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Analysis

High drug prices are not justified by industry's spending on research and development spending

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KEY MESSAGES

- From 1999 to 2018, the world's 15 largest biopharmaceutical companies spent more on selling, general, and administrative activities (\$2.2 trillion) than on research and development (\$1.4 trillion), although the gap narrowed over time.
- Most of these companies also spent more on share buybacks and dividends than on research and development.
- Most new medicines developed during this period offered little or no added benefit over existing treatments, making it difficult to sustain the argument that high prices are needed for valuable innovation.
- The biopharmaceutical industry could generate more medically valuable innovation with existing resources using affordable pricing, but government action would be needed along the lifecycle of new medicines.

30 **Contributors and sources**

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32 Tropical Medicine and a Visiting Fellow at the London School of Economics; he was a 2021-
33 2022 Scholar at the National Institute for Health and Care Excellence. RP graduated with an
34 MSc in International Health Policy from the London School of Economics and works at a
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40 European Observatory on Health Systems and Policy and has written over many years on
41 pharmaceutical policy, including drug pricing, reimbursement schemes, and medicines
42 regulation. All sources of information used in this article are publicly available. AA is the
43 guarantor of the article.
44
45

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50

51 **Patient involvement**

52 No patients were involved.
53
54

55 **Conflicts of Interest**

56 We have read and understood [BMJ policy on declaration of interests](#) and have the following
57 interests to declare:
58

59 AA declares past research grants from Novartis and Krystal Biotech, advisory fees from the
60 European Commission, and shares ownership in a health tech company developing
61 software tools for decision-making; none relate to the topic of this work. RP was previously
62 employed in the mergers and acquisitions team of Roche's diagnostics division.
63
64

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73 High drug prices are not justified by industry’s spending on research and
74 development

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76 *Angelis and colleagues question the industry’s claim that high drug prices are necessary to*
77 *sustain valuable medical innovation. They examine the amount spent by biopharmaceutical*
78 *companies on research and development vs other budget items, like marketing and share*
79 *buybacks, and they also review the evidence around the added clinical benefits of new*
80 *drugs.*

81

82 ***The longstanding debate over fair drug pricing***

83

84 Concerns over the prices of new medicines have been growing over the past decade. In the
85 US, estimated net prices of newly launched prescription drugs have increased from a
86 median of around \$1,400 in 2008 to over \$150,000 in 2021.¹ Zolgensma, a gene therapy
87 approved by the US Food and Drug Administration (FDA) in 2019 for spinally muscular
88 atrophy, was at the time of approval the most expensive drug ever, with a price of over \$2
89 million for a single dose treatment.² Several more recent rare disease drugs are priced even
90 higher,³ with Hemgenix becoming approved by the FDA for hemophilia B in November 2022,
91 becoming the newest most expensive therapy at \$3.5 million per dose.⁴ But even old and
92 very common medications have seen inexplicable price increases: in the US, the list price of
93 some insulin products has increased more than 2-fold from 2007 to 2018⁵, while a US
94 government report identified 1,216 products whose prices rose above inflation between July
95 2021 and July 2022, with an average increase of 31.6% but in some cases much more. For
96 example, the price of sulfasalazine, first approved in 1950, increased by 100% over this
97 period, while the price of fluconazole, available since 1988, increased by 1000%.⁶

98

99 The biopharmaceutical industry has long argued that high prices are needed to sustain
100 research and development (R&D) for new medicines. When asked to justify a price tag of
101 \$10,000 per month for a drug used to treat prostate cancer, a senior executive at Johnson &
102 Johnson responded: “The easy diseases have largely been solved. It gets harder and harder
103 as we go after new treatments for ever more challenging diseases.”⁷ Pharmaceutical
104 companies frequently note how their shareholders and investors could easily shift their
105 investments to other more profitable and less risky sectors. Indeed, there are large financial
106 risks associated with bringing new medicines to market, as many candidate molecules will
107 not make it because they are ineffective or harmful, or both.

108

109 There are, however, reasons to be sceptical of these arguments, given that the
110 pharmaceutical industry is one of the most profitable sectors.^{8,9} Although comparisons of

111 profits by the pharmaceutical and other industries are complicated due to accounting rules,¹⁰
112 data suggest that pharmaceutical companies are particularly profitable, even after adjusting
113 for R&D spending as a share of revenues.⁸ There also seems to be a disconnect between
114 product R&D costs and prices. One recent study found no association between how much
115 pharmaceutical companies spend on R&D and the prices they charge for new medicines.¹¹
116 The industry's justification of high drug prices also ignores the sizeable public investments
117 into drug discovery and development, which has contributed to the basic and translational
118 research underpinning all new drugs approved by the US Food and Drug Administration
119 (FDA) from 2010 to 2016;¹² more than 1 in 4 new drugs approved by the US FDA from 2008
120 to 2017 were linked to public investment during the late stages of development.¹³ This
121 means that society is potentially paying twice for new drugs, first in the form of publicly-
122 subsidised research and second through high product prices.¹⁴

123

124 As we show in this Analysis article, the largest biopharmaceutical companies spent more
125 over the past two decades on selling, general and administrative (SG&A) activities—a
126 heading that includes almost all business costs not directly attributable to making a product
127 or performing a service, including marketing and advertising—than on R&D, which includes
128 both preclinical and clinical research. In most years, these companies also spent more on
129 share buybacks. Taken together with evidence that most new medicines offer little added
130 benefit over existing therapies, this makes us question the claim that high drug prices are
131 needed to sustain R&D for valuable innovation.

132

133 ***Biopharmaceutical companies spend more on SG&A and share buybacks than on***
134 ***R&D***

135

136 Based on publicly available financial reports from 1999 to 2018, the 15 largest
137 biopharmaceutical companies earned a total of \$7.7 trillion in revenues from 1999 to 2018.
138 Over this period, they spent \$2.2 trillion on SG&A activities and \$1.4 trillion on R&D (Figure
139 1). The precise details of what is included within R&D and SG&A activities can be unclear,
140 with boundaries somewhat blurred. For example, companies may conduct so-called seeding
141 trials as part of the reported R&D spending, with these trials having been described as
142 “company-sponsored trials of approved drugs that appear to serve little or no scientific
143 purpose”,¹⁵ and considered by some as marketing strategies.¹⁶ Notwithstanding this
144 limitation, it is clear that companies spent more on SG&A than on R&D every year from 1999
145 to 2018, which is consistent with earlier evidence from 1975-2007.¹⁷

146

147 Most of the same companies also spent more buying their own stocks, a practice known as
148 share buybacks, than on R&D during this period. Share buybacks are expected to lift share
149 prices and thus benefit shareholders, including senior company executives whose income is
150 often directly linked to the share price. A drug pricing investigation by the US House
151 Committee on Oversight and Reform revealed that, from 2016 to 2020, the 14 largest
152 pharmaceutical companies spent \$577 billion on share buybacks and dividends—\$56 billion
153 more than on R&D—at a time when annual executive compensation grew by 14%.¹⁸ The
154 findings of the Committee’s report were consistent with earlier findings by the Institute for
155 New Economic Thinking.¹⁹ Using data from 2006-2015, the Institute found that 18 large US
156 pharmaceutical companies spent more on share buybacks and dividends than on R&D,¹⁹
157 seemingly prioritising short-term financial returns over long-term investments in innovation.
158 This spending reflects the growing financialisation of the pharmaceutical industry in the past
159 decades, which has generally focused on maximising shareholder value.²⁰ At the same time,
160 share buybacks may signal that a company has more cash than investment opportunities
161 (that is, there are not enough potentially profitable projects to enter into the portfolio), and
162 therefore the company chooses to return “unproductive” cash on the books to shareholders.
163 However, if excessive buybacks take place repeatedly over many years, it raises questions
164 about commitments to truly valuable and risky biopharmaceutical R&D.

165
166 While companies spent more on both SG&A activities and share buybacks than on R&D
167 over the past two decades, SG&A expenses (as a share of revenue) dropped from 35% to
168 27% over this period while R&D spending increased from 16% to 21% (Figure 2). This is
169 consistent with data for the 10 pharmaceutical companies with the largest R&D budgets
170 between 2005 and 2015.²¹

171
172 We also know that pharmaceutical companies engage in mergers and acquisitions to access
173 promising new products.²² Alongside evidence that large pharmaceutical companies are not
174 involved in the discovery of most new drugs,²³ this suggests a shift of strategy from early-
175 stage research and discovery to late-stage acquisition and development.

176

177 ***The real innovation crisis: most new drugs provide no added clinical benefit***

178

179 While manufacturers, regulators, payers, clinicians, and patients may differ in their views of
180 what constitutes pharmaceutical innovation, Light and Lexchin argued that the “real
181 innovation crisis” in pharmaceutical R&D does not relate to the absolute number of new
182 drugs approved, but rather the proportion representing therapeutic advances.

183

184 In the 1970s and the 1980s, it was estimated that around 1 in 6 (16%) new drugs approved
185 by the US FDA offered important therapeutic gains, based on FDA-assigned scores.²⁴

186 Another study covering products approved from the mid-1970s to mid-1980s found that only
187 1 in 10 (11%) new drugs globally were therapeutically and pharmacologically innovative.²⁵

188 These figures are consistent with several other recent studies, suggesting that only a small
189 fraction of new drugs offer major clinical benefits (Table 1).²⁶⁻³¹ Analyses of drug evaluation
190 reports put out by health technology assessment bodies in France and Germany in the
191 2010s suggest that the majority of new drugs offer no added clinical improvement, with only
192 a fraction offering important or major improvements.³²⁻³⁶ Another recent study from the
193 Belgian Health Care Knowledge Centre concluded that there was considerable uncertainty
194 about the benefits of many new cancer drugs measured by overall survival and quality of life,
195 despite an increase in their prices.³⁷

196

197 On the positive side, the majority of products under development during 1997-2016 targeted
198 novel mechanisms of action.³⁸ At the same time, though, we have seen a shift in R&D focus
199 from “blockbuster” drugs, typically targeting chronic diseases and sold in high volumes
200 globally, to “nichebuster” drugs targeting rare diseases or narrow indications for which high
201 prices can be charged. Publicly available FDA data show that the proportion of drug
202 developed for rare diseases has increased over time from 25% of all approvals in 2001-2005
203 to 48% in 2016-2020.³⁹ In 2021, orphan drugs accounted for 52% of all approvals.³⁹ This is
204 probably due, in part, to companies targeting additional market exclusivities and other
205 incentives granted for rare disease drugs,⁴⁰ alongside regulators’ willingness to relax
206 evidentiary requirements in case of unmet health need and payers’ higher willingness to pay
207 for these products.

208

209 Not only have past spending patterns not delivered a pipeline of truly innovative drugs in
210 terms of added therapeutic value, but many health needs remain unmet by the current
211 pharmaceutical business model. This includes neglected diseases, antimicrobial resistance,
212 and other emerging infectious diseases.⁴¹ Most biopharmaceutical R&D investments are
213 aimed at maximising shareholder value, leading companies to pursue drug products that can
214 be sold in commercially attractive markets, with extensive marketing to support this goal.
215 This is, in part, why companies invest heavily advertising directly to consumers, sponsoring
216 scientific meetings, and distributing free samples to doctors and patients.⁴² In many
217 important markets, the current system rewards new products irrespective of comparative
218 advantages or contribution to public health priorities,⁴³ which in part reflects the fact that

219 regulatory authorities are tasked with evaluating new drugs based on their individual benefit-
220 risk balance rather than the demonstration of added clinical benefits.⁴⁴

221

222 Another root cause of the misalignment between the R&D outputs and people's health
223 needs is that the main economic incentive for medical innovation is the award of patents,
224 which in turn provide companies with monopoly powers that keep competition at bay and
225 allow to charge high prices and boost profitability. And patents are awarded based on
226 chemical novelty and inventiveness of the product, independent of the therapeutic benefit a
227 product may, or may not provide. As a consequence, companies prioritize R&D on
228 patentable products that can be sold in the market, rather than medical breakthroughs or
229 addressing people's health needs *per se*.

230

231

232 ***Biopharmaceutical innovation must serve public health objectives***

233

234 Over the past two decades, pharmaceutical companies have spent more on SG&A activities
235 and share buybacks than on R&D, at a time when the costs of many of its components have
236 fallen. Many of the roles once undertaken by humans, such as switchboard operators and
237 typists, have disappeared. Costs of travel have fallen as the quality of teleconferencing has
238 increased. Similarly, the growth of the internet has permitted advertising to have a much
239 greater reach than was possible with promotional material in journals or delivered by sales
240 representatives. Yet even though R&D spending increased, most new drugs developed still
241 provide little or no added therapeutic value. It thus seems hard to justify the claim that ever-
242 rising high drug prices are necessary for companies to continue investing in R&D for
243 valuable innovation, to come up with new and better drugs.

244

245 In theory, the biopharmaceutical industry could generate more medically valuable innovation
246 with its existing resources, without passing R&D costs on to patients and health care
247 systems in the form of ever higher and increasingly unaffordable prices. For this to happen,
248 government intervention or regulation would be needed along the lifecycle of new medicines.
249 Possible government actions include reforming national patent systems to make patent
250 awards more stringent, to avoid rewarding chemical novelty and inventiveness independent
251 of therapeutic value; clear communication by public health authorities to lay out health
252 needs-focused R&D priorities and the strategic use of public research funding to support
253 those; smarter allocation of public research funds with retention of (partial) ownership that
254 can be leveraged to pursue public health objectives, including affordable pricing; raising
255 evidence standards for market authorisation by requiring companies to conduct comparative

256 clinical trials designed to establish added therapeutic value whenever possible; reforming
257 pricing and reimbursement systems to reward companies that develop drugs that deliver
258 added clinical benefit and disincentivize me-too and evergreening strategies (Table 2). With
259 the exception of comparative clinical benefit assessment approaches for pricing and
260 reimbursement adopted by several health technology assessment bodies, the other
261 interventions (which would occur during earlier stages of medicines' lifecycle) have largely
262 remained unimplemented, although this could change if the political will were there.

263

264 For specific therapeutic areas where market incentives seem inadequate, such as antibiotics
265 for patients with drug-resistant infections, a comprehensive set of “push” and “pull”
266 incentives for manufacturers may be needed. The former include research subsidies to
267 lower R&D costs, while the latter include outcome-based rewards to guarantee financial
268 returns (e.g., advanced market commitments).⁴⁵ Although such mechanisms have been
269 implemented in several contexts, ranging from R&D subsidies for diseases with unmet need,
270 to advanced market commitments for vaccines, they could be more strategically re-oriented
271 to promote both socially desirable innovation and affordable prices. For example, the UK, in
272 2022, implemented a subscription-style payment model (i.e., “pull” incentive) for two new
273 antimicrobial drugs.⁴⁶

274

275 Increased transparency around medicine pricing, patent status, R&D costs, and clinical trial
276 data, as recommended in a 2019 World Health Assembly resolution, could help redefine the
277 social contract between all stakeholders involved in drug development and align incentives
278 towards public health goals. As the WHO Council on the Economics of Health for All has
279 argued,⁴⁷ the economic, fiscal, and industrial policies governing the sector must be
280 redesigned to improve health outcomes and ensure that health innovation is for the common
281 good.

282

283 When designing and implementing government interventions, including drug pricing policies,
284 it is important to examine the impact of such measures on both inputs (e.g., R&D
285 investments) and outputs (e.g., health outcomes) over the long term, in order to determine
286 the full implications of the intervention and make well-informed decisions. This also requires
287 detailed financial analyses, ideally considering more accurate metrics than mere profit
288 margins, such as return on equity, to better understand the impact on investors decisions
289 and the potential knock-on effects. The non-partisan US federal Congressional Budget
290 Office has estimated that the prescription drug provisions in the Inflation Reduction Act
291 (which, among other things, allows Medicare to negotiate the prices of some medicines) will
292 save billions per year and likely only lead to a modest decrease in the number of new drugs

293 developed over the next 30 years (decrease of 1%).⁴⁸ This might be an acceptable trade-off,
294 especially if many of the drugs we would go without would be low-value ones.

295

296 Past spending patterns by biopharmaceutical companies, alongside evidence on the clinical
297 benefits of new drugs, suggest that high drug prices are not justified on the grounds of
298 sustaining R&D for valuable innovation. Biopharmaceutical companies seem to charge as
299 much as each market can bear, with pricing focused on maximising revenues. A transition is
300 needed towards fostering the development of therapeutically superior drugs that can
301 enhance patient outcomes. This may require a shift of more resources from SG&A to R&D
302 activities and companies to prioritise disease areas with clinical unmet needs. Governments,
303 policy makers, drug regulators, health technology assessment bodies, and payers need to
304 re-think the incentives for valuable biopharmaceutical innovation, creating policy and
305 regulatory environments that will meet public health objectives. These stakeholders should
306 ensure that the current supply-driven R&D portfolios can improve the world's population
307 health by addressing unmet medical needs, improving our therapeutic arsenal, and ensuring
308 equitable access. The world needs a truly value-based health care system for incentivising
309 and rewarding improvements in health outcomes and population health.

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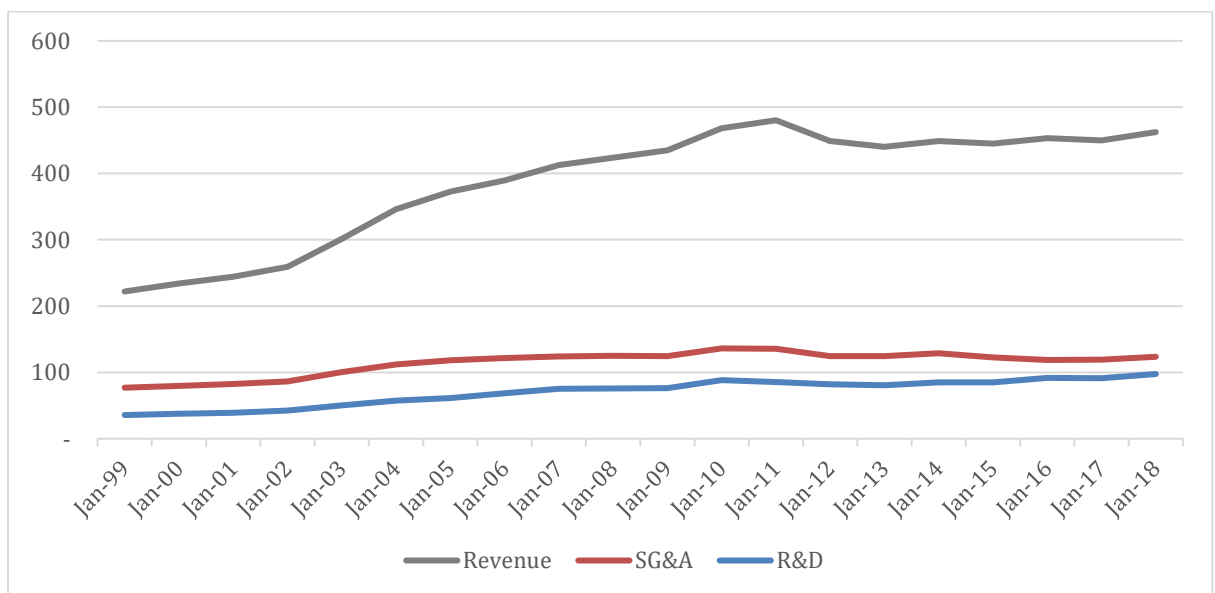
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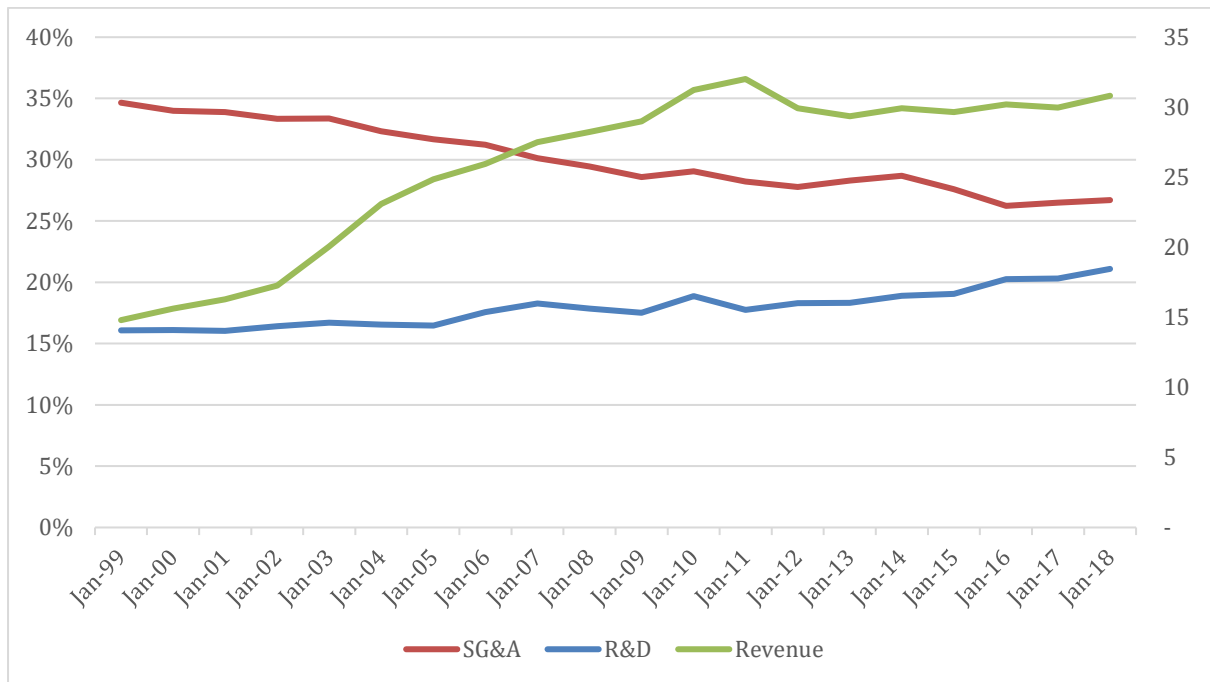
Figure 1: Total revenues, SG&A spending and R&D spending (US\$ bn) for the 15 largest biopharmaceutical companies, 1999-2018



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Note: R&D indicates research and development; SG&A, selling, general, and administrative (activities). Sources: Data were obtained from US company annual and quarterly forms filed with the United States Securities and Exchange Commission and non-US company annual financial reports.

476 **Figure 2:** Average SG&A expenses vs R&D spending (% of revenue, left Y-axis) and
 477 revenue (\$ billion, right Y-axis), for the largest 15 pharmaceutical companies in 1999-2018
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 481 Note: R&D, research and development; SG&A, selling, general, and administrative (activities).

482 Sources: Data were obtained from company annual and quarterly forms filed with the United States
 483 Securities and Exchange Commission and company annual financial reports.

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505 **Table 1:** Review of studies assessing the added therapeutic benefits of new drugs

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Study	Time period	Country	Drug sample	Rating / assessment	Clinical benefit
Kaitin et al, 1991 ²⁴	1978-1989	US	218 new FDA approved drugs	FDA ratings	16% offered important therapeutic gains
Barral, 1996 ²⁵	1974-1994	International	new marketed drugs	Authors	11% therapeutically and pharmacologically innovative
Morgan et al, 2005 ²⁶	1996-2003	Canada	1147 CPMPRB appraisals	Authors based on the CPMPRB classifications	68 (6%) "new breakthrough" 74 (7%) "me-too breakthrough" 1005 (88%) "without substantial improvement over existing products"
Motola et al, 2006 ²⁷	1995-2004	EU	176 EMA approvals	Authors based on Motola's rating system	49 (28%) with an important degree of therapeutic innovation
Luijn et al, 2010 ²⁸	1999-2005	EU	122 EMA approvals	Authors based on European Public Assessment Reports	13 (10%) clinically superior
Lexchin, 2012 ²⁹	2004-2009	Canada, US, France	136 TPD decisions, 145 FDA decisions, 12 HDAP decisions, 624 Prescrire ratings	TPD (priority review), FDA (priority review), HDAP evaluations, Prescrire ratings	TPD: priority reviews to 46 of 137 products (34%) FDA: priority review to 71 of 145 drugs (49%) HDAP: innovative drugs 12 of 120 (10%) Prescrire: innovative new drugs and new indications for older drugs 49 of 624 (8%)

Vitry et al, 2013 ³⁰	2005-2007	Australia	217 Therapeutics Goods Administration approvals (59 drug indications with therapeutic value assessment included)	Authors based on Motola's and Ahlqvist-Rastad's rating systems	<p>Motola's rating system (out of 59 drugs): 31 (53%) pharmacological/technological innovations 4 (7%) modest innovations 17 (29%) moderate innovations 7 (12%) important innovations</p> <p>Ahlqvist-Rastad's system (out of 59 drugs): 19 (32%) "added therapeutic value" 25 (42%) "similar therapeutic value" 5 (8%) "inferior therapeutic value" 10 (17%) "uncertain therapeutic value"</p>
Lexchin, 2018 ³¹	1995-2016	Canada	623 drugs approved by Health Canada	Health Canada pathways/evaluations	185 of 623 drugs (29.7%) through an expedited pathway 55 of 509 (10.8%) drugs with therapeutic evaluations as therapeutically innovative
Rodwin, 2020 ³²	2009-2016	France	680 drugs evaluated by HAS	ASMR ratings	No clinical improvement 51% (ASMR V) Minor improvement 22% (ASMR IV) Moderate improvement 8% (ASMR III) Important improvement 3% (ASMR II) Major improvement 1% (ASMR I)

Kergall et al, 2021 ³³	2014-2020	France	132 drugs evaluated by HAS	ASMR ratings	No clinical improvement 23% (ASMR V) Minor improvement 40% (ASMR IV) Moderate improvement 31% (ASMR III) Important improvement 6% (ASMR II) Major improvement 0% (AMSR I)
Rodwin et al, 2021 ³⁴	2004-2017	France	36 drugs (68 cancer indications) evaluated by HAS	ASMR ratings	No clinical improvement 32% (ASMR V) Minor improvement 38% (ASMR IV) Moderate improvement 22% (ASMR III) Important improvement 7% (ASMR II) Major improvement 0% (AMSR I)
Wieseler et al, 2019 ³⁵	2011-2017	Germany	216 drug-indication pairs evaluated by the IQWiG	IQWiG ratings	Less benefit 1% Non-quantifiable benefit 7% No added benefit 58% Minor added benefit 9% Considerable added benefit 15% Major added benefit 10%
IQWiG, 2022 ³⁶	2011-2021	Germany	20 drugs (41 rare disease indications) evaluated by IQWiG	IQWiG ratings	Less benefit Non-quantifiable benefit 15% No added benefit 54% Minor 7% Considerable added benefit 22% Major added benefit 2%

KCE, 2022 ³⁷	2004-2017	Belgium	40 oncology drugs (12 cancer indications) ; these drugs were some of the most commonly used and/or the ones with the highest annual expenditure	Authors based on observational data, the medical literature and UK economic evaluations	6 indications: minor improvements in survival 6 indications: no positive evolution in survival Impact on quality of life very uncertain
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509 Notes: FDA, Food and Drug Administration; CPMPRB, Canadian Patented Medicine Prices Review
510 Board appraisals; EMA, European Medicines Agency; TPC, Therapeutic Products Directorate; HDAP,
511 Human Drug Advisory Panel; HAS, Haute Autorité de Santé; ASMR, Amélioration du Service Médical
512 Rendu; IQWiG, Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen.

513 **Table 2:** Recommended government actions for the promotion of medically valuable
 514 innovation along the lifecycle of new medicines
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Mechanisms	Medicine lifecycle stages	Examples
Patent system reform in alignment with drugs' therapeutic value prospects or patents abolition and use of outcome-based rewards	Discovery and preclinical research	More stringent or downstream patent awards (e.g. based on mechanism of action or following preclinical research); advanced market commitments to purchase drugs at pre-agreed price and volume
Communication of needs-focused R&D priorities in alignment with unmet medical needs by public health authorities	Discovery preclinical research, early clinical development	"Health needs-based" target product profiles outlining desired characteristics or attributes of target products
Allocation of public research funds with a stake in resulting intellectual property	Preclinical research	Retention of ownership by public funders leveraged for reduced product prices
Raising evidence requirements for market authorisation	Licensing	Requirement of comparative clinical trials against existing treatments
Pricing and reimbursement policies in alignment with drugs' value	Post-licensing	Comparative clinical effectiveness and cost-effectiveness

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