The Rise of Drug Innovation in China — Implications for Patient Access in the United States and Globally

Kerstin N. Vokinger, M.D., J.D., Ph.D.,[1] Guanqiao Li, M.D.,[2] and Olivier J. Wouters, Ph.D.[3]

[1]Department of Health Sciences and Technology, ETH Zurich and Faculty of Law, University of Zurich, Zurich, Switzerland; [2]Vanke School of Public Health, Tsinghua University, Beijing, China; [3]Department of Health Services, Policy, and Practice, Brown University School of Public Health, Providence, RI.

Trade-related tensions between the United States and China have escalated dramatically in recent months. Despite a tentative agreement in May 2025 to reduce the size of newly imposed tariffs on both sides, geopolitical frictions remain. Among other implications, these tensions threaten the cross-border trade of medicines. China has long been a major global supplier of generic drugs and active pharmaceutical ingredients, and while it continues to play that role, it has also emerged in recent years as an important player in new drug development — a field traditionally dominated by the United States and European countries. This shift has implications for global access to promising new medicines and presents challenges for U.S. regulators and policymakers.

The rise of Chinese pharmaceutical innovation is reflected in the number of new drugs that were approved in China before being approved in any other country, which increased from 9 in 2018 to 45 — not including 3 traditional Chinese medicines — in 2024 (see graph).[1] Of the 45 new drugs first approved in China in 2024, 40 were developed by Chinese manufacturers.[1] More than 10 Chinese-made drugs have been approved in the United States and Europe since 2019. For example, fruquintinib, a small-molecule drug used

to treat colorectal cancer, was initially approved in China in 2018 before being approved by the U.S. Food and Drug Administration (FDA) in 2023 and the European Medicines Agency (EMA) in 2024. Efbemalenograstim alfa, a biologic for chemotherapy-induced neutropenia, was authorized in China in May 2023 and subsequently approved by the FDA in November 2023 and the EMA in March 2024.

Several Chinese-made drugs have been first-in-class medicines or demonstrated important added therapeutic benefits over existing treatments.[2] Zanubrutinib, a next-generation Bruton's tyrosine kinase inhibitor developed by a Chinese biotech company, was shown in head-to-head phase 3 trials to be more effective and safer than ibrutinib when used to treat chronic lymphocytic leukemia and has been approved by the FDA and the EMA. Ivonescimab, the first antibody to target both the programmed cell death protein 1 and the vascular endothelial growth factor pathway, was approved in China after leading to longer progression-free survival than pembrolizumab in a phase 3 trial in patients with lung cancer. The drug is now being tested in trials in North America and Europe as the manufacturer pursues approvals in markets outside China.

The rise of Chinese drug development has been fueled by multiple factors, including growing investment in research and development, international partnerships, and regulatory reforms. China's total biomedical research-and-development expenditures have steadily increased – from 2.4 trillion yuan (U.S.$331 billion) in 2020 to 3.6 trillion yuan (U.S.$497 billion) in 2024.[3] Beginning in 2015, the government introduced a series of regulatory measures to encourage domestic drug development and accelerate patients' access to new medicines. These measures have included streamlined review procedures and shorter review timelines, such as a 60-working-day review period for clinical trial applications that was introduced in 2018, which was reduced to 30 working days in pilot cities in 2024.

Regulators have also implemented multiple expedited approval pathways, such as conditional approval, which was introduced in 2017 and mirrors the FDA's accelerated approval pathway.

In recent years, U.S. regulators have had a mixed response to Chinese-made products, including rejecting some drugs tested exclusively in China. For example, in 2022, the FDA rejected sintilimab, a checkpoint inhibitor used to treat lung cancer, because the pivotal trials were conducted in China and the FDA was concerned that the results might not be generalizable. The FDA has stated that drug applications relying on only international clinical data can be approved only if the data are considered relevant to the U.S. population and U.S. medical practices. In other cases, the FDA has cited concerns about data integrity and noncompliance with good manufacturing practices when rejecting applications for products developed in China or issuing warning letters to Chinese manufacturers.

U.S. policymakers have also pushed back against the expanding role of Chinese companies in drug development. In 2024, the U.S. Congress considered the BIOSECURE Act, which would have prohibited U.S. firms from entering into contracts with, or providing grants to, several Chinese companies because of concerns about data security. Although the bill didn't pass, tensions have continued to grow, with the Trump administration threatening to impose new tariffs on pharmaceutical products in a bid to move manufacturing to the United States and reduce the U.S. health care system's reliance on China and other countries.

Despite these tensions, China's growing role in pharmaceutical innovation presents an opportunity for patients in the United States, Europe, and elsewhere to gain access to new drugs. The United States and China could each play a role in facilitating increased access to promising Chinese pharmaceutical products.

First, it will be important for Chinese companies to fully comply with international regulatory standards, especially those related to data traceability and integrity, and for Chinese regulators to enforce these standards to ensure compliance. The Chinese government has taken steps to align practices with international regulatory standards. In 2017, China's National Medical Products Administration (NMPA) joined the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use; in 2021, it applied for membership in the Pharmaceutical Inspection Co-operation Scheme, which aims to harmonize good manufacturing standards and support quality assurance. Further efforts are needed to enhance data integrity and regulatory compliance to build mutual trust. One example might be implementing risk-based oversight measures, such as evaluating the past performance of individual laboratories and manufacturers to determine the necessary frequency of regulatory inspections.

Second, regulatory collaboration between the FDA and the NMPA could help streamline approvals in both jurisdictions. The FDA engages in international partnerships to accelerate drug approvals. One key initiative is Project Orbis, which was introduced in 2019 to streamline the submission and review processes for promising cancer drugs across regulatory agencies in multiple countries (Australia, Canada, Brazil, Israel, Singapore, Switzerland, the United Kingdom, and the United States). The national medicines agencies involved in Project Orbis review applications in parallel but retain independent approval authority. China accounts for approximately one-quarter of cancer cases globally. Its inclusion would help ensure that countries participating in Project Orbis represent around 47% of the global cancer patient population (up from 22% today).[4]

Third, to secure sustainable access to critical medicines, we believe the U.S. federal government should prioritize trade stability with China. Implementing tariffs on

pharmaceutical products could disrupt supply chains, increase health care costs, and limit access to both generic and innovative therapies for U.S. patients.[5] A stable trade environment would not only benefit U.S. patients but could also strengthen global supply-chain resilience, ensuring that political disputes don't compromise the availability of lifesaving treatments in the United States and elsewhere.

The rapid rise of Chinese drug development presents an opportunity to enhance global access to new treatments. The United States should continue investing in biomedical research to support valuable medical advances, a priority highlighted in a recent report from the U.S. National Security Commission on Emerging Biotechnology. At the same time, it can foster closer ties with China, for instance by engaging in regulatory collaboration, to accelerate access to promising new drugs. While such collaboration is unlikely to gain much traction under the current administration, it remains an important long-term goal.

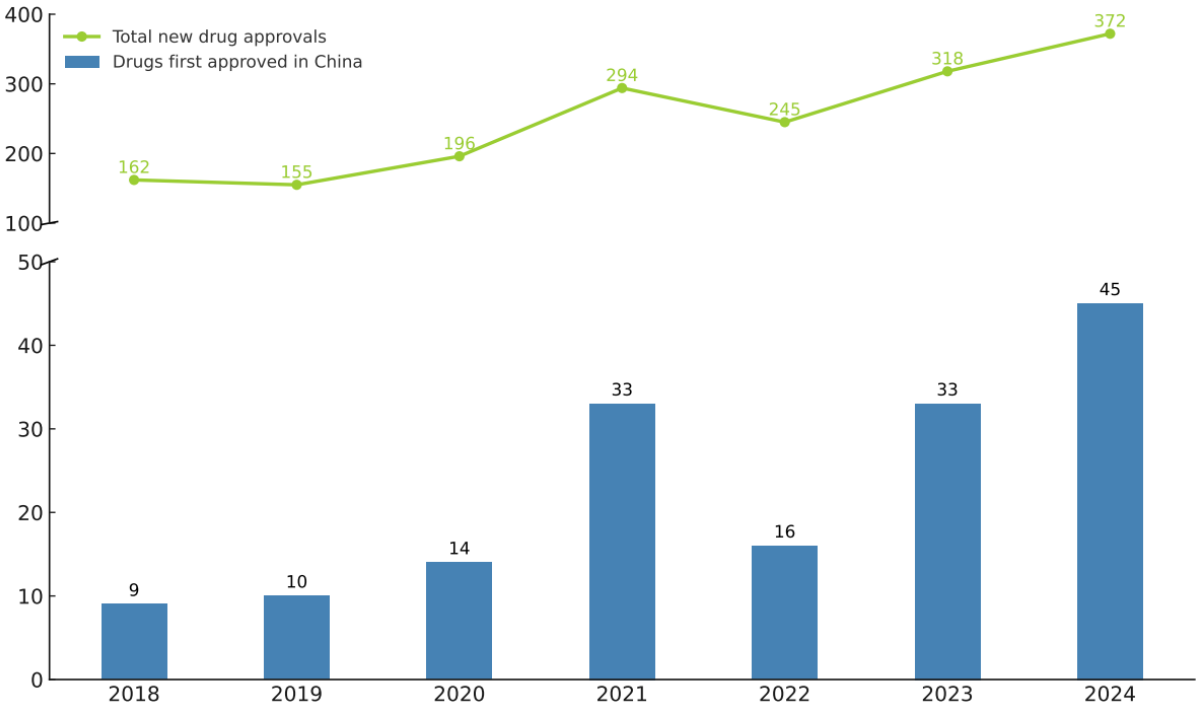
Disclosure forms provided by the authors are available at NEJM.org.

References

1. Zhi X, Li Q, Shao L. Approvals by the China NMPA in 2024. Nat Rev Drug Discov 2025;24: 160–1.
2. Chen Z, Zhong H, Hu H, Kong F, Liang W, Li G. Chinese innovative drug R&D trends in 2024. Nat Rev Drug Discov 2024;23:810–1.
3. National Bureau of Statistics of China. China's expenditure on research and experimental development (R&D) exceeded 3.6 trillion yuan in 2024. January 24, 2025 (https://www.stats.gov.cn/english/PressRelease/202502/t20250207_1958579.html).

4. Asia Society Policy Institute. Advancing global health equity: enhancing clinical trials access and cooperation to save millions of lives from cancer. 2023 (https://asiasociety.org/sites/default/files/2023-11/Cure4Cancer_Digital_Advancing%20Global%20Health%20Equity_fin2.pdf).
5. Wosińska ME. Will pharmaceutical tariffs achieve their goals? Washington, DC: Brookings Institution. March 27, 2025 (https://www.brookings.edu/articles/pharmaceutical-tariffs-how-they-play-out/).

Approval of New Therapeutic Agents in China, 2018-2024.*



* Data on drug approvals include both small-molecule drugs and biologics; preventive biologics and traditional Chinese medicines are excluded. The bars show the number of new small-molecule drugs or biologics that were approved in China before being approved for marketing in any other country. The green line represents the number of new drug approvals, including new molecular entities, new active ingredients, new dosage forms, and

new combinations. Data are from the National Medical Products Administration’s Center for Drug Evaluation.