to the industry; the authority to limit such potentially superfluous duplication might help to ensure that patient requirements are better met. And while an advisory role for the agency in conducting cost-effectiveness studies to help in differentiating products of similar therapeutic value might represent a contribution here, it is

¹⁴⁰ In the same study, companies have unsurprisingly expressed their interest in an expansion of the scope of products covered by the centralised procedure.

not likely. Beyond consumer groups, neither the Commission nor the member states appear interested in a tighter definition of the EMEA's innovation criteria.

From the Commission's point-of-view, time-to-market and high use of the centralised procedure is a good thing. Not just with regard to promoting the single market, but also in making Europe more attractive for pharmaceutical research and development. Here, as "The first aim would be to make an absolute priority of raising the number of innovative drugs produced" (Bosanquet 1999, 136), limiting what constitutes an innovation would prove defeatist. Indeed, a paper recommending clarification of the innovation criteria – based on a five-point innovation capacity scale – was put to the agency's management board by Gianmartino Benzi of the Italian Institute of Pharmacology¹⁴¹ already in December 1995 (SCRIP 2106), but was not acted upon. And as each of the member states employs its own criteria (Table 6-3), the imposition of a single model is not likely to prove acceptable.

Table 6-3: Selected Member State Definitions of 'Innovation'

COUNTRY	WORKING DEFINITION/GUIDELINES
France	'one that will bring more therapeutic benefits to the market than existing products'
Germany	'a new indication/faster mode of action/reduced side-effects/better potential for patient compliance'
Italy	'one which treats a previously untreatable disease or has fewer side effects'
Spain	'provides advantages that existing products do not have'

Source: adapted from IMS Health (1997).

The loose EMEA understanding of what constitutes an innovative gain nevertheless carries a drawback for manufacturers. While many products qualify for centralised authorisation, the result is potentially longer approvals because of backlogs. The fear that the agency would not be able to cope with all the applications was expressed by many commentators, even prior to the agency's establishment¹⁴². Given the gains, however, this appears something the companies can live with.

4-3 Other considerations

Other concerns have to do with the appointment procedures. Regulation 2309/92 stipulates that CPMP members be "... chosen by reason of their role and experience in the evaluation of medicinal products for human and veterinary use as appropriate and shall represent their national authorities." (Article 52(1)). This is a somewhat vague criterion for appointment. For despite members being required to sign a declaration of interests, it

¹⁴¹ Prof Benzi is also one of the European Parliament nominations to the EMEA management board.

¹⁴² For instance Griffin (1990), Gardner (1996), or Mossialos & Abel-Smith (1997).

means that each member state can appoint according to its own view of appropriate 'experience'. There is also no common appointment protocol and no central EU accreditation for the net of experts used by the agency. Further, the EMEA has no internal mechanisms for quality assessment. It relies on the degree to which the companies express satisfaction with the work carried out; and it is clear that the main measure for company satisfaction is speed of approval. An independent (internal) scientific review committee to assess the quality of the assessments undertaken by the experts ought to be a priority here, especially as not all experts are used with the same frequency and national authorities retain their own procedures and requirements.

This relates to the earlier point that the companies generally choose *rapporteurs* they perceive most sympathetic to their needs. Hence, the first and second-choice *rapporteur* was overwhelmingly the UK, with France second and the Netherlands third (Cameron McKenna 2000, 86-87). These tend to be the preferred *rapporteurs* primarily because they are the best resourced and most efficient agencies (Abraham & Lewis 2000). Although all member states should have 'equal opportunity' to be both *rapporteur* and *co-rapporteur*, looking at total distribution of *rapporteurships* between 1995-2000, France led the way with 46, followed by Sweden and the UK with 45 each and the Netherlands with 42 (EMEA 2000a, 27). Most member states have at least once acted as *rapporteur* (except Austria, Greece and Luxembourg) or *co-rapporteur* (except Finland, Ireland and Luxembourg).

A further issue is that, unlike many national authorities, the EMEA has no say in the pricing and reimbursement of the medicines it approves – neither in terms of insisting a product be reimbursed, nor with regard to participation in the national pricing debates which follow approval. The preamble to Regulation (EEC) 2309/93 reads in part:

The provision of this Regulation shall not affect the powers of the Member States' authorities as regards the price setting of medicinal products or their inclusion in the scope of the national health system of the of the Member States' authorities or their inclusion in the scope of the social security schemes on the basis of health, economic and social conditions. (CEC 1993b)

The industry does not favour any Community influence on pricing (unless, possibly, to establish free pricing), while the member states often pursue industrial policy goals in their exercise of these measures, and will not therefore accept any impingement on their authority. Moreover, Article 152 rules out any Community involvement in member state healthcare systems. Pricing and reimbursement remains a matter between the companies and the national governments (see Chapter 7).

The agency also has a minimal role in post-approval regulation. Pharmacovigilance is part of its remit, but as this is limited mainly to issuing documents on guidelines and practices to

be observed by the member states and marketing authorisation holders¹⁴³, it pales compared to the FDA's post-approval activities. These cover: post-marketing surveillance; monitoring and reporting on medication errors (due to poor advice, incorrect labelling, etc); ensuring accurate prescription drug advertising and promotional labelling; evaluation of drug shortage situations (with plans to alleviate them); monitoring industry behaviour; and reporting on 'therapeutic inequivalence' – that is, evaluating reports of "therapeutic failures and toxicity which might indicate that one product is not equivalent to another similar product"¹⁴⁴. This clearly reflects a more dedicated focus on consumer safety and patient health, particularly as the FDA has the power to punish.

Another example of the difference in approach between the agencies is their handling of product applications in so-called 'specialist areas'. The FDA's ability and willingness to review products in oncology for instance, can be compared to the EMEA's shunning of such therapies (Cameron McKenna 2000). The FDA is regarded as less conservative, which can be seen as a patient benefit in bringing more therapies to market. Although this could be viewed as a boon to industry as well, industry officials often argue that the FDA does not adequately take their costs into account when making its decisions. Here the EMEA is held up as the preferred model (particularly by officials from American industry): "It tries to be client-friendly... the FDA, by contrast, is oriented towards compliance and comports itself like a policy agency. The FDA commonly treats drug companies like adversaries and constantly pushes the regulatory envelope." (Miller 1999, 3)

Notwithstanding the benefits a single mechanism brings in minimising protectionism and preventing the authorisation of new products being denied because of reimbursement concerns, it should also be noted that the creation of the EMEA has had certain negative repercussions for the member states. National cost-containment goals (healthcare policy) have been affected given the agency's role in deciding on approvals. Sovereignty more generally has also been affected as the states lose much of their ability to decide according to their own (often historical and cultural) criteria, what medicines are appropriate for their market. A right of appeal exists, but as Fernand Sauer has noted, "In practice, however, the CPMP's recommendations are almost always followed." (as cited in Ross 2000b, 50) Also, with potential disputes referred back to the CPMP for resolve, this ultimately means that national regulatory officials are generally excluded from deliberations which directly impact on the health of their constituencies. The Commission's underlying assumption that "... the national regulatory agencies are more alike than they are different" (Kidd 1996, 201) is, therefore, debatable. Nevertheless, the devolution of authority to the

¹⁴³ For example, the 2001 position paper on pharmacovigilance regulatory obligations (EMEA 2001b).

¹⁴⁴ According to the FDA's CDER Handbook.

agency promises to continue once the recommendations of the Commission's recent review of pharmaceutical legislation are implemented (COM 2001).

Finally, although not a failing of the EMEA itself, patients often face long delays between (supranational) market approval and (national) market availability¹⁴⁵. Despite a centralised procedure, the availability of new medicines post-authorisation varies considerably between the member states (Edmonds et al 2000). The agency is not required to accommodate the circumstances specific to each member state and its healthcare system – and accepting that some of these delays are unavoidable given differences in marketing and pricing systems – but this lack of a post-approval mandate begs two questions. First, what contribution the agency actually makes to a single market in pharmaceuticals: a single binding approval regime without commensurate health(care) authority (such as over pricing and reimbursement) is on its own insufficient. And second, whether speeding time-to-market represents a patient benefit in practice as opposed to simply in theory.

4-4 Regulatory capture?

On the basis of the discussion so far, it can be seen that the main beneficiary of the EMEA procedures is the pharmaceutical industry. Compare the public health oriented criticisms already outlined with the fact that 92% of applicants declare themselves 'satisfied' or 'very satisfied' with the work of the CPMP, and that 83% of those who received scientific advice from the agency felt that it was 'useful' or 'very useful' (Cameron McKenna 2000, 80). Such satisfaction is also due primarily to the EMEA's reduction in approval times for new products (Koberstein 1999). While a link between quicker approvals and improved health protection can be drawn – as the Commission does – it is contingent on numerous assumptions or conditions. These include that the drugs being authorised are those which are most needed; that medicine licenses are actually sought by producers primarily to improve public health (rather than to turn a profit); and that the authorising body is empowered to serve public health interests.

As already evidenced, none of these hold. Instead, it is far easier to see how industrial policy and industry interests are served by a binding authorisation regime which, rather than assessing products against stricter approval criteria than those employed in the member states, instead emphasises time-to-market and turning over applications as quickly as possible. As noted, its limited mandate is in stark contrast to the FDA's more pro-active role. This is only compounded with no consumer/patient representation in the

¹⁴⁵ This affects the companies as well. But as they are used to engaging in lengthy post-approval discussions with national governments (about pricing in particular), their primary concern is quicker authorisation.

work of the agency, and intimates some degree of regulatory capture¹⁴⁶. Here, further evidence comes from the Commission's recent review of pharmaceutical legislation (COM 2001). Not only does it contain suggestions for speeding market access for new medicines, but the Commission proposes a review of the agency's management board to include two representatives from industry¹⁴⁷. This is not tempered by the inclusion of two patient representatives to be chosen by the Commission; especially as so many patient and disease groups are today sponsored by the industry.

5 Conclusions

One of the purposes of this chapter was to refute the Commission's claims that the EMEA was set up firstly as a benefit to the European patient. Here, it has been demonstrated that economic (single market) rationale were the driving force. Consequently – and in support of the chapter's second aim – it was shown that the industry is the main beneficiary. Indeed, there is no evidence to suggest that the Commission's prime concern in replacing the failing authorisation procedures under the auspices of an agency was patients' needs; rather, progress on the single market was the underlying objective.

5-1 Involving patient interests?

Evidence of this comes from the gradual freezing out of the consumer position from the policy-process. Despite calls for patients (and the medical profession) to be consulted before any final decision was reached (e.g. Mann 1988), consumer groups – with the exception of the Consumer's Consultative Commission – were really only involved until mid-1989. The BEUC had been asked to comment on the 1988 CPMP report and the April 1989 compilation document, but a third document was circulated in December 1989 which, according to Mr Hankin of DGIII "... had a slightly more limited circulation in that it primarily went to the governments of the Member States at that stage as the ideas were beginning to harden further into the beginnings of formal proposals." (as cited in HoL 1991b, 55) Mr Hankin further stated that while none of the three documents was formally published by the Commission, "... they were as public as an unpublished document can be." The cryptic nature of this statement aside, the reason for not publishing them was – apparently – the problematic nature of having to translate them into all Community languages.

¹⁴⁶ Vos (1999) suggests, perhaps conservatively, that there is a 'risk' of capture. Others, such as Abraham & Lewis (2000) are more critical.

¹⁴⁷ The proposal is to drop the number of members from 34 (2 from the Commission, 2 nominated by Parliament and 2 from each member state) to 16 (4 from the Commission, 4 from the member states, 4 from the Parliament, and 4 from industry and patient groups; with the latter to be nominated by the Commission).

Further evidence comes from the fact that the original 1988 report did not involve DGV. Responsibility for pharmaceutical policy at the time fell to DGIII's Pharmaceuticals and Cosmetics Unit, but the repercussions of an inefficient CPMP procedure should also have been discussed from a welfare point of view i.e. asking how patients could be better served under a revised regime. Were initial interest in a future 'centralized Community system' truly based on concerns for the European patient, DGV would have been at least consulted before the report went to the Council. Moreover, it was shown that beyond the Parliament's two appointments to the management board, there is no consumer representation within the EMEA structure. As Vos (1999) notes, this need not be the case:

Although the EMEA increasingly seeks contacts with interested parties (as required by Community legislation), the way in which contacts are made depends on the goodwill of the Management Board and the Commission; they determine *who* may participate, *where* and *how*. (250)

By marginalising one of the stakeholders in the policy network in this manner – and by keeping them out of the agency's current work – the Commission made it clear that single market concerns were (and remain) its priority.

Streamlining the approval process was more a means to standardise national authorisation regimes, serve national industrial policy interests and address industry concerns, than it was to improve the quality of drugs available in Europe via more stringent assessment criteria. According to the German consumer association, the *Arbeitschaft der Verbraucherverbände e.V.* (AgV)¹⁴⁸, "Centralization is supposed to lead to increased transparency of the evaluations in the single market... Main aims of the EMEA have to be to define high standards of admission criteria i.e. quality, efficacy, and safety of products." (AgV 1994, 3) But as already shown, transparency is clearly lacking. The AgV goes on to note that instead of establishing strict registration criteria, the "... short duration and low costs of admission procedures are described as aims of the European Medicines Evaluation Agency." (3) The agency thus represents – and was clearly intended as – a major step in the Commission's search for: i) an integrated pharmaceuticals market; ii) a successful European industry in industrial policy terms (e.g. employment); and iii) competitive advantage for Europe *vis-à-vis* the US and Japan – both in terms of attracting and rewarding R&D, and strong global sales by domestic EU industry. Maintaining a high standard of health protection was implicit in the new regime, but definitely not its focus.

The last of the chapter's aims was to provide support for the contention that the establishment of the agency was a case of entrepreneurial politics within the policy network. Although this has in part been done through an examination of the positions of

¹⁴⁸ Since 2000, the AgV is under the umbrella of the *Verbraucherzentrale Bundesverband e.V.*, the Federation of German Consumer Organisations.

the stakeholders and the role of the Commission in proposing and pushing the legislation, a final look is required. What requires brief explanation is why and how the EMEA 'policy' came to favour the industry in the manner it does. For as a case of entrepreneurial politics it ought to have been a regulatory intervention where the 'producer' loses out to the 'public interest' due to the presence of an entrepreneur. As this was not the case, the argument is that in the latter stages of the EMEA's creation i.e. once the decision to set up an agency was all but taken, the policy shows characteristics of client politicking.

5-2 The industry 'hand'

Recalling the industry's representations, it is obvious that EPFIA lobbied hard employing arguments about competitiveness *vis-à-vis* the United States and the need to support Europe's industry. Thus, in assessing the extent of the industry's influence one need only consider that the agency's structure closely resembles that of the UK's Medicines Control Agency. Primarily because the MCA was seen as one of the most conducive to industry's interests in terms of time-to-market, it was the preferred model as expressed by industry officials (Staples 1994). Unsurprisingly, this has meant that it is the MCA and its officials which, more often than other national regulatory authorities, act as the *rapporleur* for the EMEA under the centralised procedure (recall Section 4-3).

A more tangible example of the industry's hand is that the format of the authorisation procedures clearly reflects the wishes of industry to avoid a single route along the lines of the FDA which was seen to be unduly bureaucratic and excessively slow. Its demands for a binding mutual recognition process (based on 'safeguards') and a loose definition of what constitutes an innovative product were met. Furthermore, the companies' insistence on control over who was to undertake the evaluation resulted in the centralised procedure being revised to include a *co-rapporleur* of the applicant's choosing.

The competition between national agencies brought about under the decentralised route – once it was clear that they would compete over time-to-market rather than who could set the strictest criteria – was also in the industry's interests. For the ability to select the Reference Member State allows companies to exploit the disparate national regulatory systems to their advantage; for example, by putting their products on those markets first, which other member states who employ either a reference or average price system may use as benchmarks in setting their own prices. This allows the companies to indirectly affect the price of their products. Even the choice of location for the agency – London, with the UK as Europe's biggest investor in pharmaceutical research and development – can be attributed to industry pressure (NCC 1994). If one takes the view that this not inconsiderable influence played a major role in setting the agency's mandate, the

establishment of the EMEA may, like the SPC, be regarded as a case of client politics. That said, the early background was different.

There was a clear political element involved. Industry data was not as important – DGIII in any event had the 1988 memorandum prepared by EPFIA to support its case during the SPC campaign. And the Commission had a very fixed aim and accompanying deadline. A centralised approval process via a Community agency was viewed as a major step in promoting an integrated pharmaceuticals market, and in pushing it through, the EMEA undoubtedly represents the Commission's biggest achievement in this direction. An acknowledgement of the Commission's role can be found in the EMEA's first annual report where the DGIII is cited as primarily responsible for the preparatory work behind the agency's establishment (EMEA 1996). It should also be added that complimentary to the provisions establishing the agency in 1992 were four Directives pertaining to wholesale distribution, classification of the supply, labelling, and advertising of human medicines respectively¹⁴⁹. Known together as the 'rational use' package, these Directives were aimed at completing the internal market.

5-3 Costs versus benefits – final remarks

The costs versus benefits configuration in the entrepreneurial politics scenario involves a policy outcome in which a small group is likely to bear the (high) costs on behalf of a much larger group expected to reap the benefits. The likely 'losers' within the policy network are, therefore, expected to campaign against the policy; either behind the scenes trying to keep the debate quiet, or else publicly opposing the legislation (often by resorting to the use of misinformation). Meanwhile, because the benefits are to be widely spread – so much so that individual gains will be fairly minimal – most people outside of the network are unaware of or even apathetic to the proposal. The benefits are simply insufficient to mobilise the potential beneficiaries to push for the regulatory intervention. Hence, an intermediary or 'policy entrepreneur' is needed to sell the proposed policy, and often this actor has an agenda of its own. The EMEA 'policy' is a clear example of this

Both in the run-up to its creation and in its work, the EMEA reflects the clash between health and industrial interests in the sector. Because of this the proposals for a centralised medicines agency were pushed by the Commission despite, initially, widespread disinterest amongst the stakeholders including hostility from the industry. While this may seem paradoxical as the EMEA now manifests a pro-industry leaning, this only developed after the Commission made it clear that it would pursue an agency. That is, when the

¹⁴⁹ Directives 92/25/EEC, 92/26/EEC, 92/27/EEC and 92/28/EEC.

operational details of the new office were being finalised in consultation with the industry, and when the industry could therefore impress its views. Rather than dominating the policy network through the strategic use of information (as was the case during the SPC campaign), the industry was able to take advantage of the Commission (and member states') single market priorities; its own (industrial policy) interests overlapped.

The member states and patient groups were agreed on the need for speedier access, but did not perceive sufficient gains from a Community agency to actively push for its creation – an entrepreneur was needed to secure their support, and this role was adopted by the Commission. And here, recognising that all member states were keen on revising Community authorisation procedures in principle (even if not agreed on an agency), the Commission was able to take the lead. As noted by Robert Hankin of DGIII at the time, "... what is reassuring from the Commission's point of view is that there are no alternative proposals on the table... it is more a case of being the job of the Commission... to try to win them over." (as cited in HoL 1991b, 57) Thus, not just the impetus, but so too the campaign for an agency approach to medicines regulation in the Community, was the work of an entrepreneurial Commission interested in attaining a single market for pharmaceuticals. And despite the pro-patient rhetoric which came later, industrial policy goals within the single market had clearly been the prime concern.

CHAPTER 7

'MAJORITARIAN POLITICS': THE PRICING AND REIMBURSEMENT OF MEDICINES IN THE EU

Introduction

It has been mentioned several times to this stage that the major hurdle in the Community's efforts to establish a single pharmaceuticals market is the question of (harmonising) pricing and reimbursement. This is not just because of subsidiarity but also given the formal stipulation of Article 152 of the Amsterdam Treaty confirming healthcare as the exclusive purview of the member states. The result is that each member state is free to set its own medicine prices and reimbursement levels for those products sold to national healthcare organisations. As drug expenditure in most EU countries is mainly reimbursed by social security systems, this has resulted in fifteen distinct systems with prices for the same preparations varying, at times wildly, between markets. Notwithstanding its exclusion from healthcare concerns, as differing prices are inconsistent with a single market, the Commission has made several ultimately unsuccessful attempts to introduce harmonising legislation. It is the purpose of this chapter to examine how and where it has done so.

The discussion is oriented around three initiatives. These are Directive 89/105/EEC, the so-called 'Transparency Directive' of 1989; the Commission's 1994 'Communication on the Outlines of an Industrial Policy for the Pharmaceutical Sector'; and the series of three 'roundtable' meetings organised under the auspices of the DGIII in 1996, 1997 and 1998. These have been chosen for three reasons. First, they represent different Commission strategies to address the issue of price harmonisation. Second, because they show just to what extent the Commission is handcuffed in this area. And third, because each can be viewed as its own policy network. The initiatives are treated as a 'mini' case-studies of stakeholder involvement, but as the Transparency Directive represents the only formal Community policy in the area of pricing and reimbursement, it is given the most attention.

The chapter makes two contentions. First, that what has been undertaken *vis-à-vis* pricing and reimbursement, as with the wider Community regulatory framework itself, has been driven by industrial policy interests, neglecting or even excluding consumer interests. Second, that the Commission's inability to develop a common EU policy (or policies) enables the application of the majoritarian politics characterisation of the policy-process. Recalling that this involves diffuse costs and diffuse benefits such that resolution takes place at the national rather than EU level (Majone 1996), this suggests that there is little incentive for any actor, either singly or in co-operation with another, to pursue such a

policy. The discussion will show that while the Commission seeks Community policy in this area, the other stakeholders have consistently rejected this on the basis of perceived costs. Policy remains decided at the national level, as the supranational policy networks which emerge over specific initiatives are unable to reach consensual policy decisions.

Moreover, as the ECJ plays a role in the absence of policy and “... has been most effective when its rulings have altered the balance of power in the policy-making process so as to facilitate the passage of legislation which might otherwise have failed” (Wincott 1996, 183), it is also relevant to the discussion. For even if otherwise exerting only an indirect influence on the broader regulatory framework, by establishing that in principle national pricing and reimbursement systems are permissible under European law providing they do not conflict with the Treaty’s free movement goals (Hancher 1991), it is argued that the ECJ has essentially consolidated pricing and reimbursement as an area of majoritarian politicking. Several of the Court’s more important rulings are, therefore, looked at. Finally, conclusions are drawn with regard to outstanding issues and recent initiatives.

1 Pricing and Reimbursement – defence of national competence

Before turning to the three initiatives, it should be asked why the member states are unwilling to forgo sovereignty over pricing and reimbursement. Despite general recognition that price liberalisation is necessary for a genuine single drugs market, governments are fiercely protective of their national systems and have consistently rebuffed what they regard as Commission interference. Considering the basis for this defence of their autonomy helps to put into context the positions expressed by the national governments (and the other stakeholders) in the policy discussions outlined in following.

1-1 Healthcare and industrial policy goals

The main reason for the member states’ unwillingness to devolve any regulatory role to the EU over pricing and reimbursement – despite the host of legislation in other matters, including licensing – is that it is in this area that the clash between healthcare and industrial policy objectives is most difficult to reconcile (Kanavos 1998). It is particularly acute in countries with a domestic pharmaceutical industry as governments’ interventions to contain healthcare costs may jeopardise the regulatory environment *vis-à-vis* the companies’ ability to recoup investment. Pricing controls are implemented by all member states, with individual drug prices set both to ensure the manageability of health expenditure and to promote industrial policy objectives such as the sustenance of local industry or job creation/preservation (recall from Chapter 2 the divergent strategies of price regulation). So while prices in the UK are based on a system of profit control on manufacturers aimed

at promoting industry – the Pharmaceutical Price Regulation Scheme (PPRS)¹⁵⁰ – in Germany, medicine prices are 'reference-priced' against the lowest-price equivalent so as to enforce the prescribing of less expensive generic products¹⁵¹. Reimbursement controls are used in similar manner. Negative lists, for instance, are used to cut pharmaceutical expenditure, while policies such as linking reimbursement to a product's origin can advance local industry by 'discriminating' against imported products.

Medicine prices are thus not based on market forces, but rather the type of product, the amount of innovation which went into its development, along with wider healthcare requirements and industrial aims. Further, they result from 'pricing deals' between governments and the industry. National authorities may be willing to accept companies' price demands in return for guarantees on investment; whether in terms of research and development or simply with regard to the location of production facilities. This is especially the case in the higher-priced countries where the economic thinking behind several of the large multinationals maintaining costly research laboratories might otherwise seem questionable (Marsh 1989). Such arrangements help to explain the continuing over-capacity in the EU pharmaceutical sector (Mossialos et al 1993), as well as why neither the member states nor the industry (nor indeed the Commission which is interested in promoting job creation) have raised the issue of (over-)employment in discussions about improving Europe's industrial competitiveness. It should also be noted that in the member states different offices are responsible for price-setting. While this duty befalls the Department of Health (DoH) in the UK, it is the responsibility of the *Bundesausschuss der Ärzte und Krankenkassen* (BÄK, the Federal Standing Committee of Physicians and Sickness Funds) in Germany¹⁵². This too reflects differing objectives and regulatory systems, and poses a further obstacle for the Commission to overcome.

Because of differing healthcare priorities, national reimbursement methods are as varied as price controls. Cost-containment is the priority for most member states, even for countries such as the UK, France and Germany where, as three of the world's biggest pharmaceutical exporters, national authorities are said to be 'ambivalent' compared to their other European counterparts (Burstall et al 1999). Along with Spain, Germany has used positive lists since 1993, the UK employs a series of limited lists, while France introduced a set of compulsory reimbursement guidelines for doctors in 1994 – the *Référence Médical*

¹⁵⁰ The PPRS regulates companies' allowable profit, permitting higher profit margins for those with larger sales and research investment in the UK.

¹⁵¹ The German reference-price system has been reformed numerous times since its enactment in 1989. Although it has resulted in a reduction in patented drugs prices, this has been tempered by the number of prescribed medicines having increased over the same period (Giuliani et al 1998).

¹⁵² Charging the BÄK with price-setting has allowed the sickness funds to make considerable cost savings (Busse 2001), but this has been queried under both German constitutional law and European law. The question is whether the system infringes on European competition law. The German Federal Supreme Court referred this to the ECJ on 3 July 2001. For a discussion see Kaesbach (2001).

Opposables – all to cut costs. Since 1996 Italy has guidelines restricting reimbursement to specific cases, and Dutch and Finnish authorities employ pharmaco-economic studies in deciding reimbursement. Differing priorities have seen member state pricing and reimbursement systems moving further apart rather than converging (under the single market), and since the early 1990s a ‘North-South’ divide has emerged (Redwood 1992). The former have sought to implement controls on doctors, pushing them towards more economic prescribing (e.g. generics). This has contributed to higher prices for branded drugs as volume consumption has dropped. In the latter, volume consumption is higher as price controls on individual products (and hence lower prices) were implemented.

Detailing each of the national pricing and reimbursement regimes is not possible here. Suffice it that the majority of countries employ either or both direct price controls or reference pricing mechanisms – the UK being an exception in operating a profit control system – and most use negative or positive lists with reimbursement often correlated to disease type or frequency (Appendix 2-1). Although this generalisation belies a host of variables, the main issue is that medicines are delivered via national healthcare systems and, in some countries, are priced and reimbursed to pursue industrial and well as healthcare objectives. The member state governments are therefore not prepared to renounce any autonomy over such a sensitive area.

1-2 ‘Filling the gaps’ – the European Court of Justice

While such diverse national arrangements are on the face of it inconsistent with the free movement principles of the single market, not only does Article 152 give rise to them, but the ECJ has consistently sanctioned them. The Court has generally ruled that European law does not prevent governments from pursuing their own measures to contain health expenditures via price controls or reimbursement restrictions on medicines. The qualification being that such measures do not amount to ‘quantitative restrictions’ against imported products. This recognises the right of the member states to exercise healthcare policy as they see fit, and is in part based on the caveat of Article 30 (ex 36) which permits a derogation to the free movement of goods on the grounds of ‘public policy or public security’ and ‘the protection of health’ amongst others.

An example comes from the 1982 *Roussel* case¹⁵³ involving a Dutch system of price controls which distinguished between local and imported drugs. The Court ruled in favour of the Dutch government on the grounds that such a policy was not a *de facto* impediment to the marketing of the imported medicines. This was subject to the proviso that:

¹⁵³ Case C-181/82 *Roussel Laboratoria BV & Others v. Netherlands* (ECR 3849).

... although such systems [national price controls] do not in themselves constitute measures having an effect equivalent to a quantitative restriction, they may have such an effect when the prices are fixed at a level such that the sale of imported products becomes either impossible or more difficult than domestic products.

The ruling clarified that only if "material discrimination or disadvantage" was demonstrable would such controls be in breach of Article 28 (ex 30). This line of interpretation has also been applied to reimbursement policies, as in the *Duphar* case¹⁵⁴ two years later.

Here the Court's ruling enabled member states to organise their healthcare and social security systems in a financially sustainable manner. The case again surrounded a Dutch law, one which excluded certain drugs from the compulsory healthcare scheme on the basis that cheaper medicines with the same therapeutic effect were available. Such restrictions were ruled to be permissible if they promoted the financial security of the health insurance scheme. Aware that this might be seen as an indirect restriction on imports, however, the Court stressed that the choice of which medicines to exclude from reimbursement had to meet certain criteria. These had to be applicable without any reference to the origin of the medicines, and verifiable by any importer. Where these were met, any medicine could be imported providing that it was cheaper in bringing the same therapeutic effect as one already available. An important by-product of the ruling was that controls on doctors' prescribing behaviour – in terms of only certain products being reimbursable – was also deemed consistent with the Treaty. It thus set the legal basis for the national implementation of negative and positive lists, and the *Duphar* judgement has since been widely invoked to underline that Community law does not detract from the member states' power to organise their social security systems (e.g. Palm et al 2000).

Irrespective of the Court's free movement reasoning in such cases, permitting national pricing (and reimbursement) regimes causes difficulties within the context of the internal market, the most problematic of which is price variations between countries for the same product. This is unlike price differentials in other sectors which are more the result of market forces, and it has led to the controversial practice of parallel trade in medicines.

Parallel trade

In Chapter 3 it was stated that parallel trade is one of the most vexing issues in the pursuit of a single market, and brings not only the clash between the Community's policy and legal frameworks to the fore, but also reveals the divisiveness of the pricing question where the stakeholders are concerned. Price differentials amongst the member states are the main reason for the development of parallel trade in prescription medicines. This does not occur

¹⁵⁴ Case C-238/82 *Duphar & Others v. Netherlands* (ECR 523).

to same extent in other sectors where the Commission has taken steps to harmonise prices. In the UK the retail price for the identical product often exceeds that in France or Spain by up to 100% (Kanavos 2000). Currency fluctuations have played a contributory part¹⁵⁵, as have differing demand patterns and income differences between the member states. Distinct national regulatory systems have compounded the issue.

Medicine *arbitrage* can thus be seen as a natural product of an imperfect market. It has flourished in Europe in part because it is seen as an acceptable manner of ensuring relatively equal access to the same drugs throughout the EU. Commentators have sought to underline its public health value in enabling national healthcare systems to afford otherwise expensive innovative medicines¹⁵⁶. Another reason is that it can, in theory, help check what many view as excessive industry profits¹⁵⁷. By promoting competition in the market – potentially leading to a greater range of choice for the purchaser – parallel trade also has cost-saving implications for those medicines provided and reimbursed via healthcare systems. In the UK, indication of this comes from the fact that 'parallel traded' products are estimated to have an annual growth rate of 15-20% (ABPI 2001b).

Given their divergent interests in pharmaceutical regulation generally, the views of the stakeholders on parallel trade is suitably nuanced. Because it affects profits, the research industry argues that it undermines their ability to recoup the expenditure necessary for R&D¹⁵⁸. The claim is that this discourages innovation and reduces competitiveness. So while the innovative industry views parallel trade as anti-competitive, generic manufacturers see it as the opposite (EGA 2000b). Consumer and patient groups are also supporters. Differing healthcare and industrial policy priorities mean that while the German and British governments share concerns about the negative affects on their domestic industry, Denmark and the Netherlands have actively encouraged it as a government regulated manner of reducing healthcare spending, and Spain is a net parallel exporter. In any event, manufacturers want the practice stopped and have adopted various tactics to prevent it¹⁵⁹. One of the most egregious, and thus heavily criticised tactics, is that companies withdraw products on non-health-related grounds, as AstraZeneca did over its

¹⁵⁵ This has been mitigated by the introduction of a single currency in the 'Euro-zone' countries.

¹⁵⁶ For instance CECG (1993) or Macarthur (2001). Although parallel trade can be shown to have an effect on prices, any welfare gains are difficult to substantiate (Ganslandt & Maskus 2001). The only clear beneficiaries are the wholesalers who engage in the practice (Burstall et al 1999).

¹⁵⁷ The wider availability of parallel-imported medicines might also, eventually, bring about some degree of price convergence. It is unclear whether this will mean higher or lower-priced drugs; industry fears the latter, but some commentators (e.g. Towse 1998) have suggested the former.

¹⁵⁸ As with the intuitive welfare gains for consumers, to what extent parallel trade actually harms the research industry is also indeterminate.

¹⁵⁹ Other industry 'tactics' include claiming safety and quality of the products suffer given attempts to repackage them; limiting availability via small batches; altering dosage by country (different licenses); supplying direct to pharmacies at reduced prices; and making different pack sizes or altogether different packaging.

antiulcerant Losec in Finland last year (PharmaLaw 2001). For the most part, however, companies have turned to the courts.

Although European law prohibits restrictions on imports or measures 'having equivalent effect', Treaty Article 30 (ex 36) permits certain derogations, including where the protection of industrial and commercial property is concerned. This is permitted insofar as it does not constitute a 'means of arbitrary discrimination or restriction on trade between Member States', and has often been invoked by the innovative industry as grounds on which to prevent parallel trade. However, the ECJ has generally ruled that once the manufacturer makes a medicine available in two member states, it cannot then employ the intellectual property exception to prevent any resale of that product between them. Beyond this, the 'exhaustion of rights' doctrine, the Court has also had to address other, overlapping issues, including the extent to which parallel trade is in keeping with internal market priorities, and questions relating to competition. Although the Court's decisions have primarily been based of the free movement of goods principles (Kanavos & Mossialos 1999), wider social concerns have also featured in its judgements. Reviewing such cases is not the purpose here,. Suffice that the Court's role has been complex though crucial¹⁶⁰.

The Court's decisions have made it clear that intellectual property rights cannot be used to prevent parallel trade in medicines. As well, the ECJ seems to have adopted the view that parallel trade in medicines is not only consistent with the SEM, but it could help bring about closer market integration. The most likely result is that parallel trade will continue for the foreseeable future. Ultimately, therefore, it is in the absence of Commission authority that the ECJ has been so involved. Moreover, the Court's role in this regard gives additional indication of why there is no supranational regulation in this area, and why it is therefore presented here as a case of majoritarian politics. Nevertheless, the Commission has constantly stressed the need to overcome the distortions caused by price differentials. And although bound both by Article 152 and the ECJ's rulings, it has tried to address the issue in reference to the free movement principles whenever possible. The most significant initiative in this direction was the so-called Transparency Directive of 1989.

2 The Transparency Directive – the 'one step at a time' strategy

Directive 89/105/EEC represents the first explicit push for a European dimension to medicine pricing. The legislation, which came into force on 1 January 1990, was designed to ensure open and verifiable criteria in member state pricing and reimbursement decisions. This was to ensure that national policies on pricing, the range of products

¹⁶⁰ For a discussion see Hancher (2000).

covered by the insurance system, and any controls on manufacturers' profits did not inhibit the trade of medicines within the Community. It was also to limit the *quid pro quo* pricing deals between governments and industry. In addition, the Directive called for co-operation between the member states and the Commission towards developing future proposals to minimise the disruptive effects created by national controls. As Terry Venables, former Director of the European consumers group (BEUC), noted at a September 1987 symposium: "... the extent of price differences throughout Europe for the same pharmaceutical product is unheard of in other industrial sectors." (as cited in Clive 1989) In other words, it aimed to kick-start the process of bringing pharmaceuticals in line with other sectors as required by the 1985 White Paper.

2-1 Community pricing and reimbursement transparency: 'take one'

There is much analysis of the Directive, most of which suggests that it has not worked as well as envisaged or that its effects are difficult to measure. Rather than assessing its impact, what is important here is that the final text was much thinner than the original – issued on 23 December 1986 – wherein the Commission had actually proposed measures to promote price harmonisation (COM 1986a). Because of strong opposition (particularly from the member states) the Commission was forced to accept that price harmonisation was not realistic at the time, and the provisions were removed. The preamble to the final text refers simply to "further progress towards convergence", and the Commission acknowledged the Directive as a first step.

Published on 23 June 1987, the proposed 'Directive on the transparency of measures regulating the pricing of medicinal products for human use and their inclusion within the scope of the national health insurance system' (CEC 1987) contained thirteen Articles aimed at ensuring that the member states' pricing and reimbursement policies were not in breach of the internal market. *Inter alia* these involved:

- a time-limit for issuing decisions on pricing, reimbursement, any later price increases (with the need for written reasoning if this was not to be granted), and potential price freezes;
- the release of criteria relating to any controls on the profitability of manufacturers or importers¹⁶¹;
- publication of pricing and reimbursement criteria, and the reasons for rejection under the latter;
- the member states were to communicate to the Commission the 'therapeutic classification' used for reimbursement purposes, along with their criteria *vis-à-vis* transfer pricing (the Commission envisaged two later Directives aimed at approximating national provisions regarding the former and on the fairness of the latter);

¹⁶¹ This was aimed especially at the UK's PPRS, given not just its opaqueness, but that it was generally recognised as a means of promoting local industry as much as it was to control costs.

- the establishment of a 'Consultative Committee on Pharmaceutical Pricing and Reimbursement' to ensure implementation and adherence of the Directive – each member state would contribute one member, though it would be chaired by a Commission official; and
- publication by the member states of a list of all products covered by insurance (subject to common guidelines laid down in the Directive), for communication to the Commission.

As if several of these were not already likely to draw criticism, even more controversial was Article 9 obliging the Commission 'in the light of experience' to "... submit to the Council a proposal containing appropriate measures leading towards the abolition of any remaining barriers to or distortions of the free movement of proprietary medicinal products." (Eventual) price harmonisation was the message¹⁶², and the draft had been preceded by a communication pertaining to pricing and reimbursement specifically (COM 1986b).

The Communication set out what the member states were and were not able to do within the parameters established by the *Rousset* and *Duphar* judgements. More importantly, it provided the Commission's own interpretations, including that pricing had to be 'realistic' and 'transparent', price controls specific to imported products were not permissible, nor could member states pursue measures to prevent or hinder wholesalers and retailers obtaining their supplies outside the national market. As for reimbursement controls, decisions had to be made on objective criteria which did not discriminate against imported products. In the UK for instance, reimbursement was often linked to the product licence, with the intent being to "... stop pharmacists dispensing medicines made in other countries." (Marsh 1989, 935) And while financial grounds were not an acceptable basis for denying reimbursement, they could be applied where a cheaper product with equivalent therapeutic effect was already available.

According to Patrick Deboyser, then of DGIII/E/F and author of the Communication¹⁶³, these views were "non negotiable" as the Commission was trying to prepare a later directive on price harmonisation (SCRIP 1153). As if to reinforce this, two cases were brought before the ECJ relating to aspects of the Italian and Belgian pricing systems which were said to be in breach of the guidelines¹⁶⁴. The Court ruled against an element of Italy's regime which employed different criteria for local and imported medicines, but the case against Belgium's system of maximum prices was dismissed for an inability to show "material discrimination or disadvantage". In both the ECJ reiterated its position on allowing national controls. In any event, the focus of the proposed Directive was on preventing national favouritism by making the process transparent to not just the

¹⁶² The provision that this was to be based on twice-yearly Commission studies on pharmaceutical prices across the Community was dropped from the first draft.

¹⁶³ Patrick Deboyser is currently head of Unit D4 (Food Law and Biotechnology) in DG Sanco.

¹⁶⁴ Cases C-56/87 *European Communities v Italy* (ECR 2919) and C-249/88 *Commission v. Belgium* (ECR I-125).

Commission, but the other stakeholders as well. However, the member states, the industry and consumer interests all expressed concerns.

2-2 Community pricing and reimbursement transparency: 'take two'

The initial responses of the member states were varied. The West German authorities were most opposed, though felt that transparency was to be sought in principle. Based on free pricing, drug prices in West Germany were at time the highest in the Community, and it was felt that other countries were therefore maintaining artificially lower prices – greater transparency would reveal to what extent this was true or not. For this reason the idea of a consultative committee seemed particularly irrelevant i.e. why should a body be established to monitor price controls when Germany did not use them? Meanwhile the UK accepted the proposals (though wary of the effect on the PPRS), and the Department of Health and Social Security reported to a House of Commons Select Committee that implementation of the Directive would involve no significant financial implications.

The industry – via its trade body EFPIA – despite accepting the notion of increased transparency of national systems, was unhappy with the transfer pricing and consultative committee proposals. The former were seen as vague and a matter for the member states' fiscal authorities rather than the Community. The group's 1986 annual report expressed concerns over increased Europeanisation of the sector, with the latter seen as superfluous at best and intrusive at worst (EFPIA 1986). It thus lobbied the Commission for the abandonment of the committee, highlighting the lack of member state support. This continued even after the Directive had been implemented (EFPIA 1992a).

Given industry's endorsement in principle, it is not surprising that the BEUC saw the draft as too industry-focused. And it had a point. According to the accompanying memorandum, the proposed Directive had a twofold aim:

... to ensure that the measures taken by Member States to control pharmaceutical expenditure do not pose a barrier to the creation of a genuine internal market for the pharmaceutical sector by 1992. However, the realisation of the internal market is not an end in itself but the means to the creation of a more favourable environment for stimulating enterprise, competition and trade. (COM 1986a, 7)

The Commission indicated its wider intentions *vis-à-vis* pricing and reimbursement as: encouraging "the future development of the innovative pharmaceutical industry"; preventing companies from making "excessive profits in dealing with national health services"; and preventing European patients from becoming "dependent on research in third countries". This was to be undertaken within Treaty competition rules, taking into

account "... the needs of the Member States in ensuring the availability of an adequate supply of medicines at a reasonable cost for their citizens." (8) The 3rd recital even asserts that reimbursement "... should also be intended to encourage research and development into new medicinal products, on which the maintenance of a high level of public health within the Community ultimately depends." The BEUC suggested that the result would be the eventual upwards convergence of prices.

Although not in favour of a European pricing regime, the group argued that the Community had to implement measures which balanced the legitimate requirements of the research companies against those of the generic industry (including permitting parallel imports). Promoting price competition was a key point, and it was felt that the proposals were more a response to industry complaints than a real attempt to address the more important issues, particularly the opaqueness surrounding (high) prices. Not just pricing, but the BEUC has also generally regarded the structure of the market and the volume of drugs available as a major barrier to the free movement of medicines (Anon 1988).

Based on the report prepared by the section for Industry, Commerce, Crafts and Services, the Economic and Social Committee (ESC) also noted the document's pro-industry leaning. The ESC's primary concern was the lack of competition in the market and that one of the aims of the Directive ought to be to help remedy this (ESC 1987). In its Opinion of 23 September 1987 it described the measures to increase the transparency of national systems as 'useful', but stated that:

... in order to achieve a clearer and more objective relationship between the pharmaceutical industry and the controlling authorities, the draft Directive must: (a) require firms to indicate the economic data and therapeutic properties of individual medicaments; (b) require the Member States to publish "transparency lists"; (c) urge the Commission to set up a data base covering the pharmaceutical market. (2)

Giving further indication of its more consumer-oriented focus, the ESC proposed that since national negative and positive lists can create 'complications', "In the interests of both manufacturers and of consumers it would be desirable to harmonise the systems of lists... the Committee, in the interests of clarity, would opt for a positive list." (5) The Commission did not incorporate this in its revised proposal. It had no authority to pursue such a policy, but would in any event have been opposed by the member states and the industry.

On 15 December 1987 the report prepared by the Parliament's Economic and Monetary Affairs and Industrial Policy Committee was released (EP 1988a). Controversially, and in order to allay some member states' industrial policy fears, it deleted several of the provisions against which EFPIA was lobbying. These included that the Commission be

later able to propose legislation on approximating national criteria on the fairness of transfer pricing policies, and harmonising national rules on classifying drugs by therapeutic category for reimbursement. Dutch MEP Alman Metten was unhappy with these suggestions and sought numerous amendments, including that: companies be required to provide more data in support of any arguments for price rises (governments would be allowed to reject these if the data proved insufficient); that a Community drugs price databank was required to help improve competition in the sector, and to promote the more efficient use of medicines; and that two years after implementation of the Directive, the Commission should submit a proposal towards ensuring that the 'necessary supplies' of medicinal products are 'available at the lowest possible prices.' In light of this Mr Sauer invited Mr Metten and Pierre Lataillade, *rapporteur* of the committee report, for discussions on achieving a compromise.

Ignoring Mr Metten's amendments, the Council agreed an informal text in November, although it did include the vague stipulation that companies provide "sufficient information" to support any calls for price increases. With a Council text almost identical to its own, the economic and monetary affairs committee then adopted the report on 15 December¹⁶⁵. At the Parliament's 19 January 1988 plenary, however, the debate was stopped mid-session because of a growing number of proposals for changes (including several of those proposed by Mr Metten), and the document was referred back to the committee.

2-3 Community pricing and reimbursement transparency: 'take three'

Only on 9 March did Parliament find sufficient time to resume its reading, approving the committee's revised draft. The committee vote had again been an unconvincing endorsement (13 for, 1 against, and 8 abstentions, with Mr Metten the lone dissenter), but its new draft contained several amendments (EP 1988b). Most controversial was the reintroduction of the databank. This was to include the consumption, prices and daily costs of treatment of the top 2,500 medicines in each member state, and was to be made open to public scrutiny. Not only was EFPIA dead-set against such an initiative, but so too several member states – notably France and Germany (Reich 1989). The industry's fear was twofold: that it would result in lower prices as governments could make comparisons more easily, and that the provision of such detailed information on products would facilitate parallel trade. The member states feared that it would be later used as a mechanism for the Commission to pursue price harmonisation, even evolving into a European body to oversee pricing.

¹⁶⁵ Mr Metten's was one of the votes against in a 27-14 vote.

With a view to achieving a compromise, in its Common Position of 22 June 1988 the Council agreed the databank as a Declaration, separate from but adjoined to the main text (SEC 1988). Not officially part of the legislation, the databank would nevertheless "... start becoming operational when the present Directive is implemented for medicinal products authorized in a majority of member states of the Community." This acknowledged the strength of consumer pressures in the Parliament, and Fernand Sauer expressed the Commission's satisfaction with this compromise noting that Parliament would reject any draft which failed to include the databank (SCRIP 1321)¹⁶⁶.

The economic and monetary affairs committee unanimously gave its support, noting that the Commission had incorporated all of the amendments from the first reading, and it recommended that Parliament accept the 'slightly amended' changes made by the Council (EP 1988c). It endorsed narrowing the brief of the consultative committee to (breaches in) the application of the Directive, and only noted the Council's deletion of the databank from the main provisions asking how it would be set up. The consultative committee, however, remained a sore point for EFPIA, as it allowed only the Commission and the member states direct access. With the Parliament's subsequent endorsement, the Internal Market Council finally (and unanimously) approved the draft legislation on 21 December 1988 with a view to member state adoption by 31 December the following year (CEC 1987).

This was not the end of the story. As envisaged under Article 9, the Commission's next step was to attempt a follow-up pricing directive. But after several years of political wrangling this fell through. Detailing the intricacies of these deliberations is not possible here. But as it again involved all stakeholders, a brief summary of what was proposed and the reaction it elicited is necessary. For the failure of the Community to adopt a second version is further evidence that pricing and reimbursement is a majoritarian politics issue.

2-4 Transparency revisited?

In January 1991 the Commission circulated a discussion document and questionnaire (CEC 1991a) to the member states, industry, and professional associations, seeking feedback on how to reconcile three conflicting goals:

- doctors' freedom to prescribe the 'most appropriate' medicine versus promotion of the 'rational use' of medicines i.e. limiting reimbursement to least expensive products in each therapeutic category;
- promoting increased competition between companies versus supporting them in developing innovative products; and

¹⁶⁶ The elements to be listed for each drug in the databank included: the SPCs; the ex-factory price; the retail price; the estimated cost of treatment based on daily dosage; and the cost and manner of dispensing. Many of these were already available in the public domain, albeit not from one source. The content of the databank was limited to this information because of industry pressure.

- short-term controls on medicine costs versus long-term support of the industry (adequate research and development investment for innovative drugs, and ensuring it remains competitive compared to the United States and Japan).

The document acknowledged the extent of the divergence between national controls and noted the north-south divide mentioned earlier. In the interests of promoting the single market, the Commission outlined its intent to pursue increased price transparency and harmonisation of packing and therapeutic classifications in a further document, which assessed application of the Transparency Directive (CEC 1991b).

There had been a flurry of national reforms after the Directive, as several member states sought to recast elements of their pricing and reimbursement systems to accommodate growing cost pressures¹⁶⁷. This resulted in numerous queries (and Parliamentary questions) as to whether the new or reformed systems were in keeping with the Directive. While the member states accepted the Commission's goals on price transparency, they were not so keen on the ensuing proposal for a Directive to tackle prices.

The proposed amendments – based on the fact that national measures to control medicine prices had not really led to lower expenditure, but had actually made the market more rigid by neutralising competition (Hodges 1997) – were gradually watered down over at least five drafts. At their most stark, they included: progressive dismantling of direct price controls towards promoting price competition; procedures for informing the Commission and other member states as to any planned changes to national systems; the need to clarify the concept of 'interchangeability' of medicines (towards establishing a system of objectively comparing medicines with different active ingredients but similar pharmacological effects); and measures to introduce co-payments, generic substitution and increased transparency of information in the event that prices were liberalised. The early drafts of the original Transparency Directive had been criticised for similar proposals, and this time was no different.

Via EFPIA, the industry continued to voice its concerns about member state price controls and any Europeanisation measures. In its comments on what was to become the final draft before the amendments were shelved, it highlighted what it saw as the inconsistency in the Commission's position: "... whilst the Commission continues to advocate deregulation, it is also pursuing initiatives to manage competition [sic]." (EFPIA 1992a, 2) EFPIA insisted that what it wanted to see in a potential recommendation to accompany the amended Directive was "... a suggestion that Member States eliminate any measures affecting competition [sic] on the market place (such as encouragement to prescribe, or

¹⁶⁷ Burstall (1992), however, notes that "... the impact of the Transparency Directive is only one factor among many, and one that is difficult to separate from the rest... it would be difficult to prove that it was the major consideration." (5)

incentives to substitute, generics)." (4) More importantly, however, the industry was disappointed with the extent to which the final draft had been cut back. There were no longer any proposals to inhibit member states' ability to price and reimburse as they saw fit, and twelve separate, heavily-regulated markets would remain.

The position set out by the BEUC was equally unequivocal: "We do not believe that the harmonisation of price controls, or of prices or reimbursement systems would bring substantial benefits to consumers at this stage. There are many more important things to be done." (as cited in Albedo 1991, 16) Their position reflects their focus on the patient, and follows on from their earlier arguments stressing the need for not only common European standards, but a uniform review procedure for the withdrawal of old or superfluous drugs from member state markets.

Finally, the member states – at least those who responded to the Commission's questionnaire¹⁶⁸ – again emphasised that they would not accept any Community infringement on their sovereignty in healthcare. The UK opposed any suggestion that member states be obliged to inform the Commission of potential pricing measures at the draft stage. It argued that as its pricing regime was a 'negotiated agreement with no legal basis', "The UK could not accept revealing its negotiating objectives to the Commission, Member States and other 'physical or moral persons from the private sector' in advance of concluding an agreement." (DoH 1992, 5) France opposed any further formalisation of the prices databank, saying that it saw no need for the reintroduction of this provision which had been taken out with Directive 89/105/EEC (CEC 1992c). Ultimately then, the stakeholders remained unhappy with the Commission's continued interest in price harmonisation. Member states' objections in particular meant that the Commission's 'technical amendments' would not clear the Council, and they were dropped in December 1992. Commission Vice President, Leon Brittan, put the decision to shelve the proposals down to the subsidiarity principle, which he saw as representing a formal limitation on the further development of Community pricing policy (Brittan 1992). Meanwhile, in the words of Fernand Sauer, while still head of DGIII/E/F:

If we were only to please industry, we would have proposed it [a revised Directive] a long time ago, but it would be stuck... because nobody would adopt it. We have to negotiate back and forth between industry and governments to get a consensus. (as cited in Koberstein 1993, 36)

This represents an acknowledgement of the policy network at the time, along with its tensions. One commentator summed it up best: "... no one outside Brussels wants a sequel... The overwhelming view of pricing and reimbursement is 'Keep Brussels out!'"

¹⁶⁸ Only Denmark, France, Greece, Netherlands, Spain and the UK responded.

(Albedo 1991, 16) As the Commission was to find out with regard to subsequent initiatives, this view would continue.

3 An EU 'Industrial Policy' for Pharmaceuticals – the 'shared interest' or 'competitiveness' strategy

In light of the disparities amongst the stakeholders seen during the transparency network, the Commission's next step was to identify an area of common interest, one to which it could tie pricing and reimbursement. It attempted this on 2 March 1994 with its 'Communication on the Outlines of an Industrial Policy for the Pharmaceutical Sector in the European Community' (COM 1993).

3-1 Co-operating with the industry?

Taking as its underlying assumption that a successful industry was in the interests of all stakeholders, the Communication set out measures to improve industrial performance. Asserting that the European pharmaceutical industry "... is not well enough prepared to brace itself against stiffening competition and with the relentless rise in the cost of pharmaceutical research, and that its industrial competitiveness could prove insufficient in regard to its main competitors" (4), the document focused on comparative industrial statistics and provided an assessment of competition policy and legislation in other major industries and markets (mainly the US and Japan). It acknowledged that the 1992 programme had not 'radically changed' the industry and argued that the continued fragmentation of the market was harming European interests.

Areas of especial concern included the lack of European presence in biotechnology and the decline in employment in the sector. The Communication cited 65% of biotechnology patents being American compared to only 15% European and 13% Japanese by 1992. And in respect of employment, 1993 was identified as a turning-point, with the number of jobs in the industry having gone down for the first time in over ten years (by 1.3%). It suggested that some 27,000 jobs could be lost by 1995 through 'delocalization' or the closing of research and manufacturing sites, resulting in massive disinvestment¹⁶⁹. The Commission argued that a more integrated market with freer competition and price deregulation was what the sector required, and in the Communication set out its case that European policies were the remedy¹⁷⁰. Several of the more important proposals were:

¹⁶⁹ Despite no legislative follow-up to the Communication, this predicted loss of 27,000 jobs did not happen. According to the industry's (and Community's) own data, employment in the sector has in fact gone up rather than down: from 439,572 in 1996 to an estimated 495,000 by 2000 (EUROSTAT 1998 and EFPIA 2001).

¹⁷⁰ It should be noted that the context to this was the SPC of 1992 and the EMEA of 1993 which, in the preceding chapters, were already shown to have been driven by the Commission's industrial policy priorities.

- consolidating and updating existing Community pharmaceutical legislation in a transparent manner (increasing accessibility for industry and health professionals, and to enable the member states to transpose and implement it easily);
- promoting the rational use of medicines by providing health professionals and consumers with sufficient information e.g. harmonising package labels and indications for use, and setting up the pharmaceutical prices database;
- quick introduction of the future marketing system (the EMEA) to achieve health(care) and industrial policy goals;
- enforcement and improvement of intellectual property protection for genuinely innovative drugs (to match that in other countries) and creating a favourable environment for biotechnology;
- increasing competition in the market via improved price transparency;
- monitoring the (distortive) effects of member states' pricing and reimbursement controls and their implementation of Directive 89/105/EEC, with a view to adapting it "in the light of experience"; and
- contributing to global harmonisation efforts e.g. the ICH to reduce research and development overlaps and facilitate the opening of external markets to Community medicines.

After the failure to entrench pricing and reimbursement within the Community's agenda following Directive 89/105/EEC, the Communication was clearly a trade-off. The premise was that through the development of measures to maintain the industry's competitive position, it would be obvious to all stakeholders – especially the member states – that pricing needed to be addressed next.

3-2 Reaction (and rejection)

This industrial policy strategy, one without any immediate attached conditions/proposals relating to pricing, was heavily criticised. The AgV, the German consumer association, complained that: "In the communication, an industrial policy is drafted based on an analysis that it is oriented towards industry interests only. Thus the policy is disadvantageous to consumers." (AgV 1994, 3) The BEUC dismissed several of the document's conclusions, most notably that the industry was somehow in decline (BEUC 1994). It reproved the Commission for not giving enough attention to fostering competition in the sector, and for instead choosing to help industry to consolidate its position. In a speech to the Commission's June 1994 hearing on the Communication, Jim Murray, Director of the BEUC, attacked the proposals for paying too much attention to improving industry's competitiveness (Murray 1994). He argued that lifting price controls as a means of improving competition was unrealistic and disputed many of the conclusions drawn in the document. For example, accepting as "... clearly a matter of legitimate concern" that the number of new medicines originating in Europe was declining compared to an increase in Japan over the same period, he indicated that a closer look revealed the broader picture:

... the majority of the increased Japanese share has come almost entirely from medicines which represent very little therapeutic advance; for the most part they

are “me too” medicines and the increasing Japanese strength in this area has parallels in Japanese industrial development in other areas also. (Murray 1994)

Indeed, part of Europe’s ‘decline’ could also be related to the European recession of the early 1990s, rather than better regulatory conditions in the US and Japan. And this need for a closer look was echoed by the Parliament’s Committee on the Environment, Public Health and Consumer Protection. Its draft opinion of 8 December 1994¹⁷¹ points out that “Progress in the pharmaceutical sector has produced savings largely in excess of the increase in its costs.” (EP 1994, 4) Further, the report called for the rationalisation of promotion and advertising given the opaqueness which surrounds them, and argued against abolishing price controls.

The reaction of the generics industry was predictably scathing, arguing that the SPC had already worsened its competitive position and the proposed Communication would only further harm generic interests. In a letter to the Social Affairs DG (DGV) for support, Greg Perry, Director of the European Generics Association¹⁷², complained about the existing restrictions on generic research and suggested that “... if the Commission’s objective is to encourage greater competition within the medicines market... then greater attention will have to be paid to those factors which affect both the demand and supply of generic medicines in the European market.” (Perry 1993a)

Anticipating member state opposition likely to stem from such criticism¹⁷³, the Commission argued its case at a special session of the Parliament’s economic and monetary affairs committee (which had been assigned the Communication) on 27 September 1995. This was attended by MEPs along with representatives of both industry segments, consumer groups and member state officials. Mr Deboyser emphasised that the Communication was only about improving competition and industrial competitiveness, not public health or healthcare policy. He argued that the document should, therefore, only be examined in this light, lest it prove a wasted opportunity to keep Europe competitive. While this resonated with the research industry, the other stakeholders rejected this line of argumentation. It was said that several members of the parliamentary committee launched “... a string of largely hostile questions at the European Commission and the industry speakers, on jobs, on costs, on orphan drugs, and on the reliability of the data on which the Commission had based its policy document.” (Anon 1995, 6) Indeed, industrial and health(care) policy are not so easily separated as the Communication was suggesting. If

¹⁷¹ It was only an advisory committee, with the Economic and Monetary Affairs and Industrial Policy Committee responsible for delivering the report on which the Parliament would base its reading.

¹⁷² Now the European Generic Medicines Association (EGA).

¹⁷³ For instance, the reaction of the UK House of Commons Select Committee on European Legislation was: “We consider that the following [aspects of the Communication] raises questions of political importance, but make no recommendation for its further consideration.” (HoC 1994)

not already clear that the proposals were in trouble, this showed just how far the Commission was from finding common ground.

The result was the tabling of some 66 amendments in Committee's 19 March 1996 report, most of which related to restraints on industry (EP 1996a). These included: increasing the cost-effectiveness of research rather than using subsidies to promote industry; the need to monitor mergers in the sector; enabling generic research and regulatory preparedness prior to patent (or supplementary protection certificate) expiry; concentrating on research into therapies for as yet untreatable diseases; and ensuring that national measures to cut the costs of using medicines were promoted (with safeguards against the development of monopoly situations). It also called for transparent Community procedures for switching prescription drugs to over-the-counter. This had in fact been raised by Hubertus Kranz, Director-General of the *Association Européenne des Spécialités Pharmaceutiques Grand Public* (AESGP, or Association of the European Self-Medication Industry), at the September special session. The report was adopted by a narrow margin of 26 to 24, reflecting the difficulties inherent in the Commission's new 'competitiveness' approach.

Following on from the autumn's special committee meeting, Parliament attacked the proposals at its 16 April 1996 sitting. The Commission was accused of being "... out of touch with reality in claiming that normal market operation is feasible in the pharmaceutical industry and that it is merely necessary to cut back on government intervention schemes to achieve this." (EP 1996b) Calling for a more overarching view of the sector, Parliament made numerous suggestions covering issues from increasing R&D into areas which may deliver therapeutically beneficial new medicines, to generic promotion. These suggestions also included several 'outliers' e.g. ethical queries regarding animal experiments and increasing the uptake of homeopathic medicines. Furthermore, Parliament suggested the Commission take a greater role in dissemination of the effects and risks of medicinal products. The Parliament may have been correct in its underlying critique – that consumer/patient interests were not sufficiently served – but by tying industrial policy to such a wide range of concerns, its Resolution could not offer a way forward. This was precisely what Mr Deboyser had feared when he addressed the special session.

The Council's (Internal Market) views followed a week later, and its 23 April Resolution was equally general (CEC 1996). Passing reference was made to the peculiarities of the market and the need to balance health(care) interests against any industrial policy initiatives. Amongst the few workable suggestions, the Council called for measures to support small-to-medium sized enterprises (SMEs) in the sector. This was because they have 'local knowledge' and 'specialised know-how' which would benefit competition as well as serving public health interests. However, given the perceived costs of its

implementation, the Resolution was rebuked by all of the stakeholders (again, save the research industry). Having delivered little that could be enacted, there has been no policy follow-up on the Communication since the Council's Resolution.

3-3 Policy network exclusions

As with the legislation to establish both the SPC and EMEA, consumer interests were of secondary importance i.e. it was implicit in the Communication that they would be served by measures to promote the industry. While this competitiveness approach had been a Commission initiative, the Communication was actually the product of the 'Pharmaceutical Industry Policy Task Force' – a joint industry-Commission group established by Commissioner Bangemann in the wake of the aborted attempts to amend the Transparency Directive. According to the Parliament's Intergroup on Community Affairs (ICA), the underlying purpose of the task force was

... to explore the broadest possible manner the whole range of factors which affect the international competitiveness of the European pharmaceutical industry... [and] to identify in concrete terms the needs of the industry, and what role the Community can play in meeting them. (ICA 1993, 4)

ICA was concerned that consumer interests would not feature in any conclusions reached by the task force as their views had not been solicited. This fear proved justified, and not simply because of the document's clear pro-industry leaning, but because prior to the Communication's publication there had been a draft to which only the industry had been privy. In his response to the published version, Jim Murray of the BEUC said that:

It was apparently stated in a previous draft of the Communication, that pharmacists should be permitted to dispense the cheapest multi-source medicine when the prescription allows it but this positive sentiment seems to have been watered down in the current Communication. (Murray 1994)

Not only does this indicate that he had not seen the previous draft, but one can assume that the provision he refers to was removed because of pressure by the research-based industry. The reason being that in June 1992 EFPIA sent the Commission a 'Memorandum on an Industrial Policy for the European Pharmaceutical Industry' which, in a section entitled 'avoiding pitfalls', argued that "Measures such as incentives or sanctions to prescribe or dispense the cheapest product... pose a considerable potential threat to the continued viability of the research-based pharmaceutical industry and... are anti-competitive." (EFPIA 1992b, 24). This suggests that EFPIA was already involved with the pharmaceutical policy taskforce. Moreover, the Memorandum made the dubious claim of a double victory: "The results will be measurable not only in terms of better healthcare – a significant achievement in itself – but also in economic terms." (26)

Even clearer indication of the Commission's intentions comes from the fact that the EGA had not been consulted about the Communication, although it was aware of its existence. In a letter to Commissioner Bangemann, Greg Perry claims not only to have received no reply from DGIII to two EGA submissions, but protests that:

Furthermore we were not even informed by your cabinet of the existence of the circulated version of the first draft Communication. When I phoned your cabinet to obtain a copy I was informed that the European generics industry was not entitled to receive one. I was subsequently given a copy by a source other than the Commission. (Perry 1993b)

The Commission's commitment to "... intensify the dialogue already initiated in the pharmaceutical field", as stated in the draft document, would seem to have meant excluding all but the research industry, else applied only post-publication when the document was a *fait accompli*¹⁷⁴. Mr Perry went on to criticise the document for only vague references to promoting generic prescribing without addressing the real issue of market access as soon as possible after patent-expiry.

Beyond the lack of dialogue, what had proven even more controversial in the unpublished draft was that it was said to have included measures for the outright abolition of national price controls. It had recommended these be replaced by more indirect reimbursement mechanisms to contain national spending and that prices be actively converged (Anon 1994). This was presented as necessary to ensure the industry's further contribution to the Community economy (Hodges 1997). Dr Bangemann had often spoken of his wish to see pricing and reimbursement separated, particularly since the Transparency Directive, thereby endorsing industry's campaign for free pricing¹⁷⁵. In consulting with the member states, however, the Commission was unable to secure support for such proposals. More importantly, the price deregulation idea proved unpalatable to Social Affairs Commissioner Pádraig Flynn (DGV). The fear was that free pricing equated to higher prices.

Of especial concern were so-called 'break-through' drugs. If these were to be subject to free pricing, could the member states simply be expected to pay the emergent 'market price' for these new, innovative products? For the companies would be expected to set high prices for such medicines which had little or no competition i.e. the superiority of a single product in a given therapeutic category, else a medicine which essentially creates its own category. This was not desirable from either the member states' cost-containment perspective, nor DGV's public health and consumer protection viewpoint. With both opposed to these price deregulation proposals, DGIII was forced to drop them from the subsequent draft. In the words of a newspaper editorial "... the purge was engineered by

¹⁷⁴ This represents a clear exclusion of the consumer position.

¹⁷⁵ For example Bangemann (1991).

Social Affairs Commissioner Pádraig Flynn, backed by President [of the European Commission] Jacques Delors and 'half the commission.' (WSJE 1994, 8) According to one source there had in fact been at least ten different drafts of the Communication (Mossialos & Abel-Smith 1997). As these appear only to have been shared with industry, comparing them is not possible. Nevertheless, the point to be made is that the final text – like the transparency legislation – was very different from the initial drafts. The stakeholders' views were simply too disparate to be overcome in such a document, especially one which was about promoting industry first and addressing other issues second.

The Commission had tried to sell this new approach on the grounds that improving industry's competitiveness would benefit all stakeholders. But it can perhaps better be seen as a trade-off to the research industry over the need to tackle other issues related to promoting the internal market, most notably liberalising prices. And its failure can be put down to the fact that the stated intent of the Communication "...to monitor the impact on the functioning of the internal market of national pharmaceutical pricing and reimbursement measures... to assess the need to adapt [the Transparency] Directive in light of experience" did not assuage governments' concerns over cost-containment (Furniss 1997). DGIII went on to claim that the Communication had been intended more as a means of facilitating dialogue than as a final policy statement (Deboyser 1995).

4 The Bangemann Roundtables – the 'dialogue' strategy

Viewing the Communication as a minor setback, the Commission stuck with this competitiveness strategy in its next 'big idea'. Accepting first that price harmonisation was unlikely – at least not via a top-down approach – and second that dialogue with all stakeholders, not just the research industry, was necessary, Commissioner Bangemann organised a series of 'Roundtables'. Chaired by the Commissioner, they convened twice in Frankfurt (1996, 1997) and once in Paris (1998). Without detailing each gathering, on the basis of the positions voiced by the stakeholders, the main tensions can be teased out.

It should first be noted that the roundtables were essentially closed door affairs with restricted guest-lists, giving rise to accusations of secrecy and deal-making (Furniss 1998). Representatives of the Commission, the industry (trade organisations such as EFPIA and the EGA and individual company officials), national regulatory authorities and member state governments, professional and consumer groups, along with selected 'independent' experts were invited. Proceedings for all three meetings were published, but the media was barred entry to the 1997 and 1998 gatherings. Moreover, the initial roundtable was sponsored by EFPIA with a grant from the Pharmaceutical Partners for Better Healthcare

group¹⁷⁶. Although the next two were financed by Community grants, this may suggest that the agenda was already clear.

The underlying theme of all three meetings was liberalisation of the market generally, and the question of how to pursue a pricing regime which would meet the interests of industry, the member states and consumers in an equitable manner specifically. Amongst the topics discussed were how to overcome national price controls to relieve market fragmentation; the role of over-the-counter and generic medicines; developing Europe as a strong base for R&D; enhancing Europe's position in biotechnology; taking advantage of advances in information systems and 'e-commerce'; and what EU enlargement would mean¹⁷⁷. Impacting on all of these, parallel trade was thus a hot topic.

4-1 What to do about parallel trade?

As noted earlier, the Court has traditionally ruled in favour of the parallel importation of drugs, and four days before the first Roundtable it did so again. In the joint *Primecrown* cases¹⁷⁸, the manufacturer's (*Merck*) concern was that as patent rights did not apply to Spain and Portugal pre-accession, existing case-law allowed them to produce and export copies of original drugs (themselves becoming parallel importers). *Merck* asserted that exhaustion at the time of sale could not apply – how could it exhaust rights it did not have? Thus it argued for a complete re-consideration of the existing case-law given both the increase in *arbitrage* since the *Stephar* ruling, and because the Supplementary Protection Certificate would lose its meaning if parallel imports from the Iberian countries were to be permitted; price differences between Spain and Portugal and the rest of the Community were argued to be much greater than at the time of the *Stephar* case.

Despite the Advocate General's recommendation that the patent holder should be able to prevent parallel imports from the two countries, the Court stuck with its exhaustion line from the previous rulings (recall Table 7-1). Its decision that price distortions resulting from different member state legislation were to be remedied "... by measures taken by the Community authorities and not by the adoption by another member state of measures incompatible with the rules on free movement of goods" (ECJ 1996) nevertheless permitted the patent-holders to continue using their patents to prevent parallel importing for a limited period. These rulings ensured that parallel trade would continue to be a major discussion-point at subsequent roundtables.

¹⁷⁶ The PPBH is a an industry-financed pharmaceutical think-tank which researches healthcare reform.

¹⁷⁷ This latter point of especial concern to the industry, see EFPIA (2000). For a more general discussion regarding the impact of enlargement on the sector, see Forte & de Joncheere (1999).

¹⁷⁸ Joint Cases C-276/95 and C-268/95 *Merck v. Primecrown* [1996] ECR I-6285

On the one side were consumer representatives who stressed the importance of parallel trade as a manner of ensuring affordable medicines, along with some national representatives who argued that it promoted sustainable healthcare financing. On the other side, the research industry along with DGIII (and officials from other member states) pointed to the distortions it created. They were supported by the *Groupement International de la Répartition Pharmaceutique Européenne* (GIRP, the European Association of Pharmaceutical Wholesalers). GIRP argued that, even if legal, parallel trade did not serve efficiency: "... whilst full line wholesalers do not encourage such trade, market forces are such that it cannot be ignored... the main cost savings in healthcare will come from the more efficient use of medicines rather than the restricting of their use." (GIRP 1998, 2)

The Commission had nevertheless endorsed the ECJ's position in its 1998 Communication on a single pharmaceuticals market, by stressing it as a "... driving force for market integration where there are significant differences in price", despite the inefficiencies it creates (COM 1998). And though some effort was made to bridge the gap between member states' and industry interests *vis-à-vis* parallel trade, these efforts have been described as more "metaphorical and rhetorical than concrete and tangible" (Albedo 1998).

4-2 What to do about price differentials and national controls?

Pricing and national controls was the most hotly debated issue at the roundtables. While the recurring theme in all of Commissioner Bangemann's presentations was the abolition of strict price controls (as they were a disadvantage to Community industrial policy goals), the other stakeholders were equally adamant with regard to their own positions¹⁷⁹.

The industrial policy Communication had earlier been watered down in part because of the intervention of DGV. Commissioner Flynn's submission to the 1996 roundtable reiterated the reasons for this. Namely, that measures affecting price (de-)regulation could only be pursued within the broader context of public health policy and the development of member state health systems. Although Mr Flynn was not in attendance at the meeting, similar views were expressed by other parties in the open discussions which followed.

For instance, Michael Noonan, Irish health minister, acknowledged that while "... unrestricted free movement is not compatible with unrestricted governmental intervention in the domestic market", he asserted that "... member states **cannot** [sic] give ground on the prerogative to set health policy within their own jurisdiction." The result of this paradox, according to the Danish health minister, Yvone Anndersen, was that member states' cost-

¹⁷⁹ The citations in following can be found in the official proceedings of the 1996 roundtable (IMS Health 1996).

containment measures had pushed the industry into pricing its products at high levels. Jim Murray of the BEUC thus asserted "... the fundamental challenge is to develop and maintain the necessary price sensitivity in the market for medicines, in other words to keep pressure on prices." Unsurprisingly this was challenged by industry representatives. Pierre Douaze of *Novartis* linked price controls to Europe's declining position in the global sector, arguing that the benefits to industry brought by Commission policies such as the EMEA and SPC "... have been more than outweighed by the negative impact of the combined effort of national cost containment, currency erosion and the spillover effect of such actions into other markets."

Claude Le Pen, a French academic and one of the 'independent' experts invited by the Commission, tried to guide the discussion to answer whether the goal was to eliminate price differentials between the member states or to reduce government intervention. The two, he suggested, were not the same thing. But his proposition to find "... a method which is a bit more reasonable and efficient for governments to fix prices [is] better than leaving everything to market forces" was vague. In any event, Professor Le Pen's contribution (and presence), along with that of the other expert invited by the Commission, Patricia Danzon, can be seen as more decorative than useful. Both are economists, and a review of their publications would seem to show them both sympathetic to the industry.

Such divergence between the actors continued in the second meeting when two working groups set up after the first roundtable reported their findings. Group I had been charged with developing solutions to reconcile the free movement-national price controls clash from the member state perspective. Group II meanwhile, was to look at the pharmaceutical industry itself, considering the possibility for member state co-operation on pricing.

The report of the first group concentrated on balancing industrial and healthcare policy within the parameters of member state competence. One suggestion regarding pricing was to establish 'broadly based' contractual arrangements between member states' health services and individual pharmaceutical company suppliers (WG I 1997). The idea being that prices could be agreed which served both their interests, with the company/ies trading-off lower prices for stability. The report also stressed improving the R&D element to promote investment and innovation. The more market-oriented perspective of the second group saw its report focused on competition. It concluded that so long as the member states are responsible for healthcare expenditure, there was no question that they should continue setting their own medicine prices (WG II 1997). A uniform pricing system applied centrally was deemed neither desirable nor practicable, and with regard to the future, the group offered three alternatives, claiming that each had its own merits:

- i. continuing with the *status quo* on the basis that it was 'inevitable', and even 'desirable' in public health terms – although parallel trade had to be limited in this context
- ii. actively seeking price convergence which would be "... desirable in an environment where all Member States are comfortable with the resulting balance between access and affordability on the one hand and innovation and industrial development on the other"
- iii. neither of the former two 'extremes', though member states should work together on identifying and addressing those aspects of the market which were 'suitable' for price convergence

Discussing these options, Jim Attridge, *rapporteur* of Group II and executive-director of the British Pharma Group¹⁸⁰, admitted that there had been disagreement on several issues. The most divisive had been over the relationship between the current European regulatory environment and declining innovation and investment in the sector. The industry argued a clear link made worse by ever-stricter national controls (recall Douaze quote above), while some member states had refuted this on the grounds of insufficient evidence. Both groups were comprised of a mixture of Commission staff (DGs III and V), industry and government officials – no consumer representatives – and thus delivered compromise conclusions.

Nevertheless, the results of the second meeting were described by Commissioner Bangemann as 'encouraging', with 'excellent' co-operation between the industry, Commission and member states (Bangemann 1997b). That translated into no conclusions, but agreement on the need for a third roundtable based again on 'tripartite dialogue' (i.e. minimal consumer representation). Dr Bangemann suggested that the Commission would work on an action plan or Communication in the meantime.

The final roundtable was possibly the least satisfying to each of the parties. On 25 November 1998 the Commission released its 'Communication on the Single Market in Pharmaceuticals' (COM 1998). The Communication pleased no one, and much to the detriment of any substantive analysis regarding possibilities to address the pricing problem, it became the focal-point for much of the discussion. The Commission had intended it as an amalgamation or consensus-generating document to bring together the views expressed by the stakeholders over the past few years – building especially on the work of the two working groups – and one which highlighted the concerns of each stakeholder on an equal basis. But it was roundly attacked: by representatives of the research industry for not going far enough with regard to promoting research and development; by generic representatives for not paying enough attention to their requirements; and by member state officials and consumers for not showing sufficient appreciation for healthcare and public health requirements. With regard to the content, Herxheimer (1999) has summarised that:

¹⁸⁰ The British Pharma Group then represented the interests of: Glaxo, Fisons, Boots, SmithKline Beecham, Zeneca and Wellcome.

It is not clear whether any of the participants knew much about health issues, but the text of the Communication suggests that none did. References to health amount to no more than superficial generalities, whereas industrial and economic issues were discussed in detail. (25)

Ultimately, any potential for serious debate at the final roundtable was compromised by the Commission's document.

4-3 Much ado, but nothing

Looking at the roundtables as a single initiative, while some degree of appreciation for each other's stances was achieved within the policy network, there appears little to suggest that as a result of the meetings any actor changed its views on any of the topics discussed. The evolution of the meetings shows DGIII to have become less dogmatic about price deregulation as the sole way to achieve further harmonisation – endorsing a more gradual approach – but even this indirect manner to address pricing and reimbursement yielded no answers. No real policy decisions resulted.

Beyond the fact that the interests at stake are simply too sensitive to concede on, this was due to the parties having spent more time addressing each others positions than they did actually explaining their own. The merits of a dialogue-oriented approach notwithstanding, despite meeting as a group on three occasions, the stakeholders have been unable to agree on a way forward. Recalling the industrial policy Communication, this may in part due to the Commission's seeming willingness to side with the industry – indeed throughout the meetings Commissioner Bangemann harped on the need to improve Europe's lot in the biotechnology field and made numerous references to electronic trade and free pricing – but it has more to do with the majoritarian politics nature of the issue. For even the conscious creation of the network represented by the roundtables failed to achieve progress. And, since Dr Bangemann's departure in 1999 there have been no further meetings. However, on 26 March 2001 a new network, which again brings the stakeholders together, was set up by Erkki Liikananen, Dr Bangemann's successor at the new DG Enterprise (see Section 5-1).

5 Conclusions

As the discussion has shown, despite three major initiatives (and policy networks), the pricing and reimbursement conundrum has still not been solved. There is doubt as to whether it can be given Article 152 and the cost-benefit implications for the stakeholders. But if the consequences of a spate of recent ECJ decisions on the compatibility of the free

movement principles with national healthcare policy are anything to go by¹⁸¹, the member states are being pushed into accepting increased European intervention in healthcare matters (Mossialos & McKee 2001). Not only that, but as the European industry continues to exert pressure on national governments and the Commission with regard to loss of competitiveness *vis-à-vis* the US – both of which appear to be listening to these complaints – Hancher (2001a) suggests that:

The recent findings that institutional and regulatory factors might serve to protect and insulate the European industry from competition as opposed to forming barriers to the further expansion of what it usually viewed as one of Europe's most competitive sectors may well offer the Commission a new point of departure from which to tackle the vexed issue of price regulation. (20)

Here, EFPIA has stated that: "We recognise, with the Commission, that competitiveness of the pharmaceutical market is an essential prerequisite for price deregulation." (EFPIA 1999, 2)

That said, is the Commission really seeking this 'new point of departure'? The recent review of pharmaceutical legislation (COM 2001) – called for under Article 71 of Directive 2309/93 creating the EMEA – and the establishment of the 'High Level Group on Innovation and the Provision of Medicines' (otherwise referred to as the 'G10'), are very much in keeping with an industry-focused, competitiveness approach. Based on interviews with interested parties, the former assesses mainly how EU market authorisation is working, while the latter can be seen as a formalised mini-roundtable. A brief look at this new policy network is required, as pricing and reimbursement is a key discussion-point.

5-1 The 'G10' – same wine, different bottle?

Enterprise Commissioner Liikanen's establishment of the G10 on 26 March 2001 is the most recent example of the Commission's continued strategy of trading with the industry i.e. seeking to develop measures to improve companies' international competitiveness in exchange for more latitude on proposals to free up the market and address pricing. The product of a 22 December 2000 meeting organised by DG Enterprise to discuss the findings of a report it had commissioned to assess the competitiveness of Europe's pharmaceutical industry, the G10 is to: "work on a new agenda to improve the framework for competitiveness in the pharmaceutical industry and to harness its power to deliver on Europe's health care goals." (CEC IP 2001) The report, 'Global Competitiveness in Pharmaceuticals: A European Perspective' (Gambardella et al 2000)¹⁸², published in November 2000, found that Europe is continuing to fall behind the US and argued that a

¹⁸¹ See footnote 88.

¹⁸² Often referred to as the 'Pammolli Report' after one of the authors.

higher reliance on market-based competitive measures was central to remedying this¹⁸³. The G10 joins together the Enterprise and Health and Consumer Protection DGs, and is comprised of what one assumes the Commissioner sees as the sector's main interests. Table 7-1 presents the parties to the G10 broken down as stakeholders.

Table 7-1: Membership of the 'G10'

COMMISSION
(Erkki Liikanen) Commissioner for Enterprise and Information Society
(David Byrne) Commissioner for Health and Consumer Protection
INDUSTRY
(Alessandro Banchi) Board Member at <i>Boehringer Ingelheim</i> , and representative of the European Association of the European Self-Medication Industry (AESGP)
(Jean François Dehecq) President and Chief Executive Officer at <i>Sanofi-Synthélabo</i> , and President of the European Federation of Pharmaceutical Industry Associations (EFPIA)
(Andrew Kay) Chief Executive Officer at <i>APS Berk</i> and Chairman of the European Generic Manufacturers Association (EGA)
(Chris Viehbacher) Chairman of Europe at <i>GlaxoSmithKline Pharmaceuticals</i>
MEMBER STATES
(José Miguel Boquinhas) Spanish Secretary of State for Health
(Francisco Ramos) Portuguese Minister of Health
(Philip Hunt) United Kingdom Health Minister
(Bernard Kouchner) French Minister of Health
(Lars Rekke) Swedish Minister for Industry, Employment and Communications
(Ulla Schmidt) German Minister for Health
CONSUMERS
(Angela Coulter) Chief Executive of the Picker Institute
OTHER (PURCHASER REPRESENTATION)
(Ueli Müller) President of the <i>Association Internationale de la Mutualité</i> (AIM)

The table shows the group's constitution as somewhat strange with only selected membership. Compared to the other parties (most notably industry), consumer interests are under-represented. The only representative with a clear consumer focus is the Picker Institute. However, its mission statement: "We specialise in measuring patients' experiences of health care and using this information to improve the provision of health care", suggests it as an odd choice if DG Enterprise was truly seeking a relevant consumer perspective. The involvement of the *Association Internationale de la Mutualité* (AIM), which represents European health insurance and social protection bodies, is also a strange choice. It has only a limited consumer focus – more a purchaser perspective – and is not a strong enough player in its own right to counterbalance the industry presence; AIM has also not been so directly involved by the Commission before. Moreover, only six member states are represented, and even then, only by their ministers with a health portfolio.

¹⁸³ As an aside, it would be interesting, were it possible, to ascertain what sort of information and data the companies provided the researchers. For as this study has stressed several times, the strategic use of information by industry plays a considerable role in shaping EU policy. And this has had played a large part in ensuring a regulatory framework which favours industry interests.

Discussions about pharmaceutical pricing and reimbursement (and the competitiveness of industry) must surely involve finance ministries as well; employment is after all such a key issue. This 'narrowing of the field' is clearly an attempt by the Commission to be seen to be doing something, and an attempt to convince the stakeholders of the apparently pressing industrial policy needs facing Europe; especially in light of the strength of the industry with the network. Unsurprisingly then, Per Haugaard, spokesperson for DG Enterprise, summarised the G10 as "... a good occasion to have industry in one place... the meeting will help to encourage innovation, and it's generally accepted that we are lagging behind [the US] in innovation." (as cited in Anon 2001)

The group first convened on 11 December 2001 to discuss the competitiveness report, and options for addressing pricing were raised. But on the basis of the consultative document which emerged on 26 February 2002 (G10 2002), the G10 appears unlikely to come up with anything new; least of all with regard to pricing and reimbursement. The document contains 14 recommendations, primarily aimed at promoting the industry. Those pertaining to complex issues such as pricing are sufficiently bland as to offer no real indication of a way forward. For instance, it proposes the Commission develop 'a comprehensive set of indicators' to measure the industry's performance against its competitors. Moreover, that these indicators be tied to data on morbidity and mortality so that the performance of individual products can also be assessed. For pricing, it is simply suggested that:

Respecting national competence, member States should examine the scope for improving time taken between the granting of a marketing authorisation and pricing and reimbursement decisions in full consistency with Community legislation. (8)

That the Commission and the Member States should secure the principle that a Member State's authority to regulate prices in the EU should extend only to those medicines purchased by, or reimbursed by, the State. Full competition should be allowed for medicines not reimbursed by State systems or medicines sold into private markets. (10)

In other words, it still befalls the Commission and the member states to find ways forward.

Admittedly, the G10 is a forum for dialogue rather than decision-making, and its somewhat prosaic recommendations reflect the stakeholders' compromise views on a host of issues beyond pricing. The hope expressed by Paul Weissenberg of DG Enterprise that:

In this group we need to focus on issues where there is a reasonable prospect of clear recommendations on practical steps. The way forward must avoid the impasse in the debate 'price control for state health services' versus 'single market free circulation of goods'. (as cited in AESGP 2001, 4)

seems to already have been dashed. The policy network represented by the G10 may be able to present a policy document, but the recommendations contained therein show that it cannot agree measures which will effect policy. This will prove a disappointment to the Commission, for it had expressed the hope that the G10 "... will be able to agree on policy approaches that do not necessarily require the Commission to take legislative action" (CEC IP 2001). But it reflects clearly the constraints the pricing and reimbursement issue carries.

Part of the reason for this rehashing of old arguments and delivery of bland recommendations is that the group's initial consultation paper, issued by DG Enterprise (CEC 2001), sparked almost as many different views as there were respondents. At one pole was the BEUC, which felt that the document concentrated almost exclusively on how to promote the industry with little attention paid to consumer interests. The consultation's aim was stated as: 'to secure the development of a competitive (innovative-based, generics, non-prescription) industry', and this has been continued in the 2002 paper. The BEUC concluded that: "The G10's tentative suggestions need to be significantly improved in line with consumers' and citizens' needs." (BEUC 2001, 2) Speaking about his participation in the December meeting, Ueli Müller – president of AIM, and thus one of the few G10 members without a direct industrial policy interest – shared this view:

I insisted that the proposals drafted within this group should strive to balance the interests of a truly innovative industry, the general interest of public health and fair access to medicines... the consultative document on which all interested parties were to give their opinion seems to make little reference to the public health and consumer protection dimensions on the issue... increasing the competitiveness of the pharmaceutical industry does not mean increasing consumption and raising prices. (Müller 2001, 1-2)

This can be compared to EFPIA's opinion at the other pole, which was that industrial policy considerations such as intellectual property rights were not given the necessary priority (EFPIA 2001c). Indeed, the *Verband Forschender Arzneimittelhersteller e.V.* (VFA), the German Association of Research-Based Pharmaceutical Companies accuses the document of giving too much attention to issues which impede innovation, specifically generic promotion and the potential use of cost-effectiveness as a criterion of innovation assessment (VFA 2001). Although too lengthy for analysis here, the views of other parties reveal a host of positions between these poles. In any event, with such a mandate, and such a select membership, it should not come as a surprise that the G10 is unable to deliver any novel recommendations.

5-2 Costs versus benefits

What the disparate views and reactions of the stakeholders highlighted in this chapter indicate, is that all are affected by the prospect of harmonising pricing and reimbursement.

Although something of a generalisation of the complex issues raised throughout the discussion, it can be concluded that each actor has something to gain and lose under a European pricing regime, such that both the benefits and costs of any 'policy' are widely dispersed. More specifically, each perceives the benefits to be insufficient to warrant bearing the costs (which may even be anticipated as high if the regulatory intervention proves unfavourable to their interests). The incentive for co-operation in pursuit of a common agenda are equally not there given the differences in interest.

Furthermore, there is also a considerable lack of clarity surrounding what manner a European price or pricing system might take, far less what it would bring. And a policy which benefits only one stakeholder is therefore likely to do so at the expense of one or more of the others. For the industry, as a Euro-regime essentially amounts to higher or lower drug prices and thus higher or lower profits, it is keen to assert its interests. Not just the industry, however, all stakeholders aim to defend their positions. The potential costs leads to a situation where there is no real motivation for any actor to 'rock the boat'. All recognise that the issues are too complex and involved for a Community regime and, as things stand, the *status quo* of national price and reimbursement controls remains preferable to the unknown.

Nevertheless, the main cost-benefit calculation is perhaps that of the member states'. Despite their own national interests, they are unanimous in their opposition to Community 'interference' in healthcare. The potential costs to be borne in terms of their control over healthcare expenditure, loss of jobs, and the income redistribution implications potentially raised by an EU pricing regime, all preclude any willingness on their part to rescind authority over medicine pricing. The Commission's view, therefore, is that national cost-containment should be addressed only from a reimbursement point of view – this is seen to be more consistent with a single market than price controls – and that European policies are required for the other industrial policy issues. Again, this is not likely given that national interests span both healthcare and industrial policy matters, and there are fifteen different systems in place to address this. Hence, with the Commission only able to address the industrial policy side of the market, the competitiveness approach is not producing results; least of all where pricing and reimbursement are concerned. The problem is that it manifests itself in measures to promote the industry (mainly innovative companies) without generating workable proposals to take the pricing and reimbursement issue forward. By comparison, the interests of the other stakeholders, particularly consumers, are neglected. Thus, irrespective of any new policy network constellations such as the G10, the majoritarian politics character of the issue will remain.

5-3 Final remarks

Two additional conclusions can be drawn from this chapter. First, the Commission's 'competitiveness approach' since the Transparency Directive has tended to fragment the stakeholders. Consensus-building has been made more difficult and more actors have been brought into play, in turn complicating the formation of effective policy networks. The majoritarian politics nature of the issue has thus brought severe constraints on the Commission's ability to regulate. One reason for the numerous redrafts of the industrial policy Communication for example, was the split that emerged within the Commission, where DGIII and DGV disagreed over proposals for national price deregulation. The final Communication was in fact signed by both Martin Bangemann and Pádraig Flynn – a first where pharmaceutical policy was concerned. The member states too were divided. Despite shared concerns about cost-containment and the potential for loss of employment in the sector, differences in national industry, market, and drug consumption patterns saw them voice different requirements both in favour and against the proposals.

Issues such as generic promotion – towards stimulating price competition – are equally divisive from the stakeholders' perspective. Indeed, this topic in particular has divided patients and doctors, two otherwise traditional allies in matters pertaining to European pharmaceutical regulation. For while patient groups such as the BEUC, Health Action International (HAI) and the UK Consumers' Association favour generic substitution from a health(care) policy perspective, the *Comité Permanent des Médecins Européens* (CP or Standing Committee of European Doctors) is more circumspect, believing that the choice of medication should lie with the doctor (CP 2001). The question of what to do about parallel imports has also firmly entrenched otherwise secondary stakeholders into the fray. The GIRP and association of European parallel trading companies can, for example, expect to have their interests taken into account by national governments. This contributes to the member states' differing positions on pricing and reimbursement more generally.

Another conclusion is that consumer interests, at least in terms of formal involvement in the policy-process, have been excluded. Jim Murray's earlier-mentioned address to the special hearing showed that the BEUC had not been privy to the previous draft of the industrial policy Communication; he was not even aware that by that time there had actually been several versions. Even the roundtables, which ostensibly sought to bring the major stakeholders together, have been criticised for not taking account of consumer concerns: "To describe the occasion as a roundtable was perhaps misleading. The concept of a roundtable implies a meeting among equals, but that was not the impression created at this event." (Furniss 1997, 28) Although this exclusion compromises the Commission's ability to make any headway, according to Hancher (2001b):

The debate on how to tackle pricing can no longer be safely confined to a privileged dialogue between industry and governments and European bureaucrats. Nevertheless, it remains to be seen to what extent the Commission can ensure broad stakeholder involvement in detailed issues... It is unlikely that consumers or health care providers could be closely involved in this assessment process. (24)

Indeed, the selective membership of the G10, as the latest major initiative in the pharmaceutical arena, appears to underline her point.

Two lines of argument were set out at the beginning of this chapter as the threads which would tie together the disparate elements of the discussion. The first was that despite limited Community competence over the pricing and reimbursement of medicines, what does exist of a supranational regulatory environment has been driven by industrial policy and industry interests, without equivalent attention paid to social policy or consumer considerations. The Commission's inability to tackle the healthcare policy aspect of the market, has meant that it has been confined to the use of industrial policy measures – in part as a trade-off approach – which have inevitably involved promoting the industry.

The second contention was that pricing and reimbursement represents a majoritarian politics issue, where the prospects for supranational policy are highly constrained. This is both because of Article 152 and the actors' divergent interests. Unlike the entrepreneurial politics scenario where there is widespread apathy amongst the actors because of the diffuse costs involved, in the case of majoritarian politics the regulator does not have the competence to address the issue. Opportunities for (compromise) policies to be reached via policy networks are therefore limited.

This is clearly the case over pricing and reimbursement policy, where the exclusion of healthcare from the Community remit means that the Commission lacks the competence to take the issue forward. Consequently, it has had to rely on Articles 28-30 (ex 30-36) on promoting the internal market in order to develop proposals. That the Transparency Directive remains the only formal policy and parallel trade continues are testament to this. As one commentator noted when discussing why the proposals for amending the Transparency Directive were shelved: "... it would not be fair to blame anything than the complexity of the problem itself." (Faus 1997, 20) And as noted, particularly in respect of parallel trade, the ECJ has also helped to consolidate pricing and reimbursement as a national level competence, ensuring it as a case of majoritarian politics.

CHAPTER 8

CONCLUSIONS

Introduction

This study has been concerned with the making of supranational pharmaceutical policy in the European Union. It has considered the evolution and shape of the Community's regulatory regime for medicines, one which does not amount to a harmonised market. More specifically, the study provided a political perspective on how and why certain policy outcomes have been achieved and others not, and did so via a theoretical approach which sought to take into account the regulatory constraints faced by European policy-makers. By way of conclusion it becomes necessary to return to the major lines of enquiry identified in the opening chapter. Recalling the study's two main objectives then, the empirical element was to address the hypothesis that the industry is the main beneficiary of the current EU framework. Second was the development of a theoretical lens through which to understand how Community pharmaceutical policy is made. It is one which, although focusing primarily on actors, takes a broad and multi-layered view of the policy context in order to test the hypothesis. The discussion begins by reviewing the theoretical element of the study in order to reiterate its application and acknowledge its deficiencies. The case-studies are afforded another look within this discussion, towards drawing some empirical conclusions in a comparative format. Thereafter some final conclusions and remarks on current Commission proposals for the sector are offered. A quick look at possibilities for future research then closes the study.

1 Theoretical Considerations

Since the 1985 White Paper on the internal market (CEC 1985), the Community's aim for the pharmaceutical sector has been the eventual harmonisation of member state markets. Although considerable progress has been made, the discussion has demonstrated that there is still a long way to go. In particular, it has shown that any further Europeanisation of the market is a difficult prospect for two main reasons. First, the interests of the European Commission, the member states, the industry and consumers, as the sector's main stakeholders, are too disparate for agreement to be reached over the outstanding aspects – most notably, pricing and reimbursement. Second, the clash between the EU's legal and policy frameworks – subsidiarity versus free movement – means that the Commission is unable to force an agenda. In addition, Article 152 of the Amsterdam Treaty excludes the Community from direct competence in member state healthcare systems, and reflects a position over which national governments have been adamant.

The implications of healthcare spending policies and income redistribution being made areas of Community authority are unacceptable to all member states.

The dilemma over supranational policy-making is clear. The EU is only able to legislate over the industrial policy dimension of the sector (i.e. within the remit accorded it by the SEM), while the healthcare aspects remain firmly in national hands. Despite this shared competence, as other EU policies, Treaty articles, and judgements by the European Court of Justice do impact on healthcare (and public health) concerns, the study endeavoured to ascertain how this came about. And it did so by looking at three examples in particular: the Supplementary Protection Certificate legislation, the creation and operation of the European Medicines Evaluation Agency, and the continued intractability of the pricing and reimbursement issue. It is the question of market harmonisation and the divergent views of the stakeholders that ties these otherwise separate elements of Community pharmaceutical policy-making together. And for all three, the study sought support for its main contention that the industry is the prime beneficiary.

To test its hypothesis of an industry-favouring regulatory framework – one which results, primarily, from industry's influence within the policy-process – the study approached the EU sector from a political perspective and argued the need to adopt a broad theoretical lens. The case was made for a lens which takes the wider policy environment into account in order to understand the preferences and actions of specific actors in the policy-process – this was then applied to the case-studies. In developing this, the discussion first showed the value of traditional European integration and policy-making theory, where the focus is often on the role of the member states and European institutions, or international organisations/influences within the international arena. At the same time, the discussion of Chapters 3 and 4 made clear why these perspectives were insufficient to test the underlying contention of the study. Neo-functionalism and intergovernmentalism were shown to account for the industrial policy leaning of the regulatory framework, but that they do not offer direct insight into how it came to serve industry interests. Thus, it was necessary to ask how policies were agreed, which stakeholders were involved in the policy-process, and in what capacity. To answer these questions, the discussion turned to the meso-level and focused on the main actors within the policy-process; thereby helping to develop a more complete perspective.

Policy networks were chosen for several reasons. First is that the process leading to EU regulatory policy outcomes is one which cannot be adequately captured by traditional pluralist or corporatist theories of interest mediation and bargaining. Variables such as the amount of resources, access to the policy arena, and the level of information which, while crucial to pluralist and corporatist analyses, have a comparatively smaller part to play here.

In support of Héritier's (1996) claim of a 'sectoralised' EU polity, consensual decision-making is crucial at the supranational level, where the gains to be accrued through compromise often outweigh the price of holding to an individualistic (e.g. national) position. It is also at this level that the relative power/influence of individual actors may be less cogent given wider considerations, and where interests tend to be more aggregated than at national level. Here the study looked to multi-level governance. Accepting it as a descriptor of the dispersal of power within EU policy-process (and the dynamics which result), Chapter 3 showed its relevance in establishing the background to network activity. And other process-oriented views such as negative and positive integration, old versus new regulatory policy were tied into the discussion. Seen from this standpoint, multi-level governance offers insight into where and how policy networks can develop and operate (within the pharmaceutical sector).

Another rationale for employing networks is the argument that not enough empirical research has been done on transposing policy networks to the EU sectoral level (Josselin 1994). This may have to do with the fact that the approach suffers from the lack of a singular theory and, as Rhodes (1990) has lamented, is therefore mainly used as a metaphor. Or it might be because the 'elusive fluidity' of the EU policy-process makes such application difficult, as Kassim (1994) has argued. Nevertheless, it remains one of the underlying contentions of this study that policy networks are a useful line of analysis in their own right, and that they are valuable in examining cases of consensual decision-making at EU level. Support for this can be found amongst numerous scholars, including Héritier et al (1996), Josselin (1996), and Börzel (1997a,b). It is especially useful where groups of interests – often with different or competing agenda – come together in the making of policy which affects them all.

With the interests of the European Commission, the member states, the industry and consumers not always convergent given the three policy inputs and resulting health(care)-industrial policy clash, this is clearly the case over pharmaceutical policy. The interests are such that any policy will carry a winners and losers effect and the stakeholders' behaviour thus conforms to Rhodes (1990) explanation of the internal dynamic of policy networks:

...[the actors] manoeuvre for advantage, deploying the resources they control to maximize their influence over outcomes and trying to avoid becoming dependent on the 'other players'... [with] the relevant resources including constitutional, legal, organizational, political and informational. (42)

Moreover, as Rosamond (2000) argues that "Policy network analysis only works when the institutional dimensions of policy-making are weak" (124), the constrained role of the Commission within the sector appears to fit squarely within this view.

Rather than joining the debate on the theoretical viability of policy networks, the study's use of the concept was based on contemporary applications such as Rhodes's, and accepted the view that "... their [policy networks] function is to develop new measures in European policy". (Héritier et al 1996, 7) Nevertheless, the discussion went beyond simply applying the accepted (interest-intermediation) conceptualisation. For on its own the approach is somewhat uni-dimensional. It enables an understanding of actor relationships – institutional or otherwise – within narrowly-defined policy fields, thereby providing for a very focused level of analysis. This is particularly so at the sectoral level where actors and their interactions tend to be fairly fixed. However, this view does not accommodate that network behaviour can be affected, if not limited, by the external policy environment.

Ignoring this context may be a valuable exercise for the student seeking principally to map structural relationships between actors but it proves insufficient to understand why specific policy is made. Chapter 3 discussed how wider political factors necessarily influence networks in the pharmaceutical sector, and do affect whether policy is achieved or not; factors which impinge on the Commission's role in particular. In order not to fall into this traditional mode of analysis, the study offered a further dimension in the use of the interest-intermediation approach. Bearing in mind the insights gleaned from the macro-theories, Wilson's (1980) 'politics of policy' framework was employed to supplement the use of policy networks. By examining proposed regulatory interventions on the basis of actors' perceived gains or losses, the framework suggests that the regulatory environment must also have an impact on the type of policy agreed. Use of the politics of policy was a means of integrating policy networks into a broader frame of analysis, thereby strengthening the theoretical value of the concept and, in turn, providing a more realistic and inclusive basis for understanding regulatory policy-making in the EU pharmaceutical sector.

2 Employing the 'Politics of Policy' in the Study of EU Pharmaceutical Policy-Making

Looking at the politics of policy itself, by establishing what type of politicking is required or results in instances of divergent views (amongst the policy network participants), Wilson's framework goes some way to capturing why certain regulatory outcomes are successful and others not. Here, regulatory policy-making and the nature of outcomes is predicated on stakeholder preference and behaviour – on the basis of perceived gains and losses from the intervention being considered – resulting in four distinct types of politicking. Outlined in Chapter 4 these were: 'client politics', 'entrepreneurial politics', 'majoritarian politics' and 'interest-group politics'. Recalling Figure 4-3, an application of the framework to selected elements from the Community's regulatory competencies, including those looked at in the case-studies, gives rise to the matrix of Figure 8-1 (overleaf).

Figure 8-1: The 'Politics of Policy' as Applied to Selected Elements of the Community Medicines Framework

COSTS VERSUS BENEFITS			
Diffuse-Diffuse	Diffuse-Concentrated	Concentrated-Diffuse	Concentrated-Concentrated
<ul style="list-style-type: none"> • Pricing • Reimbursement 	<ul style="list-style-type: none"> • Patent protection • European Agency for the Evaluation of Medicinal Products* 	<ul style="list-style-type: none"> • Packaging, inserts and leaflets • A fully integrated single market for pharmaceuticals 	
Majoritarian	Client	Entrepreneurial	Interest-group

TYPE OF POLITICS

* The arrow from 'entrepreneurial' to 'client' regarding the EMEA reflects the point made in Chapter 6, that while initial proposals for an agency came the Commission, the specifics of its mandate resulted in large part from industry pressures.

2-1 Reviewing the case-studies: Comparative network evolution

In applying the politics of policy framework to the case-studies each was treated as an area of regulatory policy-making over which policy networks develop. They were chosen as major policy areas within the regulatory regime, ones which also showed the relevance of the study's theoretical approach. Looking at the policy networks which developed around each case, their respective evolutions are represented in table format below (Tables 8-1, 8-2, 8-3). The issues at stake during each stage of the respective policy-processes are corresponded to which stakeholders where involved at the time. Although an abbreviated re-telling of the story, the tables are useful on three fronts. First they trace the development of the regulatory intervention in terms of 'who did what'. Second they enable comparisons to be made between cases, in particular with regard to stakeholder involvement. And third, by showing that industry was the most stable actor within the networks in each case, they offer a graphic representation of how the policies favoured the industry. For it is this stability which has enabled the industry to influence the policy networks which emerge over individual regulatory policy issues.

The Supplementary Protection Certificate Network

The case of the Supplementary Protection Certificate legislation provides the clearest example of how, by dominating the policy network which developed, the (research-based) pharmaceutical industry has been able to influence EU policy outcomes towards serving its interests. Chapter 5 showed that from the outset it was the industry which set the agenda. Citing patent-term erosion as harmful to the industry, to healthcare interests (and public

health), and to European competitiveness, it was able to appeal both to member states' industrial policy priorities and the Commission's single market aims. Moreover, Table 8-1- shows the industry to have been present at every stage of the policy-process.

Table 8-1: Evolution of the Supplementary Protection Certificate Policy Network

PHASES	STAKEHOLDER INVOLVEMENT	ISSUES
Pre-proposal (1) 1987	Research industry: EFPIA Commission: Competition DG (IV); Industrial Affairs DG (III)	<ul style="list-style-type: none"> Discussions begin about addressing patent-term erosion (EFPIA members already lobbying national governments) EFPIA approaches DGIV, is rejected, and then convinces DGIII to take on the case
Pre-proposal (2) 1988	Research industry: EFPIA Commission: DGIII	<ul style="list-style-type: none"> EFPIA presents 'memorandum' and begins serious campaigning DGIII sets about 'selling' extended patent terms on medicines
Proposal and legislative process 1989-1992	Commission: DGIII (Other European institutions: European Parliament and committees; Economic & Social Committee) Member States Research industry: EFPIA Consumers: BEUC; CCC; CECG Generic industry	<ul style="list-style-type: none"> Commission presents COM document suggesting 10 year extension Member states express differences; France and Italy seek their own patent extension legislation EFPIA lobbying other European institutions, especially MEPs With Parliamentary review, consumer/patient groups start to argue against the proposal The generic companies begin to campaign against SPC, though no organised representation in the manner of EFPIA Consultation and review of proposal - 10 years extra protection watered down to 5
Adoption of Directive and post-legislation 1992-	Member states: Council of Ministers (Internal Market) Research industry: EFPIA Generic industry Consumers	<ul style="list-style-type: none"> Legislation is approved in the Council - Spain, Portugal and Greece vote against EFPIA pressing for no subsequent legislation on improving conditions for generic producers Generic companies form European Generics Association (EGA) Consumers and generic companies call for mitigating measures e.g. generic substitution as <i>quid pro quo</i> (in view of public health needs and generic industry requirements), but Commission cannot/will not address them

Here EFPIA took advantage of the informational asymmetries, and was willing to provide hitherto commercially sensitive data to selected parties in order to make its case. This strategic dissemination of material led to Shechter's (1998) finding that after meeting with EFPIA, one MEP "... was simply cut off... Either [he] was to settle for information provided by the industry, or he was to face the difficulties of collecting information using his own scarce resources." (98) This was because he was known to be sceptical of industry's position. Meanwhile, for those European policy-makers more sympathetic to its demands – namely Fernand Sauer and DGIII – EFPIA presented a detailed catalogue of industry and company-specific information. Although some of its claims were not as clear-cut as DGIII took them to be when delivering its initial proposal for a 10-year extension, the lack of opposition and access to information within the network ensured that only EFPIA information featured in the policy-process. Here the issue was that the generics industry had no formal representative body of its own, to counter EFPIA, and consumer interests were scattered without a real voice. They only had a formal say once the proposal had

been sent to the Parliament and the (Internal Market) Council. The table shows the other stakeholders were involved in the policy-process only after the Commission had made up its mind. Opposition was thus weak and late in coming.

Even if opposing 'evidence' had been presented it is unlikely to have changed the Commission's stance. (Indeed, data from the US where the generic industry had had a similar battle with its research-based competitors during the early 1980s was available, and generic companies did try to bring this to people's attention). For there was also a natural convergence between the industry's demands and DGIII's concerns about European competitiveness. This pro-industry approach was only compounded by a Commission wanting to be seen to be doing something in the field of pharmaceutical policy more generally. DGIII was not difficult to convince. Further, Mr Sauer's 'deal' with EFPIA over its opposition to the transparency legislation showed DGIII to be a receptive vehicle for industry's demands. It is clear, therefore, that a client-politics scenario developed in the case of the SPC, with the research industry, via EFPIA, lobbying extensively and dominating the policy network primarily through the strategic use of information.

The European Medicines Evaluation Agency network

The EMEA legislation meanwhile was shown to have been a case of entrepreneurial politics, where the Commission forced the agenda. At the same time, it was again the industry which declared the terms. For having been involved in the policy-process from the start (Table 8-2, overleaf) – its complaints about long registration struck a chord with the Commission's single market goals – the industry helped ensure an agency which works towards speeding market approval as an end in itself. Chapter 6 showed the degree to which the EMEA mandate was shaped to accommodate industry's requirements – particularly a revised mutual recognition regime under the decentralised procedure, one in which the choice of *rapporteur* lies with the application. Along with healthcare policy, some public health issues remain beyond its remit.

EFPIA's demands notwithstanding, the idea for an agency developed from the Commission's concerns that with the 1992 deadline looming, current registration procedures were not serving single market priorities. On the basis of an initial consultation document, however, the Commission found its idea unpopular with the other stakeholders. Although all parties recognised the failings of the procedures, their respective cost-benefit calculations saw them express reservations. It was up to the Commission to overcome this initial opposition, and here it proved itself entrepreneurial. DGIII actively courted the views of the stakeholders, appealing to those elements of a potential new agency that each saw as beneficial to its own interests (recall Table 6-1). Quicker, more efficient and

Community-wide approval with minimal member state interference would address industry's priorities in getting drugs to market more rapidly, such that R&D costs could be recouped. Consumer interests would be served by quicker approval for important, innovative medicines. And faster registration could help governments to control healthcare costs, as well as support those with a local industry. In other words, all would benefit.

Table 8-2: Evolution of the European Medicines Evaluation Agency Policy Network

PHASES	STAKEHOLDER INVOLVEMENT	ISSUES
Pre-proposal (1) 1988	Research industry: national associations e.g. ABPI, SNIP; EFPIA Commission: DGIII	<ul style="list-style-type: none"> Industry calls for quicker Community registration procedures DGIII compiles report of CPMP outlining problems and need for binding authorisation (circulated to all stakeholders asking for views)
Pre-proposal (2) 1989	Commission: DGIII Research industry: EFPIA; national associations Member states Consumers: BEUC	<ul style="list-style-type: none"> DGIII publishes compilation of responses document All stakeholders recognise problems with registration procedures, though for different reasons (EFPIA opposed to any centralised agency) National governments with mixed responses - corresponding to consultation with national industry associations and cost-containment priorities BEUC calls for independent, quicker approval process with high standards of health protection in evaluation criteria
Proposal and legislative process 1990-1993	Commission: DGIII Member states Research industry: national associations; EFPIA (Other European institutions: European Parliament and committees; Economic & Social Committee) Consumers: BEUC	<ul style="list-style-type: none"> Official proposal document published Political wrangling between governments over legal basis to establish agency (Article 100a or Article 235) Member states consulting with national industry regarding pros/cons and divergent national responses to DGIII's wider future systems proposals Parliament and ESC stress agency be based on public health protection grounds BEUC (consumer perspective no longer consulted by DGIII) issues response criticising lack of public health element in proposal
Adoption and post legislation 1993-	Member States: Council of Ministers (Internal Market) Research industry: national associations; EFPIA	<ul style="list-style-type: none"> Council approves revised legislation Bidding begins between member states to host agency (London agreed as site); only established in 1995 APBI instrumental in bringing EMEA to UK

That said, the Commission's first point of contact had been the industry, in order to ascertain its views and requirements. Moreover, after initial consultation with consumer groups (the BEUC in particular), they were then frozen out of the policy discussions proper. When talk turned to the mandate of the new agency, industry and member state industrial policy priorities were all DGIII appeared interested in hearing. In keeping national regulatory agencies at the heart of the system, the Commission was able to secure member state support by ensuring them that their authority would be preserved (and that medicines approved centrally would not simply flood their market at unbearable costs). The Commission's aims, much like in the SPC case, were driven by how best to meet the requirements of the SEM – again the proposal went to the Internal Market rather than Health Council for a decision. The end result is a pro-industry agency, despite the Commission having pushed the agenda.

Pricing and reimbursement – multiple strategies and networks

The main reason for the incomplete pharmaceutical market is the lack of pricing and reimbursement competence at EU level. Despite numerous and ongoing attempts to address this, it has not been possible to secure member state commitment on even gradual price deregulation in order to lessen the effects of price differentials between countries. The constraints on the Commission's regulatory role are simply too substantial to overcome. This reflects a situation of majoritarian politics where the potential costs and benefits to the affected parties have to be reconciled if any policy is to be agreed, and is demonstrated by the different 'strategies' to address pricing and reimbursement proposed by the Commission. Table 8-3 (overleaf) compares the policy networks which formed around three initiatives in particular, only one of which resulted in a policy outcome.

It is clear that in each initiative and at each stage of the process, the research industry was present. Unlike in both the SPC and EMEA cases, however, it has not been able to impose itself. The views of the other stakeholders, in particular the unwillingness of the member states to give up their right to set their own medicine prices and reimbursement rates, has meant that the issue remains an unresolved in policy terms. The Transparency Directive notwithstanding, the member states have been unwilling to address the issue on the Commission's terms. And even then, their interests in agreeing the legislation had more to do with wanting to keep a check on what each other was doing (i.e. transparency), than they did in devolving authority to the Commission. As the table reflects, the result has been the Commission trying numerous strategies, culminating in the on-going competitiveness' approach, to address the pricing and reimbursement issue. This involves the Commission using industrial policy arguments (those elements of pharmaceutical regulation the member states are willing to countenance Community authority in) to sell a 'competition strategy' as a trade-off (with industry as well) over some price harmonisation.

Table 8-3 also shows that in trying to take the pricing and reimbursement issue forward, the Commission has slowly narrowed the field. The different strategies reflect an acknowledgement that securing member state agreement could only be achieved gradually rather than from Brussels. The Commission's aims, as reflected in the table, have therefore evolved from an initial call for price convergence and abolition of national price controls (under the original draft of the Transparency Directive) to now indirectly promoting price competition by advancing the competitiveness of the industry (the Roundtables and G10 group). This is more or less what the industry has been pushing for in its own calls for natural market forces to be introduced. The Commission has accepted that the member states must retain the authority to set their own medicine prices, as reflected in the report prepared by the second Working Group, and presented to third Bangemann Roundtable.

Table 8-3: Evolution of Commission Strategies over Pricing and Reimbursement Policy (multiple networks)

STRATEGY	POLICY NETWORKS		
	Transparency Directive (& Amendments)		
'one step at a time'	Phase	Stakeholder involvement	Issues
	Pre-proposal 1986	Commission: DGIII	<ul style="list-style-type: none"> DGIII drafts COM document calling for member state pricing transparency and price harmonisation
	Proposal and legislative process (1) 1987-1988	Commission: DGIII Member States Research industry: EFPIA (Other European institutions: EP & committees; ESC) Consumers: BEUC	<ul style="list-style-type: none"> 'Softer' official proposal presented (clause indicating eventual harmonisation remains a Commission priority) Varied responses from national governments e.g. West Germany uninterested; UK in favour so long as PPRS was left untouched EFPIA agreed on transparency, though adamantly against provisions which will impact on companies e.g. pricing databank BEUC, although not consulted, begins campaigning to Parliament on the basis that the proposals missed the point Parliament and ESC see the proposal as pro-industry; but Mr Metten's amendments are opposed by industry and refused by Commission
	Legislative process (2) and adoption 1988	Member States: Council (Internal Market) Research industry: EFPIA Commission: DGIII	<ul style="list-style-type: none"> DGIII redraft proposal to incorporate some changes Council agrees compromise with databank separate from main provisions EFPIA gives its ok (suggestion of SPC deal with Mr Sauer)
'shared interest'	Post-Directive 1989-1992	Commission: DGIII Member States Research industry: EFPIA Consumers: BEUC	<ul style="list-style-type: none"> All stakeholders reject Commission's attempts at a revised draft; DGIII finally gives up in 1992
	Industrial Policy Communication		
	Pre-proposal 1992-1994	Commission: DGIII; DGV Research industry: EFPIA	<ul style="list-style-type: none"> Approximately 10 drafts of potential document drawn up behind the scenes - only industry is privy Document the product of a joint Commission-industry task force Commission seeking abolition of national price controls and convergence of prices DGV intervenes and document has price provisions removed
'dialogue'	Proposal and legislative process 1994-1996	Commission: DGIII Research industry: EFPIA Member States (Other European institutions: EP & committees; ESC) Generics industry: EGA	<ul style="list-style-type: none"> Generics industry catches wind of discussion, though, like consumer groups, had been intentionally kept out (Internal Market) Council resolution reflects disparity in member state priorities; nothing really implementable emerges
	Roundtables		
	Roundtable 1 (1996)	All stakeholders plus: National regulatory officials; independent experts	<ul style="list-style-type: none"> Called for by Commissioner Bangemann Industry-sponsored event Parallel trade is the main discussion point, with divergent views expressed; corresponding to stakeholder priorities 2 working groups set up to provide the industry and member state perspectives
'Competitiveness'	Roundtable 2 (1997)	All stakeholders plus: National regulatory officials; independent experts; other interested parties	<ul style="list-style-type: none"> media banned this time, meeting is financed by Commission grant working groups report findings: WG1 suggests member states promote R&D climate while retaining control of pricing; WG2 offers 3 alternatives - price convergence, <i>status quo</i>, or increased member state-industry co-operation - but endorses none
	Roundtable 3 (1998)	All stakeholders plus: National regulatory officials; independent experts	<ul style="list-style-type: none"> again financed by Commission grant discussion hijacked by Commission's 'Communication on a Single Pharmaceutical Market' no proposals on moving forwards on the pricing issue; mainly accusation and counter-accusation regarding the industrial-orientation of the Communication
	G10 (High Level Group on Innovation and the Provision of Medicines)*		
Set up by DG Enterprise in 2001 and involving selected membership (recall Table 7-2). Industry is again the strongest actor with EFPIA and individual companies represented. Consumer interests are comparatively neglected with no important policy actors present, and only some member states are involved. Having met once to-date, the group has been unable to deliver any implementable policy proposals in general, and vis-à-vis pricing in particular. It is, however, an example of the continued pro-industry agenda pursued by DG Enterprise, along with its attempt to narrow the actors in order to try to achieve some sort of policy.			

* Not a case-study, but as shown in Chapter 7, a policy network in its own right.

Despite the Commission's best efforts to galvanise support on the issue, therefore, the assertion (after the industrial policy Communication) that: "The European Community's foray into pricing could overall be characterised as having achieved a minimum of interference in pricing and reimbursement programs run by the Member States" (Hodges 1997, 252) remains valid. Not only do the member states remain sceptical, but the industry and consumer interests remain for the most part happier with the current situation. This may in part be due to uncertainty over what harmonised prices might actually bring in practice (i.e. higher costs or lower costs; higher or lower prices), but as the costs to governments and industry could potentially be considerable (in the medium-term at least), neither has much interest in following the Commission's lead. Ultimately, with pricing and reimbursement "... a political issue that touches the very heart of social policy" (Deloitte-Touche 1993) – as acknowledged in a report prepared on behalf of the Commission – the result is that all stakeholders pursue individualistic agendas, even within any policy networks which form, and majoritarian politics prevails.

2-2 *Ad hoc* development of competencies and interest-group politics

In Chapter 3 the Community's history in the field of medicines policy was shown to be somewhat chequered. The (incomplete) regulatory framework is in large part an amalgam of competencies added when needed and where possible, rather than representing a concerted or integrated approach. And as the Commission has tried numerous strategies, this has resulted in a host of disparate powers most of which relate to the SEM:

The continuing influence of Brussels on drug affairs is refracted through a variety of prisms: at one extreme, the macro-considerations of the new European Medicines Agency on the discussions of the EU on balancing research strategies with health economics; at the other extreme, the micro-consideration of regulatory and legislative detail on medicines and their manufacture. (Albedo 1995a)

The result is an *ad hoc* framework which fails to address some important considerations i.e. health(care) aspects.

It has also been demonstrated that the Community's framework has in large part been shaped by struggles between the main stakeholders, with the ECJ often involved e.g. over parallel trade. The Commission, the member states, the industry and consumer interests have all pushed certain agendas within particular policy networks, reflecting different types of policy outcomes and contributing to the *ad hoc* development of competencies. This relates to interest-group politicking in Wilson's framework. It was mentioned in Chapter 4 that in involving concentrated costs and benefits, regulatory policies subject to interest-group politics are the most challenging to implement. Only a small group derives the most benefit, with the majority losing out. Furthermore, the high costs of the proposed policy are

also to be borne by a small group. The result is a host of potentially affected actors striving to have their interests met at the same time as they seek to protect what they already have; none are prepared to bear the costs. Regarding the primary stakeholders, there is, therefore, little incentive to support the policy, especially as it may not be clear who will benefit, far less at what cost. What is clear, however, is that most will be unhappy should the policy – somehow – be enacted. This is unmistakably the case over a ‘completed’ single pharmaceuticals market. Each stakeholder has a different vision as to what they want from a harmonised market and what it would bring in practice. At the same time, each is aware that they stand to lose a great deal if their interests are not met.

A single market is likely to result in increased prices (Towse 1998). This benefits only the industry, which has consistently called for market-based pricing. So long as the member states seek to retain control over healthcare policy, it is, however, unlikely. As one analyst noted at the time of the implementation of the SEM, “Total pricing freedom for pharmaceuticals throughout Europe will only come about if the national governments think it is in their best interest; no notice what so ever will be taken of the industry’s views.” (Burstall cited in MARKETLETTER 1992b, 11)

Full deregulation would, however, also result in a stronger European industry in output and export terms (*vis-à-vis* the US in particular), but will come at the price of heavy streamlining. It is worth noting that although the US has much less employment in the sector, its output is very similar (compare Appendices 2-3, 5-1 and 5-2). Rationalisation will favour the larger firms (and their ‘home’ countries), but ultimately means less employment in the sector generally. As Rovira (1996) argues:

The process of concentrating both production and employment in a limited number of countries will probably continue, especially in those countries that already have a strong presence of research-based, innovative, multinational companies. (12)

By extension, member states with weaker industries will bear the costs of this in terms of loss of employment and production, and are likely to pursue mitigating national measures which may impact negatively on other countries (or on the European industry’s competitiveness as a whole). This will also mean the closing of many SMEs, many of which are innovative companies engaged in very specific research, and their closure would also impact on the discovery of new medicines. As stressed several times, a loss of jobs is something the member states in particular do not want to see, and it helps to explain why the industry has traditionally lent its support to national governments in opposing any Community pricing policy. Although the industry favours free-pricing as would be the case in a deregulated market, because of the uncertainties over what exactly this would mean in

practice, industry often sides with the member states, using the employment issue as a bargaining-chip when discussing national pricing of its products.

Beyond these few likelihoods, however, nothing about what a single market would bring is certain. There would clearly be winners and losers amongst the stakeholders, but uncertainty and a fear of the unknown (i.e. who 'wins', by how much, who 'pays', etc) means none is committed. The Commission may be convinced of the merits of a single medicines market, but is also aware of the healthcare and social policy implications. In any event, it is unable to engender support even for price deregulation, and it lacks the authority to force the issue. As Kanavos & Mossialos (1999) note:

Clearly the desire to complete a single market passes through national channels but is subject to pressures at the supranational level... the politics involved in national and supranational decision-making add a further dimension, which cannot be ignored. (53)

Completion of the single pharmaceutical market (Commission-driven) is thus unlikely in the short term – achieving outcomes via interest group-politics is in any event a long-term undertaking when attainable. The peculiarity and sensitivity of the sector, as noted by Cecchini already in 1988, has ensured that harmonisation would not prove a straightforward process; thirteen years since publication of the report, ten since the inception of the SEM, and seven since the installation of the EMEA, and there is still no single pharmaceuticals market. Still, as this study has shown, a complex regulatory framework does exist.

In order to be more effective (and equitable), however, the multiple and varied competencies which make up this framework require consolidation under a comprehensive agenda which incorporates healthcare policy aspects as well. Entrusting pharmaceutical policy to the DG whose main duty is to promote European competitiveness, and an agency limited to an advisory role aimed primarily at speeding market approval times, does not amount to an integrated, far less appropriate, regulatory mandate. Here it has been asked why the EMEA is "... located in an industrial institution of the European Commission [DG Enterprise] despite the fact that its mission is 'to promote the protection of human health... and of consumers of medicinal products'." (Presc Int 2002, 9) Continuing to treat medicines as simply another 'good' or 'service' subject to free movement within Europe is not sufficient. However, redressing the framework would require not only a major alteration to the Treaty – to overcome the subsidiarity-free movement clash – it would also mean mitigating the costs and benefits to the stakeholders to ensure their support. Regulatory policy towards the full establishment of a single market is, in theory, achievable via interest-group politics, but the requisite widespread political will is not forthcoming.

2-3 Acknowledging certain limitations

In Chapter 4 it was acknowledged that Wilson's framework is not perfect. Not only is it something of a black and white view, and therefore quite rigid, but dividing policy outcomes into winners and losers scenarios is somewhat simplistic. Regulatory policy is admittedly more nuanced; particularly so for medicines. In addition, the politics of policy seems a view predicated on economic gain (or cost) being actors' primary concern. Interests *vis-à-vis* pharmaceutical regulation clearly go beyond this in incorporating welfare and ethical concerns as well. These short-comings do not, however, detract from the approach's wider value in establishing constraints on the regulator and the different types of politicking which can result from divergent interests (perceptions). It is towards this end that Wilson's typology has been applied to the pharmaceuticals case. This was to help understand actor behaviour within the networks, and what effect (constraints) this would have on the type of regulatory policy-making necessary to achieve an outcome i.e. by showing how and where policy outcomes are likely within the free movement-subsidiarity dissonance given stakeholder preferences and influence.

Moreover, the framework was not employed in isolation. Nor was it held up as the definitive manner of conceiving of EU pharmaceutical policy-making. But as it does help to identify certain issues not captured by other theoretical approaches, it was used as one element in a wider perspective – the configurations of actors' perceived gains and losses were employed within the context of a policy network approach. The application of this view of regulatory policy-making helped to show where and to what extent European medicines policies have been achievable (by establishing certain constraints), and how the networks have behaved. The case-studies demonstrated that policy outcomes have been the result of at least three of the policy-making styles (with the fourth scenario corresponding to the wider question of what an integrated medicines market might mean). It seems that only over policy issues involving a clear concentrated gain or loss to one or more of the stakeholders has action been possible. And while this may be true of any industry and over any type of regulatory intervention, for pharmaceuticals it has major consequences given the ethical and welfare (and healthcare spending) issues at stake.

That different outcomes in the EU pharmaceutical sector fit different dimensions of the politics of policy is an important observation. Regulatory policy-making in other industries would likely correspond to one or perhaps two scenarios at the most. This is because the issues at stake are far less divisive, both on their own merits and with regard to the way in which policy is made. Moreover, the Commission's hands are likely to be somewhat freer. Figure 8-1 thus reflected an industry in which the reaching of regulatory policy-decisions is especially complex. Indeed, when public health and healthcare concerns are coupled with

the interests of a strong and profitable industry, the stakes involved are such that there are bound to be major winners and losers over each policy; the relative per capita gains or losses will also vary significantly. It is because of this that the regulatory intervention under consideration can result in different types of politicking and, ultimately, outcomes.

By employing networks in this manner, it was expected that the study would not only benefit from, but would also contribute to, the current public policy literature by demonstrating the value and applicability of the approach in a complex field. And as it has been shown how aspects of the EU framework correspond to different cells, the typology underlines the politics and complexity of the sector, helping to demonstrate that industry can (and does) come to dominate individual policy networks. What is especially noteworthy from the application of the politics of policy framework, therefore, is that it reveals the multi-dimensional nature of the sector from a policy-making perspective. This goes beyond the market/industry peculiarities and economics of the industry which receive so much attention in the literature. It helps to show what the proscribed Commission role has meant in practice, and what the other stakeholders have done in response. Importantly, as this establishes further constraints beyond the subsidiarity-free movement clash on the Commission's ability to take the harmonisation process forward, it helps to explain the lack of a historically consistent strategy for pharmaceuticals in the Community. In turn, this provides support for the contention that, despite different politicking styles – the regulatory framework is one which tends towards industry's interests.

3 Closing Observations

The reasons for the regulatory framework favouring the industry are therefore clear. Foremost is the stability of industry within the policy-process. As set out in Chapter 1, these are because of: the natural alliance between the Commission's single market priorities and the industry's economic demands; the institutional leaning of the Commission where subsidiarity ensures that it only has competence over industrial policy matters; and the fragmented nature of the market in terms of industry being the only stable actor. All are contributing factors, and require summing up to bring home the arguments.

3-1 Continuing with an industry-oriented framework

Foremost of the three factors is the stability of industry within the policy-process when the other stakeholders were (are) fragmented. As Tables 8-1, 8-2 and 8-3 highlight, the research-based industry was shown to be present at every stage of the policy-process in all three of the case-studies; the policy networks invariably began with the Commission and EFPIA. Moreover, the industry (including generic companies) essentially voiced the same

demands in each case. Indeed, their requirements and arguments about rising research and development costs, stricter national controls, patent-term extension and speed of access to market for new medicines have hardly changed over the 30-plus years since the original 1965 Directive. This institutional as well as agenda stability is in stark contrast to the situation amongst the other stakeholders.

Beginning with the member states, different countries had different priorities at different times. The German government for instance supported the SPC, but had opposed both the Transparency Directive and, initially, the EMEA. Different cost-containment priorities and changing national administrations (elections) has also meant an inconsistent approach to EU pharmaceutical policy. Inconsistency or a lack of stability in the Commission's stance stems from the fact that policy has to be co-ordinated and agreed amongst multiple Directorate-Generals. The effect of this was most apparent over the industrial policy Communication when the social affairs Commissioner (DGV) disagreed with his industrial affairs counterpart (DGIII), forcing a compromise document which took the teeth out of the proposal. A major point of instability was of course the dissolution of the Commission in 1999 – all established lines of contact and process (path dependency) were dissolved – and in particular the resignation of Commissioner Bangemann. His departure was a major disappointment to industry, who praised his contribution to the pursuit of single market at a meeting held in the EMEA offices in April 1999, when he formally said his 'goodbyes' (Gopal 1999). That said, Enterprise Commissioner Liikanen does seem willing to don Dr Bangemann's pro-industry hat. As for consumers, their lack of stability is manifest in being at the fringes of the formal policy-process. In each of the case-studies, consumer interests were not actively involved by the Commission, although some groups were very pro-active in presenting the other side of the story to Parliament. Even then, however, when their interests were picked up by the Parliament or Economic and Social Committee, the Commission was generally hesitant to incorporate them in its policy documents.

Second, the complimentarity between industry's demands and priorities and the Commission's industrial policy (competitiveness) aims, has meant that DGIII was always a likely ally to the industry; indeed, industry always featured in its initial consultations. In the case of the SPC the Commission showed just how keen it was. Here the information used by industry to make its case was uncritically adopted by the Commission, both on its own merits and towards bringing the sector more in line with a single market. This use of information by industry itself contributes to the industry's stability. The same basic arguments, supported with data only it had access to, were reflected in all Commission proposals: the reasons for extending patent-times under the SPC; why medicine registration needed to be speeded via the EMEA; how to tackle price differentials within the context of loss of market position to the US and Japan in the industrial policy

Communication, etc. And here it is again worth noting that the SPC, EMEA and transparency legislation was always debated by the Internal Market Council.

Finally, a pro-active Commission looking to expand its competencies in a field in which it was otherwise constrained has also contributed to a pro-industry framework. Its industrial policy authority stems from member states' adamant over their retention of healthcare competence – not to mention to ensure a contributing industry – and is reinforced by Article 152. The Commission has thus sought to make policy where and when it could; and it could only in matters related to the single market. The bottom-line is that the Commission is unable to legislate over the more social policy elements of pharmaceutical regulation. This is the major constraint it faces where pharmaceutical policy is concerned and, recalling the discussion in Chapter 2, it reiterates the question of regulatory capture.

The literature on economic theories of regulation suggests that one of the ways capture can be assessed – insofar as it is measurable – is through a gradual and creeping pro-industry bias in the work of the regulator. At the national level, the exceptional patent exhaustion rights offered the industry, along with 'local content' requirements and favourable tax arrangements, do perhaps raise questions; governments are thus often accused of complicity. At EU level, the SPC, the EMEA's operations, and the Commission's competitiveness approach seem prime examples. It also appears that companies often collaborate over Community policy as means of bypassing (stricter) national level regulatory policies (recall Chapters 5 and 6). And with a Commission seeking to "... meet the political objectives of a single European market and the commercial agendas of transnational pharmaceutical companies" (Lewis & Abraham 2001, 53), EU pharmaceutical policy may be an example of (supranational) regulatory capture¹⁸⁴.

¹⁸⁴ Further evidence comes from the Commission's review of pharmaceutical legislation (COM 2001). Called for under Regulation 2309/93 establishing the EMEA, and based on a private consultants' report into the agency's work (Cameron McKenna 2000), the review contains several controversial proposals. Foremost is the introduction of a five-year pilot programme whereby companies will be able to provide information about their drugs (for AIDS, asthma and diabetes) via the Internet or in specialised publications on request from a patient or consumer group. This has met with criticism from those who see it as an endorsement of direct-to-consumer advertising of medicines. Although Commissioner Liikanen has stressed that "This is not direct-to-consumer advertising... I am against direct marketing" (as cited in Watson 2001, 184), many medical associations and independent consumer groups are sceptical. On the basis of the US experience with DTC, they fear the effects on prices, healthcare funding, and doctors' authority, especially as DTC has not been shown to bring a health benefit (e.g. HAI 2001, CA 2001). The review does contain proposals for a fast track registration for products of 'major therapeutic interest' (similar to that existing in the US) and the idea of a Europe-wide system of pre-authorisation availability for certain medicines on grounds of 'compassionate use', but these are tempered by recommendations for industry representation on the EMEA management board and reform of the agency mandate to include a role in providing scientific advice to the manufacturers. While these proposals may, in the Commission's words, aim to guarantee the highest possible level of health protection for European citizens via the safety, quality and efficacy criteria, they are clearly designed primarily to speed the authorisation process and improve the industry's competitiveness.

3-2 Broader theoretical considerations

In summary, the theoretical element of the study showed the broad-based relevance of EU integration theories to the development of EU pharmaceutical competencies and drew out some important insights to be gleaned from them. This was tied into the regulatory policy-making (process-oriented) perspective to gain a more complete understanding of how the Commission behaves and how such policy is made. Here Wilson's 'politics of policy' was employed as an important supplement in the use of policy networks. The objective having been to offer a more detailed understanding of the processes at work in shaping European pharmaceutical policy (a theoretical lens), as well as providing the means to test the study's hypothesis¹⁸⁵.

In so-saying, it is nevertheless recognised that the 'macro' and 'meso' address different things, or at least, different tiers. Indeed, Hix's (1994) distinction between theories of European integration and the 'politics of the EU policy-process' was noted in Chapter 3. However, this distinction need not always be thought of so rigidly, especially not when the intent is to provide a more all-round perspective. For it is clear that with a sector as complex as medicines, outcomes (via policy networks) are not achieved in a vacuum. Policy is influenced by the macro-environment as well as by the regulatory environment; in this case, the subsidiarity-free market dissonance and the politics of policy.

This elucidation of a specific analytical framework to analyse EU pharmaceutical policy-making runs the risk of remaining context-specific. As a proponent of new institutionalist theory, Bulmer (1997) has expressed the fear that:

We may end up with a bewildering set of policy cases explained by a further array of analytical frameworks... taken to an extreme, this situation could atomise empirical research on the EU, while failing to identify a common methodological strand for analysis of the different levels of research problem. (1)

Nevertheless, the continuing multiplicity of theoretical variations and illustrations suggests that European policy-making (and ultimately integration) remains a changing and exciting field of study. As one reason for the unique nature of EU governance is that it continues to evolve, it is one which would benefit from continuing research into individual policy cases, even if resulting in the elucidation of policy-specific frameworks – this contributes to a better understanding of the wider process itself. This is not to suggest that Bulmer's fear is unfounded. The call for a 'common methodological strand' to analyse the 'different levels

¹⁸⁵ This also offers some insight into the forces shaping the European polity itself; something which may prove particularly useful when assessing the effects that the next round of accessions may have on the industrial makeup of the EU.

of research problem' is a valuable one. But seeing it as a *de facto* case against the pursuit of frameworks specific to individual policy issues seems an unnecessary corollary.

Policy-making inter-dependencies and relationships which characterise national administrations do not feature (or at least are not yet fixed) at supranational level. Moreover, different policy fields generate their own policy-making dynamics, particularly where complex issues are at stake. Again pharmaceuticals have here been shown to be a very unique case. Understanding policy-making in this sector – in particular the constraints involved and the Commission's inhibited role – necessitates the specific analytical framework provided. That said, the study has sought a more integrated perspective in order to grasp the wider development of Community medicine competencies within the context of the SEM.

In this vein, the study can be seen as having broadly conformed to a new-institutionalist frame of analysis, even if not representing a strict application. As mentioned in Chapters 3 and 4, elements of the discussion, including how actors behave *vis-à-vis* pharmaceutical policy within the EU's formal decision-making structures, how their preferences are shaped by past actions, and how the member states operate within Scharpf's (1988) 'joint decision trap' are in keeping with such a framework. However, the focus was on meso-level interactions over specific policy issues – what the stakeholders' interests were, how they pursued them, and in what manner this affected outcomes. The study thus employed theories germane to 'different levels of the research problem' towards showing how they can be used to better understand policy-making for pharmaceuticals in the SEM. Moreover, the discussion has sought to establish linkages between them. Admittedly, over-laying or using several approaches in tandem may not be what Bulmer is calling for. But the complexity of the pharmaceutical case seems best captured by such a lens.

3-3 Possibilities for future research

Despite the theoretical limitations outlined, both the nature of the study and the approach used suggest potential further areas of research. For instance, the discussion sought to employ the interest-intermediation conception of policy networks towards characterising policy-making in the sector. As such the governance aspect of the approach has necessarily been neglected. And though scholars such as Dowding (1995) are unconvinced about this perspective in particular, it is the author's opinion that considering the network as a dynamic unto itself is indeed valid; especially within the EU as a *sui generis* policy-making system. Indeed, some scholars claim that "... the governance structure of a network shapes the incentives of the participants and induces the latter to act in a specific way"; such that "... policy network analysis explains the development of public

policies in terms of complex exchange and transaction processes between network actors within given institutional restrictions." (Windhoff-Héritier 1993, 44 & 149) Hence, using it as a theory for explaining governance at the supranational level, and relating this to pharmaceutical policy could be pursued as an area for future research. In particular, the interplay between national and subnational, the emergence of a transnational European pharmaceutical network, and the effect of comitology are all potentially interesting areas. Multi-level governance would seem the natural theoretical backbone to which such analysis could be fused.

Future research might also concentrate to a greater extent on the meso-level than was undertaken here. It would be interesting to break down the stakeholders further. Beyond citing the positions of different member states as this study has done, closer inspection is likely to reveal that different ministries (health, finance, competition, etc) were involved in different policy networks. Just as EFPIA first approached the Competition DG about patent-term extension before selling the idea to the Industrial Affairs DG, it would be interesting to compare which ministries took what decisions in each member state. This would further reveal the extent to which the countries have different priorities. A similar line could be adopted with regard to the Commission – which DG was most involved in preparing the legislation and what sort of consultation took place – as well as to the Council of Ministers – which Council approved which piece of legislation, and how did the member states vote. Such differences have only been hinted at here. These lines of enquiry are also likely to strengthen this study's contention that the industry has been able to dominate the policy networks by being the only stable actor throughout.

Ruled out for the purposes of this study, a quantitative approach could perhaps be adopted for future policy initiatives. It may be possible to quantify inter-network relationships on the basis of recorded interactions – although the researcher would have to overcome the major obstacles posed by the lack of transparency. Indeed, the informational asymmetries which characterise the sector at both national and EU level could also be studied more closely; particularly the informational monopoly held by the companies. As Davis (1997) notes, "... the pharmaceutical arena is 'data rich', but access to these data is hedged about by restrictions imposed by law, by regulation, by commercial covenant and by financial ability." (148) This too would underline the role of industry in the policy-process.

Finally, it may also be possible to apply the study's theoretical lens elsewhere. This may reveal whether actors or stakeholders in other sectors have also been able to benefit from specific regulatory interventions by dominating policy networks to their advantage. That said, the politics of policy framework seems especially interesting in the case of

pharmaceuticals because of the sector's unique characteristics, including the different policy inputs and pressures which define it.

In the opening chapter it was stated that the pharmaceutical sector is an inherently political one in involving three often conflicting inputs: public health, healthcare and industrial policy. That the outcome is a clash between governments' political and economic priorities is widely-recognised, especially as it contributes to distinguishing pharmaceuticals as peculiar in comparison to other industrial sectors. Yet, there are few political examinations of how supranational decisions are taken despite the fact that this clash is manifest in a tension between the healthcare autonomy of the member states and the imperatives of the single market; not to mention given the Commission's limited competence. There has instead been an overwhelming focus on the economic and legal issues associated with what is an economically very important industry.

This represents something of an oversight. While economic determinants are central elements in the policy-process, and ought therefore to be widely examined, they do not on their own decide outcomes. 'Politics' in the sense of competition for influence, bargaining between actors and achieving compromise outcomes is, as the study has shown, at least an equally prominent consideration. Even at national level, the salience of political bargaining by groups of (aggregated) interests in the debates on cost-containment, pricing strategies and general healthcare reform *vis-à-vis* medicines, has yet to receive the notice it is due. The role of politics in explaining regulatory policy outcomes in the European pharmaceutical sector has generally been ignored. It is this gap in the literature which the present study has sought to address. In doing so – by focusing mainly on stakeholder behaviour in policy networks – the study has demonstrated the political struggle between health(care) and industrial interests in having led to the current framework. More importantly, it revealed a Community regulatory regime which ultimately favours producer interests before those of consumers.

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APPENDIX 2-1: EU Member States' Pharmaceutical Supply and Demand Regulatory Measures (cost-containment mechanisms)

	REGULATORY MECHANISM	OBJECTIVE	NATIONAL DIFFERENCES	COUNTRIES
Supply-Side Measures	Price-capping (average prices and/or maximum price agreements)	Formula to calculate prices based on other EU and international prices	Mechanism and methodology	DAN, IRE, ITA, NETH, POR, SWE
	Negotiated pricing	Other EU and international prices may be taken into account	Countries used as comparators	DAN, FRA, GRE, IRE, ITA, NETH, SPA, SWE
	Compared prices	Cost taken into consideration	Products used as comparators	BEL, SPA
	Price cuts	Control drug expenditure	Degree and length	BEL, DAN, IRE, UK
	Price-to-volume arrangements	Linking price to volume to control expenditure	Volume levels	AUT, FRA, SPA, SWE
	Cost-effectiveness and 'pharmacoeconomic' pricing	Establish 'fair' price according to cost-benefit comparison	Methodology	DAN, FIN, IRE, NETH, PORT, SWE, UK
	Drug lists and formularies	Control drug costs by improving prescribing patterns	Consumption patterns (national or regional)	Positive lists: AUT, BEL, DAN, FIN, FRA, IRE, ITA, NETH, POR, SPA, SWE Negative lists: DEU, SPA, SWE, UK
	Reference pricing or fixed reimbursement	Lower prescription costs	Products included, and pricing formulae	BEL, DAN, DEU, ITA, NETH, SPA, SWE
	Profit control	Equilibrium between industry requirements and affordability of medicines	-	UK
Demand and Proxy-Demand-Side Measures	Co-payments	Cost reduction through patient charges	Rate of co-payment	AUT, FIN, POR, SPA, UK
	Generic substitution	Control demand-side expenditure by targeting pharmacists	-	UK
	Generic prescribing	Reducing doctors choice of/preference for branded medicines in favour of generic preparations	-	UK
	Prescription controls	Limit unnecessary prescribing	-	BEL, DEU, FIN, UK
	Prescription budgets/targets for doctors	Limit drug expenditure by influencing volume or cost of drugs prescribed by doctors	Level of implementation, and type of incentives/penalties	GER, FRA, IRE, EUK
	Drug utilisation reviews	Checking doctors' prescribing habits to identify unnecessary or over-prescribing	Targets, methodology and implementation (national or regional)	GER, UK

AUT: Austria

BEL: Belgium

DAN: Denmark

DEU: Germany

FIN: Finland

FRA: France

GRE: Greece

IRE: Ireland

ITA: Italy

LUX: Luxembourg

NETH: Netherlands

POR: Portugal

SPA: Spain

SWE: Sweden

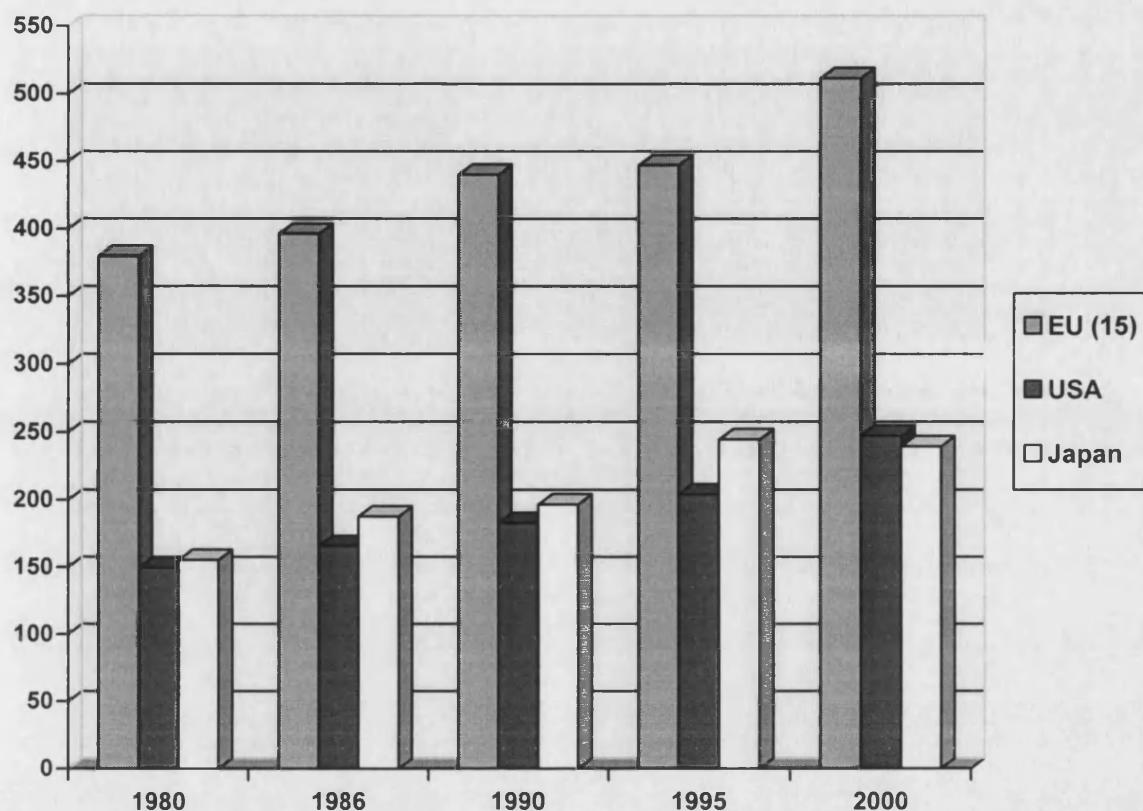
UK: United Kingdom

APPENDIX 2-2: EU Member State Pharmaceutical Production (million €), 1986-2000

MEMBER STATE	1986	1990	1995	2000
AUSTRIA	n.a.	n.a.	1,848	1,548
BELGIUM	805	1,133	2,400	4,203
DENMARK	898	1,317	2,491	3,609
FINLAND	285	457	461	600
FRANCE	10,401	15,088	22,623	25,174
GERMANY	9,277	12,210	17,443	18,558
GREECE	230	357	601	438
IRELAND	365	632	1,809	5,657
ITALY	7,621	12,133	13,821	14,668
LUXEMBOURG	n.a.	n.a.	n.a.	n.a.
NETHERLANDS	1,290	1,772	3,051	5,013
PORTUGAL	275	467	558	752
SPAIN	2,514	4,624	6,272	7,283
SWEDEN	n.a.	1,518	3,076	5,295
UNITED KINGDOM	5,027	7,350	10,801	19,755
TOTAL (EU 15)	41,139	60,383	86,955	113,125

Sources: EUROSTAT (1998), EFPIA (2002).

**APPENDIX 2-3: Employment in the Pharmaceutical Industry (thousands), 1980-2000
(EU, US & Japan)**



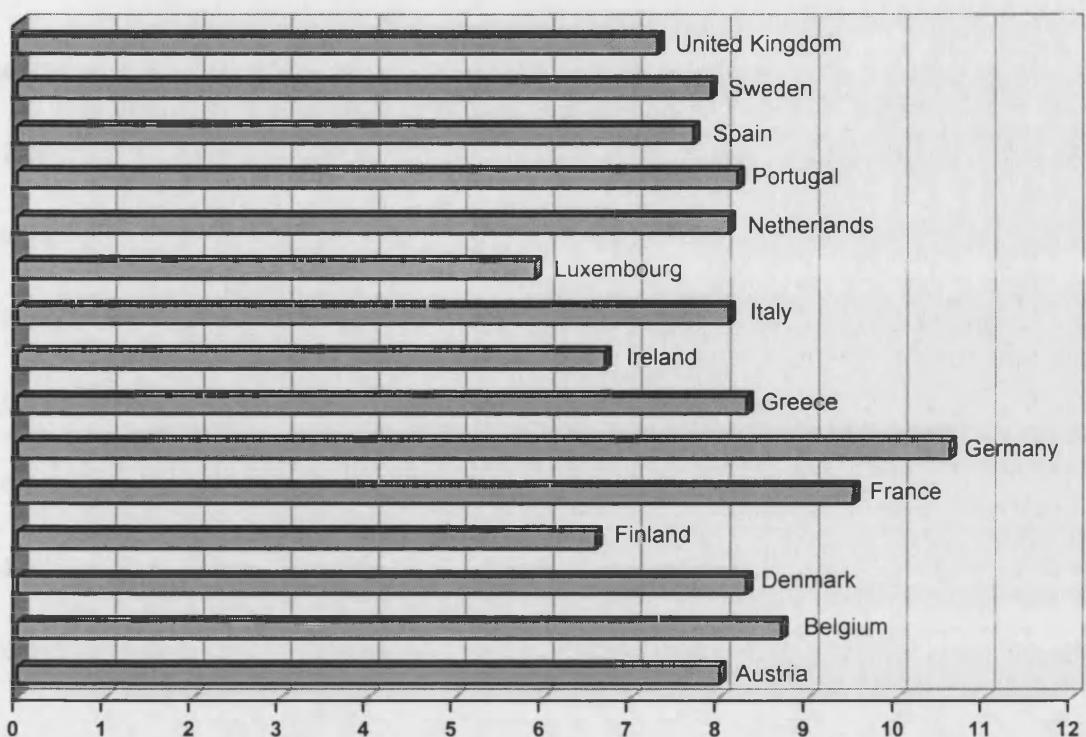
Sources: EUROSTAT (1998), EFPIA (2002), JPMA (2002), PhRMA (2002).

APPENDIX 2-4: EU Member State Employment in the Pharmaceutical Industry, 2000

MEMBER STATE	NUMBER EMPLOYED
AUSTRIA	9,200
BELGIUM	22,713
DENMARK	17,574
FINLAND	6,544
FRANCE	95,300
GERMANY	114,581
GREECE	11,500
IRELAND	16,000
ITALY	72,559
NETHERLANDS	13,200
PORTUGAL	938
SPAIN	38,700
SWEDEN	18,700
UNITED KINGDOM	65,000
TOTAL	511,959

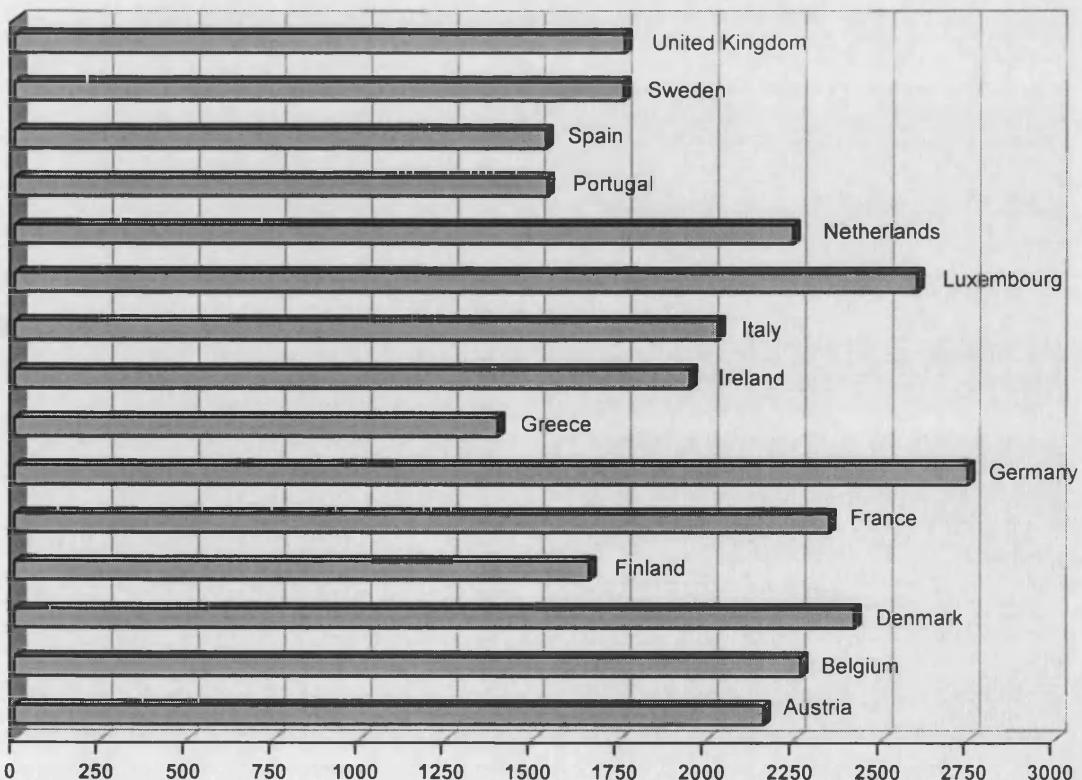
Source: EFPIA (2002).

APPENDIX 2-5: EU Member States' Total Expenditure on Health (% GDP), 2000



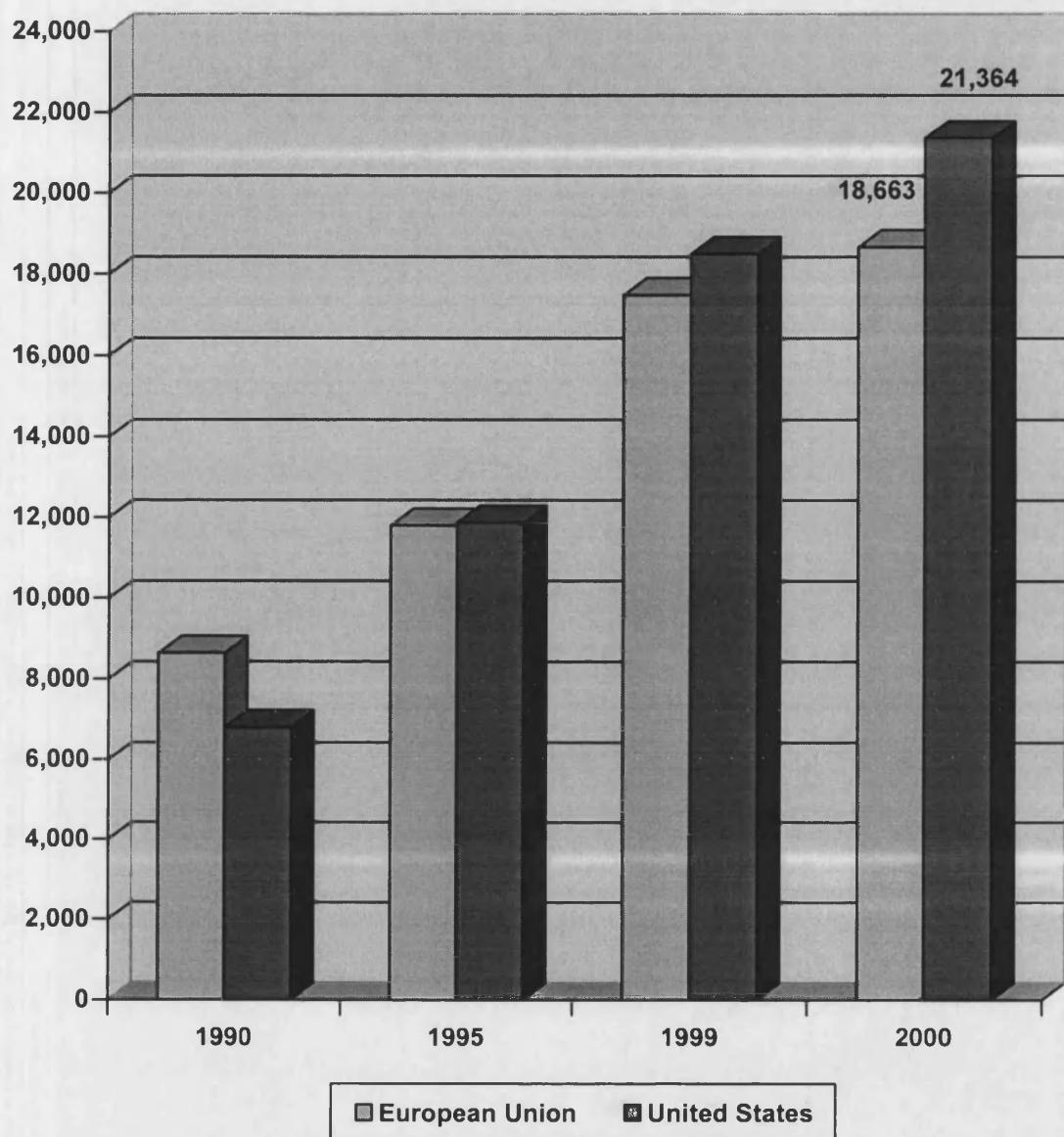
Source: OECD Health Data, 2002

APPENDIX 2-6: EU Member States' Total Expenditure on Health (per capita US\$), 2000



Source: OECD Health Data, 2002

APPENDIX 2-7: Domestic Research & Development Spending (US\$ million, EU versus US), 1990-2000



Source: PhRMA (2002).

APPENDIX 2-8: European Legislation vis-à-vis Medicinal Products for Human Use, 1965-2001

LEGISLATION IN FORCE - NAME AND TYPE*	OJ REFERENCE [▼]
Council Directive (65/65/EEC) of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products.	L22 09.02.65 p.369
Council Directive (75/318/EEC) of 20 May 1975 on the approximation of the laws of Member States relating to analytical, pharmacotoxicological and clinical standards and protocols in respect of the testing of medicinal products.	L147 09.06.75 p.1
Council Directive (75/319/EEC) of 20 May 1975 on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products.	L147 09.06.75 p.13
Council Decision (75/320/EEC) of 20 May 1975 setting up a Pharmaceutical Committee.	L147 09.06.75 p.23
Council Directive (78/25/EEC) of 12 December 1977 on the approximation of the laws of the Member States relating to the colouring matters which may be added to medicinal products.	L11 14.01.78 p.18
Council recommendation (83/571/EEC) of 26 October 1983 concerning tests relating to the placing on the market of proprietary medicinal products.	L332 28.11.83 p.11
Council recommendation (87/176/EEC) of 9 February 1987 concerning tests relating to the placing on the market of proprietary medicinal products.	L73 16.03.87 p.1
Council Directive (89/105/EEC) of 21 December 1988 relating to the transparency of measures regulating the pricing of medicinal products for human use and their inclusion within the scope of national health insurance systems.	L40 11.02.89 p.8
Council Directive (89/342/EEC) of 3 May 1989 extending the scope of Directives 65/65/EEC and 75/319/EEC and laying down additional provisions for immunological medicinal products consisting of vaccines, toxins or serums and allergens.	L142 25.05.89 p.14
Council Directive (89/343/EEC) of 3 May 1989, extending the scope of Directives 65/65/EEC and 75/319/EEC and laying down additional provisions for radiopharmaceuticals.	L142 25.05.89 p.16
Council Directive (89/381/EEC) of 14 June 1989 extending the scope of Directives 65/65/EEC and 75/319/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products and laying down special provisions for medicinal products derived from human blood or human plasma.	L181 28.06.89 p.44
Commission Directive (91/356/EEC) of 13 June 1991 laying down the principles and guidelines of good manufacturing practice for medicinal products for human use.	L193 17.07.91 p.30
Council Directive (92/25/EEC) of 31 March 1992 on the wholesale distribution of medicinal products for human use.	L113 30.04.92 p.1
Council Directive (92/26/EEC) of 31 March 1992 concerning the classification for the supply of medicinal products for human use.	L113 30.04.92 p.5
Council Directive (92/27/EEC) of 31 March 1992 on the labelling of medicinal products for human use and on package leaflets.	L113 30.04.92 p.8
Council Directive (92/28/EEC) of 31 March 1992 on the advertising of medicinal products for human use.	L113 30.04.92 p.13
Council Regulation No (EEC) 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products.	L182 02.07.92 p.1
Council Directive (92/73/EEC) of 22 September 1992 widening the scope of Directives 65/65/EEC and 75/319/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products and laying down additional provisions on homeopathic medicinal products.	L297 13.10.92 p.8
Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products.	L214 24.08.93 p.1
Council Regulation (EC) No 297/95 of 10 February 1995 on fees payable to the European Agency for the Evaluation of Medicinal Products.	L35 15.02.95 p.1
Commission Regulation (EC) No 540/95 of 10 March 1995 laying down the arrangements for reporting suspected unexpected adverse reactions which are not serious, whether arising in the Community or in a third country, to medicinal products for human or veterinary use authorized in accordance with the provisions of Council Regulation (EEC) No 2309/93.	L55 11.03.95 p.5
Commission Regulation (EC) No 541/95 of 10 March 1995 concerning the examination of variations to the terms of a marketing authorization granted by a competent authority of a Member State.	L55 11.03.95 p.7
Commission Regulation (EC) No 542/95 of 10 March 1995 concerning the examination of variations to the terms of a marketing authorization falling within the scope of Council Regulation (EEC) No 2309/93.	L55 11.03.95 p.15
Commission Regulation (EC) No 1662/95 of 7 July 1995 laying down certain detailed arrangements for implementing the Community decision-making procedures in respect of marketing authorizations for products for human or veterinary use.	L158 08.07.95 p.4
Council Resolution (96/C 136/04) of 23 April 1996 designed to implement the outlines of an industrial policy in the pharmaceutical sector in the European Union.	C136 08.05.96 p.4
Council Regulation (EC) No 1610/96 of the European Parliament and of the Council of 23 July 1996 concerning the creation of a supplementary protection certificate for plant protection products.	L198 08.08.96 p.30
Commission Regulation (EC) No 2141/96 of 7 November 1996 concerning the examination of an application for the transfer of a marketing authorization for a medicinal product falling within the scope of Council Regulation (EEC) No 2309/93.	L286 08.11.96 p.6
Council Directive (1999/83/EC) of 8 September 1999 amending the Annex to Council Directive 75/318/EEC on the approximation of the laws of the Member States relating to analytical, pharmacotoxicological and clinical standards and protocols in respect of the testing of medicinal products.	L243 15.09.99 p.9
Commission Regulation (EC) No 141/2000 of 16 December 1999 on orphan medicinal products	L18 22.01.00 p.1
Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use.	L121 01.05.01p.34
Commission Regulation (EC) No 847/2000 of 27 April 2000 laying down the provisions for implementation of the criteria for designation of a medicinal product as an orphan medicinal product and definitions of the concepts 'similar medicinal product' and 'clinical superiority'	L130 28.04.00 p.5
Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use.	L311 28.11.01 p.67
Convention on the elaboration of a European Pharmacopoeia.	L158 25.06.94 p.19
Protocol to the Convention on the elaboration of a European Pharmacopoeia.	L158 25.06.94 p.22

*Listed under Sub-section 13.30.15 (Proprietary Medicinal products) of the Analytical Register of Community Legislation in Force. Section 13 is 'Industrial policy and Internal Market'; Section 13.30 is 'Internal Market: approximation of laws'.

[▼]Official Journal of the European Communities.

Source: adapted from EudraLex Volume 1: Medical Products for Human Use (<http://dg3.eudra.org/F2/eudralex/vol-1/home.htm>, last accessed 01.08.02).

APPENDIX 4-1: Principal National Actors and Policy Objectives in the Pharmaceutical Sector

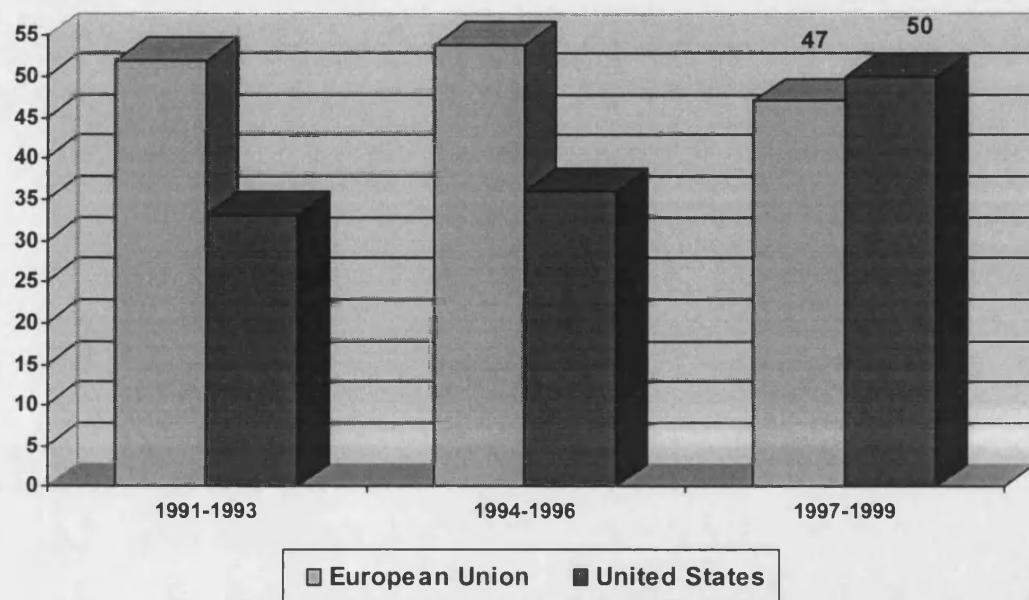
SECTOR	ENTITY	POLICY OBJECTIVES
STATE Regulation Funding Delivery Economic	<i>Ministries</i> health finance service trade, industry	<ul style="list-style-type: none"> adequate supply of safe, quality and effective medicines minimise tax-funded health expenditure maximise access to care for those most in need encourage local industry, employment, exports
INDUSTRY innovation reproduction	<i>Firms</i> research generic	<ul style="list-style-type: none"> maximise profits and safeguard research base improve competitive position
DISTRIBUTION & INSURANCE distribution insurers	<i>Firms</i> wholesalers companies	<ul style="list-style-type: none"> improve margins segment market to best advantage
PROFESSIONS prescribing dispensing	<i>Associations</i> medicine pharmacy	<ul style="list-style-type: none"> maximise autonomy and meet patient needs enlarge professional role and meet client needs
HEALTH SERVICE primary secondary regional	<i>Organisations</i> practices hospitals health systems	<ul style="list-style-type: none"> maintain local visibility and community support maintain market share and organisational visibility meet requirements of key stakeholders
OTHER consumers scientific community media	<i>Various</i> associations/patient groups journals firms	<ul style="list-style-type: none"> ensure access to safe and effective drugs advance knowledge and academic freedom enhance or maintain market segment

Source: adapted from Davis (1997), 21.

APPENDIX 4-2: Selected Actors and Affected Interests in the EU Pharmaceutical Sector

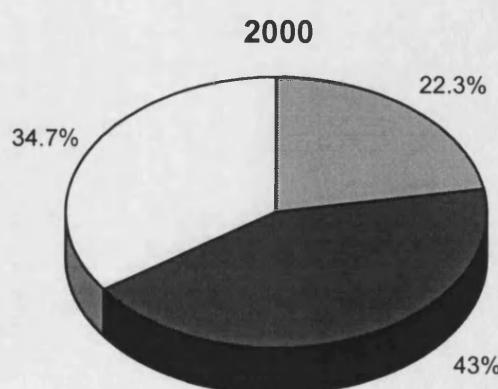
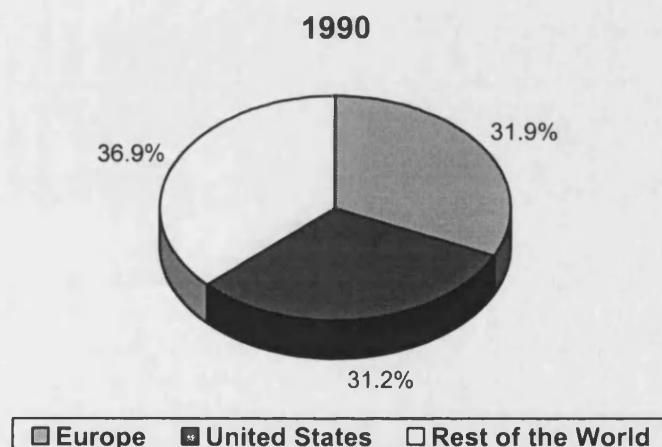
Primary Stakeholder	Actor Type	Example
Consumers	Patient/Consumer groups National EU level	Consumers' Association (UK) BEUC (<i>Bureau Européen des Unions des Consommateurs</i>)
	Disease-specific patient organisations National EU level	<i>Patientföreningar (SWE)</i> European Foundation for Osteoporosis
Industry	Manufacturers Proprietary medicines Generics	Companies e.g. Glaxo-Wellcome plc (UK) Companies e.g. PHC Pharmachemie (NED)
	Industry groups (national): Ethical OTC Generics Industry Groups (EU): Ethical OTC Generics	BPI (Association of the German Pharmaceutical Industry) PAGB (Proprietary Association of Great Britain) <i>Aschimfarma</i> (Italian Association of Bulk Pharmaceutical Chemicals Producers) EFPIA (European Federation of Pharmaceutical Industry Associations) AESGP (Association of the European Self-Medication Industry) EGA (European Generic medicines Association)
Member States	National governments	Ministries of Health
	Regulatory agencies	MCA (Medicines Control Agency, UK) BIRA (British Institute for Regulatory Affairs)
European Union	Medical Associations	BMA (British Medical Association)
	European Commission	Working Parties
	Council of Ministers (EMEA)	COREPER (<i>Comité des Représentants Permanents</i>) (CPMP (Committee on Proprietary Medicinal Products))
Secondary Stakeholder	Actor Type	Example
European Union	European Parliament	ENVI (Committee on the Environment, Public Health and Consumer Protection)
	Committees	Regulatory Committee Pharmaceutical Committee Transparency Committee
Health Professionals	Doctor Organisations	Standing Committee of European Doctors
	Pharmacist Groups	PGEU (Pharmaceutical Group of the EU)
Other	Nursing Organisations	FINE (Federation of European Nurse Educators)
	National Pharmaceutical Associations	PhRMA (Pharmaceutical Research and Manufacturers of America) JPMA (Japan Pharmaceutical Manufacturers Association)
	International Pharmaceutical Associations	IFPMA (International Federation of Pharmaceutical Manufacturers Association) IGPA (International Generic Pharmaceutical Alliance)
	International Trade or Industry Bodies	GATT (General Agreement on Trade and Tariffs) TRIPS (Trade-Related Intellectual Property Rights Agreement) ICH (International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use) WTO (World Trade Organization)
	International Organisations	WHO (World Health Organization)

APPENDIX 5-1: New Medicines Placed on the World Market (EU versus US), 1991-1999



Source: EFPIA (2001b)

APPENDIX 5-2: Breakdown of the World Pharmaceutical Market, 1990 & 2000



Sources: IMS Health data, EFPIA (2001b), EFPIA (2002).

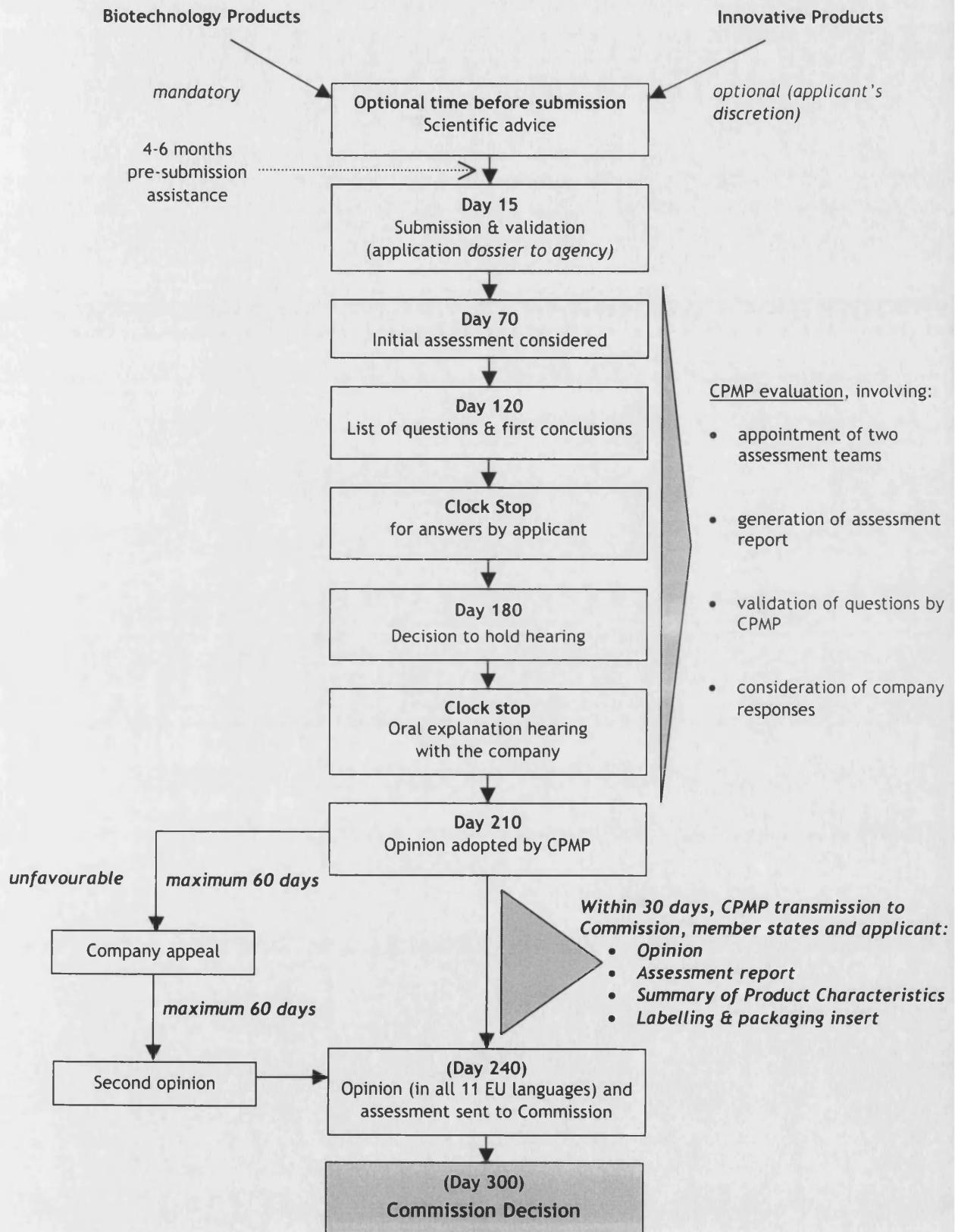
APPENDIX 6-1: Main Points of Comparison between the EU Agencies

Agency	Based	Operational	Purpose	Staff*	Budget/Funding*
Community Plant Variety Office (CPVO)	Angers (Fr)	1994	Implements and applies the European system for protecting plant variety rights (intellectual property)	30	8,200,000 90% from fees
European Agency for Safety and Health at Work (EASHW)	Bilbao (Sp)	1996	Works to support the EU institutions and the public with information on better managing safety and health in workplace	40	6,900,000 97% Community subsidy
European Agency for the Evaluation of Medicinal Products (EMEA)	London (UK)	1995	Co-ordinate existing network of national experts regarding the supervision and authorisation of medicines (human and veterinary) in the Community	200	70,000,000 70% from fees
European Centre for the Development of Vocational Training (CEDEFOP)	Thessaloniki (Gr)	1975	Assist policy-makers, Commission, the member states and social partners across Europe in making informed choices about vocational training policy	100	14,00,000 97% Community subsidy
European Environment Agency (EEA)	Copenhagen (Den)	1994	Management of a European observation and information dissemination network; helping to support sustainable development and to help achieve significant and measurable improvement in Europe's environment	100	18,300,000 97% Community subsidy
European Foundation for the Improvement of Living and Working Conditions (EFILWC)	Dublin (Ire)	1975	Contribute to the planning and establishment of better living and working conditions in the Community	90	15,000,000 97% Community subsidy
European Monitoring Centre for Drugs and Drug Addiction (EMCDDA)	Lisbon (Por)	1995	Co-ordination of a European observation network; provide the Community and member states with information concerning drugs and drug addiction and their consequences	50	10,000,000 90% Community subsidy
European Training Foundation (ETF)	Turin (It)	1995	Assist partner countries in reforming and modernising their vocational education and training and employment systems (including non-EU states)	130	16,800,000 97% Community subsidy
Office for Harmonisation of the Internal Market (Trade Marks and Designs) (OHIM)	Alicante (Sp)	1994	Co-ordinates and issues Community trademarks	700	113,600,000 97% from fees
Translation Centre for Bodies of the European Union (TCBEU)	Luxembourg (Lux)	1997	Serve translation needs of the Community agencies; working to promote collaboration and achieve economies of scale in the translation field	130	23,000,000 90% from fees

* Approximate.

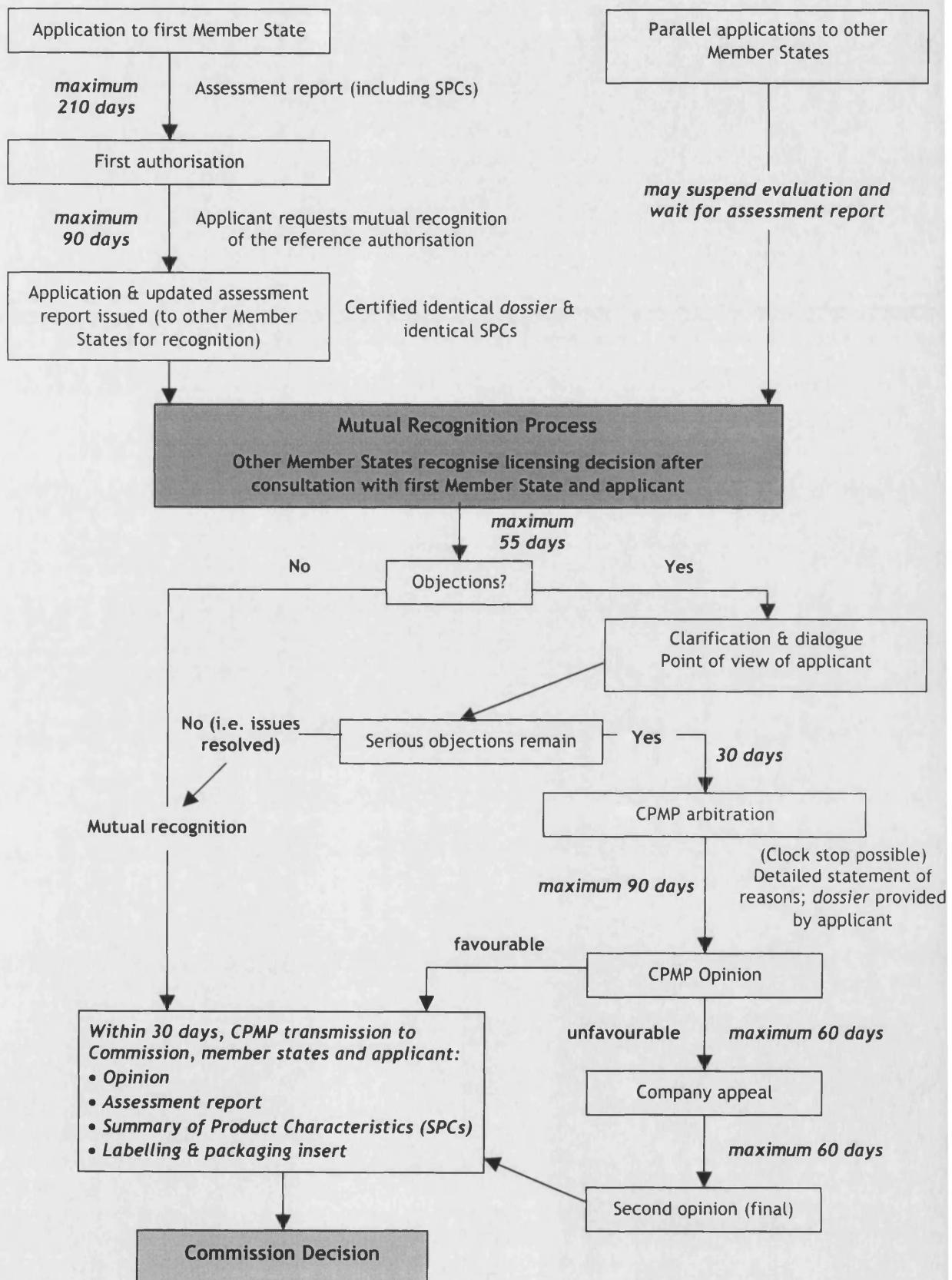
Sources: Mission statements of the agencies, and Reports of European Court of Auditors.

APPENDIX 6-2: EMEA Centralised Procedure



Sources: adapted from Jeffreys (1995) & COM (2001).

APPENDIX 6-3: EMEA Decentralised Procedure



Sources: adapted from Jeffreys (1995) & COM (2001).