Delivering for Chinese Patients: Strengthening Patient Access to Biopharmaceutical Innovation

Pharmaceutical Research and Manufacturers of America (PhRMA)

Executive Summary

China's leadership has shown commitment to strengthening biopharmaceutical innovation and ensuring Chinese patients have greater access to innovative medicines. These objectives are an integral part of China's 14th Five-year Plan and Long-Range Objectives for 2035, Healthy China 2030 Blueprint and a wide range of related legislative and regulatory reforms. These policies emphasize innovation as a central tenet and aim to ensure that China is an important part of the global biopharmaceutical industry.

China has made important strides reforming its regulatory system and has nearly eliminated the medicine registration application backlog, allowing for greater patient access to medicines. China has also made great progress strengthening its health care system and providing Basic Medical Insurance (BMI) to its vast population, thereby increasing the availability of innovative medicines. China has also improved intellectual property (IP) protections for medicines and to develop a system that more closely aligns with international norms. While these policy reforms represent progress, continued improvements are needed if China is to realize the vision of Healthy China 2030. For example, only 23 percent of new medicines launched globally in the past decade are available to patients in China, and among these roughly a third are not included in the National Reimbursement Drug List (NRDL).[1]

The global innovative biopharmaceutical industry seeks to build upon the progress that has been achieved to date in creating a growing and vibrant biopharmaceutical sector in China. Further advancing biopharmaceutical sector development and patient access in China will depend on an ecosystem that promotes innovation. A successful biopharmaceutical innovation ecosystem is

1 PhRMA analysis of IQVIA Analytics Link, country regulatory and NRDL data on new active substances first launched globally between January 2011 and December 2020. June 2021.

comprised of three core components that are closely related and equally necessary for growth and sustainability:

1) The Regulatory System: The regulatory system should establish and consistently apply clear, science-based, and neutral rules to assess the safety, efficacy and quality of products, from preclinical and clinical development to post-market surveillance and risk management. Such features will enable the regulatory system to produce consistent and predictable approval decisions within reasonable timeframes, and allow for simultaneous global development. China can further streamline its regulatory approval processes by continuing to adopt harmonized guidelines and removing China-specific requirements when possible.
2) The Intellectual Property System: A robust IP system drives biopharmaceutical innovation by providing the necessary incentives to invest substantial capital and other resources needed to research, develop and launch innovative medicines. To bring valuable new medicines to patients, biopharmaceutical innovators must be able to effectively secure and enforce patents, receive regulatory data protection ("RDP") for clinical information demonstrating the safety and efficacy of a medicine for marketing approval, and protect trade secrets and confidential commercial information. We recommend that China continue to vigorously advance IP reforms so that innovators will have the predictability and certainty that they need to collaborate with partners, compete successfully and accelerate the launch of new medicines.
3) The Pricing and Reimbursement System: The pricing and reimbursement system should reflect the holistic value that innovative medicines provide to patients and society and enable companies to continue to invest in the next generation of treatments and cures. China can enhance access to innovative medicines by adopting a more timely, transparent, predictable and evidence-based NRDL adjustment mechanism that meaningfully engages stakeholders. We also support China's efforts to strengthen supplemental commercial health insurance (CHI) as part of a multi-layer medical security system that improves access and reduces out-of-pocket costs for Chinese patients.

PhRMA and its members are committed to partnering with the Chinese government and other stakeholders to strengthen the biopharmaceutical innovation ecosystem in China and improve patient access to new medicines.

I. Introduction—the Lifecycle of an Innovative Drug

Developing an innovative biopharmaceutical product is a complex, multi-year and resource intensive activity. It takes 10 or more years, an average of USD 2.6 billion and extensive cross-border expertise and collaboration between academic researchers, scientists, physicians and other partners to develop a candidate molecule into a patient-ready biopharmaceutical product with a fully scaled-up manufacturing process. The biopharmaceutical industry has spent over USD 1.6 trillion on research over the last decade in order to make substantial contributions to patients' lives around the world in various disease areas.[2]

The benefits of this development process are perhaps most recently apparent in combating the COVID-19 pandemic, where the biopharmaceutical industry has been working tirelessly for two years to research, develop and deliver safe and effective treatments and vaccines. The decades-long investments biopharmaceutical companies have made in new technologies, research, treatments and vaccines prepared the industry to act swiftly to respond to the pandemic.

Biopharmaceutical product development starts long before clinical studies begin. Basic research is first needed to understand as much as possible about the relevant diseases and conditions and the ways in which medicines could target diseases in the body. Next comes pre-clinical research on the drug candidate in laboratories and in animals to generate safety data and parameters, among other relevant information. Once the pre-clinical work is complete, the biopharmaceutical candidate must be tested in humans typically in three stages of clinical trials. These begin with testing the basic safety of the biopharmaceutical product in a small number of healthy patients and culminate in larger "phase 3" pivotal clinical trials that examine the drug's safety and effectiveness in a segment of the intended population. There are many failures during this process; in the U.S., for example, only 12 percent of the new molecular entities that enter clinical trials receive approval for marketing.[3]

II. Availability of Innovative Medicines in China

Biopharmaceutical innovation has numerous benefits to patients and society—it improves patient health and longevity, can lower the overall cost of treating

2 Evaluate Pharma, "World Preview 2021 Outlook to 2026 …" 14th Ed. (July 2021), available at https://info.evaluate.com/rs/607-YGS-364/images/WorldPreviewReport_Final_2021.pdf.

3 PhRMA, Research & Development Policy Framework, available at https://phrma.org/policy-issues/Research-and-Development-Policy-Framework.

diseases (e.g., by reducing medical complications, hospitalizations and the need for other health care services) and contributes to economic growth through improved worker productivity, high-wage jobs and exports. For example, the use of cholesterol-lowering statin drugs has cut hospitalizations and saved the U.S. health care system at least USD 5 billion.[4] Every $24 spent on new medicines for cardiovascular diseases in OECD countries saves USD 89 in hospitalization costs.[5] In addition to lowering overall health care costs, appropriate use of medicines can increase worker productivity by reducing rates of absenteeism and short-term disability.[6] A 2012 study demonstrated that appropriate use of diabetes medicines saved 20 percent per month in medical spending after one year of initiating treatment[7] and an estimated reduction of more than one million emergency department visits and hospitalizations annually, for an annual savings of up to USD 8.3 billion.[8]

China has made important strides in ensuring its regulatory system is more closely aligned with international standards and practice. In 2017, China joined the International Council for the Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) and became a member of the Management Committee in 2018. As an active member, China has implemented approximately 64 percent of the 108 ICH guidelines as of February 2022.[9] China has also nearly eliminated a sizeable medicine registration application backlog, allowing for

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4 Grabowski, D., D. Lakdawalla et al., "The Large Social Value Resulting From Use Of Statins Warrants Steps To Improve Adherence And Broaden Treatment," Health Affairs, Oct. 2012, available at https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.2011.1120.

5 Lichtenberg, F., "Have newer cardiovascular drugs reduced hospitalization? Evidence from longitudinal country-level data on 20 OECD countries, 1995-2003," National Bureau of Economic Research, May 2008, available at http://www.nber.org/papers/w14008.

6 Carls G.S., M.C. Roebuck et al., "Impact of medication adherence on absenteeism and short-term disability for five chronic diseases," Journal of Occupational and Environmental Medicine, July 2012, available at http://journals.lww.com/joem/Abstract/2012/07000/Impact_of_Medication_Adherence_on_Absenteeism_and.7.aspx.

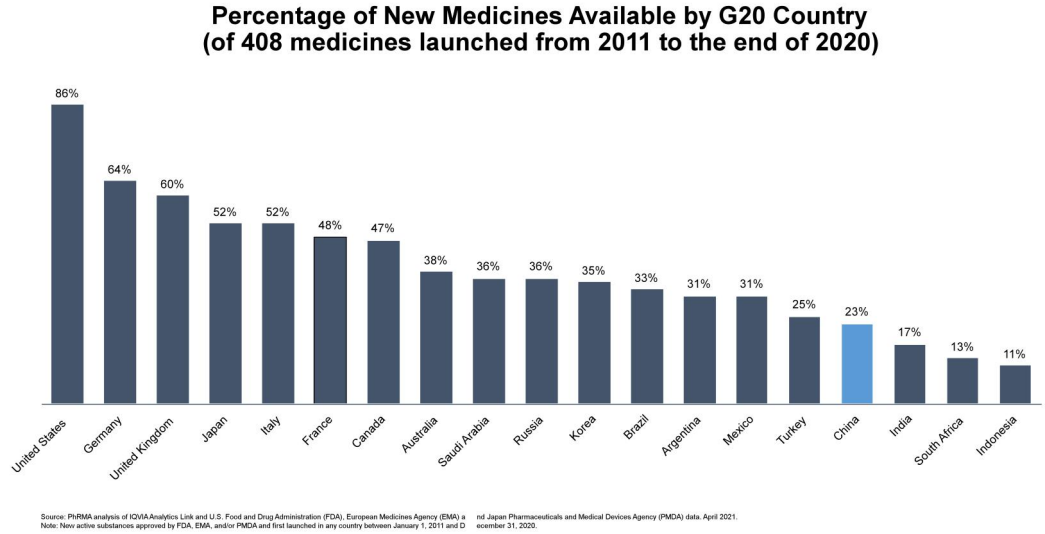
7 Jha A.K., Aubert R.E., Yao J., Teagarden J.R., Epstein R.S., "Greater adherence to diabetes drugs is linked to less hospital use and could save nearly $5 billion annually," Health Affairs, Aug. 2012, available at https://www.healthaffairs.org/doi/10.1377/hlthaff.2011.1198.

8 Slejko J.F., Ho M., Anderson H.D., Nair K.V., Sullivan P.W., Campbell J.D., "Adherence to statins in primary prevention: yearly adherence changes and outcomes," J Manag. Care Pharm., Jan. 2014, available at https://www.jmcp.org/doi/10.18553/jmcp.2014.20.1.51 .

9 ICH Guideline Implementation, available at https://www.ich.org/page/ich-guideline-implementation.

greater patient access to medicines.

China has also made great progress strengthening its health care system and providing BMI to its vast population, thereby increasing the availability of innovative medicines to patients. China has taken steps to improve the payment and reimbursement system for innovative medicines under BMI, including more frequent updates to the NRDL. While these policy reforms represent progress, continued improvements are needed if China is to realize the vision of Healthy China 2030. For example, only 23 percent of new medicines launched globally in the past decade are available to patients in China, and among these roughly a third are not included in the NRDL.[10]



III. Advancing the Biopharmaceutical Innovation Ecosystem in China

The biopharmaceutical innovation ecosystem has three components, namely: (1) efficient, effective and science-based regulatory processes for approving medicines and ensuring their safety in the post-market environment; (2) protections for IP to research, develop and launch innovative medicines; and (3) a

10 PhRMA analysis of IQVIA Analytics Link, country regulatory and NRDL data on new active substances first launched globally between January 2011 and December 2020. June 2021.

timely, transparent and evidence-based pricing and reimbursement system. These three aspects are closely intertwined and equally necessary to the growth and sustainability of the overall innovation ecosystem.

Below, we briefly review each component of the innovation ecosystem and make certain recommendations for consideration.

A. The Regulatory System

A strong regulatory system is one of the core components of a viable biopharmaceutical ecosystem. To function as intended, the regulatory system must establish and consistently apply clear, science-based and neutral rules to assess the safety, efficacy and quality of products, from preclinical and clinical development to post-market surveillance and risk management. Such features will enable the regulatory system to produce consistent and predictable approval decisions within reasonable timeframes, and allow for simultaneous global development. China can streamline its regulatory approval processes by continuing to adopt ICH guidelines and removing China-specific requirements when possible.

1. Clinical Trial Applications and Data Submission

Clinical trial applications evaluated based on a clear set of standardized criteria coupled with science-based and risk-based decision making (principles embedded in ICH guidelines) that apply equally to both local and foreign manufacturers and matches the stage of development will encourage the development and launch of innovative medicines in China.

China now permits a new drug clinical trial to move forward if the National Medical Products Administration (NMPA) has not raised objections within 60 business days and recognizes more formally the validity of foreign data, which are important steps in making the development process more efficient. To further enable simultaneous global development, we encourage China to fully implement the ICH E-17 Multi-Regional Clinical Trials (MRCT) guideline and accept a pooled region approach as well as sample size allotments for Chinese patients. In addition, it is critical that laws seeking to protect personal data and patient privacy in China do not unduly hinder China's ability to efficiently and effectively participate in MRCTs.

Further, applicants seeking to conduct a clinical trial in China are often required to submit highly sensitive proprietary information about manufacturing steps (e.g., executed batch records, validation methods and analytical testing reports) at the

clinical trial application stage. This requires applicants to copy and transport information at a critical time, risking diversion or disclosure. In contrast, other countries in the ICH do not typically do not require the same level of data, nor that the data be disclosed at such an early stage, waiting instead until the marketing authorization application stage.

These changes will encourage the development and marketing of innovative products in China, support simultaneous development and ultimately benefit Chinese patients.

2. Human Genetic Resources Requirements

To further encourage the development of innovative drugs in China and allow for simultaneous development, we recommend a more streamlined and science-based system regarding human genetic resources (HGR).

China's HGR regulations currently require approval by the Ministry of Science and Technology (MOST) HGR Office for clinical research projects involving a foreign party prior to the commencement of the clinical trial or other research. While we respect China's right to maintain biosecurity, the HGR approval process, which is unique to China, has become a source of substantial delay and uncertainty in the development process. The HGR regulations also restrict the use, analysis and transfer (including export) of such samples and various data (including critical adverse event information that must be reported around the world) unless the recipient entities and transfers are approved or cleared.[11] The HGR process has added months to the clinical development timeline, generated uncertainty about IP ownership and even caused companies to end certain studies altogether.[12]

We note that the HGR Office has recently made process improvements for HGR management, with first-time acceptance rates for filings and approvals increased and review timelines shortened. We urge China to develop a science-based system for addressing HGR. We recommend that the HGR process be streamlined to permit approval in a shorter period of time and anonymized data (particularly adverse event reports) to be transferred without approval or with only a brief notification. This would allow for faster approvals while appropriately safeguarding personal data.

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11 Human Genetic Resource Regulations, Articles 21-22 (State Council No. 717, 2019) ("HGR Regulations").

12 In a survey conducted in 2020 with PhRMA companies, 33 percent reported abandoning a study because of a rejection from the HGR Office.

3. New Drug Definition

In order for incentives for innovative drug development to apply to all innovative products that can benefit patients, we recommend that China's current approach to the definition of a new drug be reconsidered. NMPA's registration guidelines define a drug with a new active ingredient ("an innovative drug") or improvement ("improved new drug") as a drug that is new and un-marketed anywhere in the world, not just new to China. Products first approved in other countries are unable to qualify as innovative or improved new drugs in China, even if they meet internationally accepted definitions of an innovative drug. In turn, critical benefits intended to incentivize innovative medicine development, such as eligibility for expedited pathways (e.g., breakthrough approval) or patent term extension, are often linked to whether a drug is deemed new. The absence of these incentives undercuts the substantial investment necessary to bring a drug or biologic to market and potentially discourages companies from bringing their drugs to market in China.

Innovative drugs and biologics should be those that are approved on the basis of full safety and efficacy data, regardless of approval status abroad. Follow-on products of the same or similar composition would then rely on the reference product's safety and effectiveness data to obtain approval. This creates a simple and flexible structure for companies to make efficient choices in development and marketing—the kind that has worked in other comparative markets, and that will ultimately permit China to become a global leader in innovative and follow-on medicines.

4. Cross Border Marketing Authorization Holder

NMPA's policies and rules also impose distinctions based on location of manufacture, such as requiring drugs made outside of China to have foreign license holders while medicines manufactured in China must have domestic license holders. Such requirements deprive both foreign and Chinese companies from having the necessary flexibility to determine the most appropriate China marketing authorization holders (MAH) with the most knowledgeable personnel. There is no scientific basis for this administrative requirement, which can slow the development of innovative medicines by requiring foreign companies to be the MAH simply because the drug is made outside of China and a certain company holds the approval there.

B. The Intellectual Property System

To bring valuable new medicines to patients, biopharmaceutical innovators must be able to rely on a certain and predictable IP system – including effectively securing and enforcing patents, receiving RDP for clinical information demonstrating the safety and efficacy of a medicine for marketing approval, and protecting trade secrets and confidential commercial information. This foundation provides biopharmaceutical innovators with the incentives necessary to drive substantial multi-billion RMB investments needed to research, develop and launch innovative medicines.

China has begun to improve these IP protections for medicines and to develop a system that more closely aligns with international practices. We recommend that China continue to vigorously advance IP reforms so that all innovators have the predictability and certainty that they need to collaborate with partners, compete successfully and accelerate the launch of new medicines.

1. Patent Protection and Early Resolution for Patent Disputes

Patentability

China has established patent protection for medicines, their active ingredients, formulations and methods of use (i.e., indications). Unlike other major markets, China does not consistently accept data generated after a patent is filed (e.g., during the research and development process) to help demonstrate that the claimed invention, as supported by the originally filed disclosure, meets all of the requirements for patentability (i.e., "data supplementation"). Although China has made amendments to its patent examination guidelines to allow for data supplementation, it has not yet been implemented consistently in practice. This causes uncertainty about the ability to obtain and/or maintain biopharmaceutical patents in China, and has caused denials of patents on new medicines in China that received patents in other jurisdictions.

Patent Term Adjustment and Extension

An effective pharmaceutical patent system should also include mechanisms to adjust the term of a patent to compensate for patent office delays, i.e., patent term adjustment ("PTA") and to restore the patent term to compensate for the lengthy time required to secure regulatory approval for pharmaceutical products, i.e., patent term extension ("PTE").

China has incorporated PTA and PTE into its revised Patent Law and in CNIPA's draft patent examination guidelines. However, certain issues still require

clarification as to how PTA and PTE will be implemented. For example, PTE applies to patents of "new drugs," although that term is not defined in the Patent Law and the time periods covered by the provision are not specified. All innovative medicines supported by full safety and effectiveness data (regardless of where that data has been generated) and that are new to China should be eligible for PTE. Further, the formulas for calculating PTA and PTE should be clear and transparent.

Patent Linkage/Early Dispute Resolution

In order to foster a strong market for innovative and follow-on medicines in China, there should be an opportunity for patent disputes to be resolved prior to the marketing of any generic or biosimilar product. Jurisdictions with strong innovative medicine markets provide such an opportunity through early dispute resolution mechanisms, such as "patent linkage." Such mechanisms, at a minimum, (1) require notification to the holder of a patent on a biopharmaceutical product if another party applies for marketing approval for a generic or biosimilar versions of that product; (2) enable the holder of a patent on a biopharmaceutical product to seek provisional enforcement measures, such as a stay of approval, preliminary injunction or interlocutory injunction, to prevent the marketing of a potentially infringing generic or biosimilar version of that product; and (3) provide for the timely resolution of patent disputes before marketing approval is granted for a generic or biosimilar.

China incorporated an early dispute resolution mechanism into Article 76 of the revised Patent Law, and in several measures and judicial interpretations to implement the system. However, certain features of the system could make it difficult for China to achieve its intended goal of resolving patent disputes early in order to save resources and ensure continued patient access to medicines. For example, the stay period of nine months (with no stay provided for biologics) is quite limited as patent cases in China often take longer than 9 months to resolve. In addition, there is a lack of clarity about which declarations by generic or biosimilar companies trigger the ability to initiate an Article 76 dispute and the remedy if a generic or biosimilar manufacturer submits an erroneous declaration. Moreover, clarification is needed on how the features of the patent linkage system apply to biological products to achieve the same effect of early and complete dispute resolution.

PhRMA is committed to help identify which areas of the system are working or may need further enhancement in order to effectively and efficiently resolve patent disputes before potentially patent infringing products launch on the market.

2. Regulatory Data Protection

RDP complements patents on innovative medicines. By providing temporary protection for the comprehensive package of information biopharmaceutical innovators must submit to regulatory authorities to demonstrate the safety and efficacy of a medicine for marketing approval, RDP provides critical incentives for investment in new treatments and cures. RDP is equally critical to incentivizing innovation, and has been adopted by many jurisdictions with productive innovative biopharmaceutical industries.

RDP provides protection for the comprehensive package of data that innovators must submit to regulatory authorities to demonstrate the safety and efficacy of a medicine for marketing approval. This approach balances both incentivizing the innovator by protecting highly valuable data, while allowing follow-on applicants to rely on the innovator's test data to obtain approval after the RDP period has ended. RDP is particularly critical for biologic medicines, which may not be adequately protected by patents alone. Made using living organisms, biologics are so complex that it is possible for others to produce a version – or "biosimilar" – of a medicine that may not be covered within the scope of the innovator's patent. For this reason and others, U.S. law provides 12 years of RDP for biologics. This was not an arbitrary number, but rather the result of careful consideration and considerable research on the incentives necessary to ensure biopharmaceutical innovators and the associated global scientific ecosystem are able to sustainably pursue groundbreaking biomedical research.

Though China has made prior commitments to offer RDP, including in its accession to the World Trade Organization ("WTO"), its signature of the TRIPS Agreement and NMPA's 2018 draft regulation on RDP, China has not yet implemented an RDP system. We recommend that China adopt the highest international RDP standards, including 12 years for biologics and 10 years for small molecules, consistent with those in other countries that have robust innovative medicine markets.

3. Protection of Trade Secrets

Another critical component of a robust IP system is that companies must have the ability to protect their confidential know-how (e.g., manufacturing information) from disclosure and theft through trade secret protection. This includes not only the ability to pursue remedies vis-à-vis private parties, but also through support from government agencies, to ensure that such information is only submitted

when absolutely necessary (as opposed to making it available for inspection) and is held in a secure manner, and that reviewers do not have unlimited discretion to ask for supplemental documents.

C. The Pricing and Reimbursement System

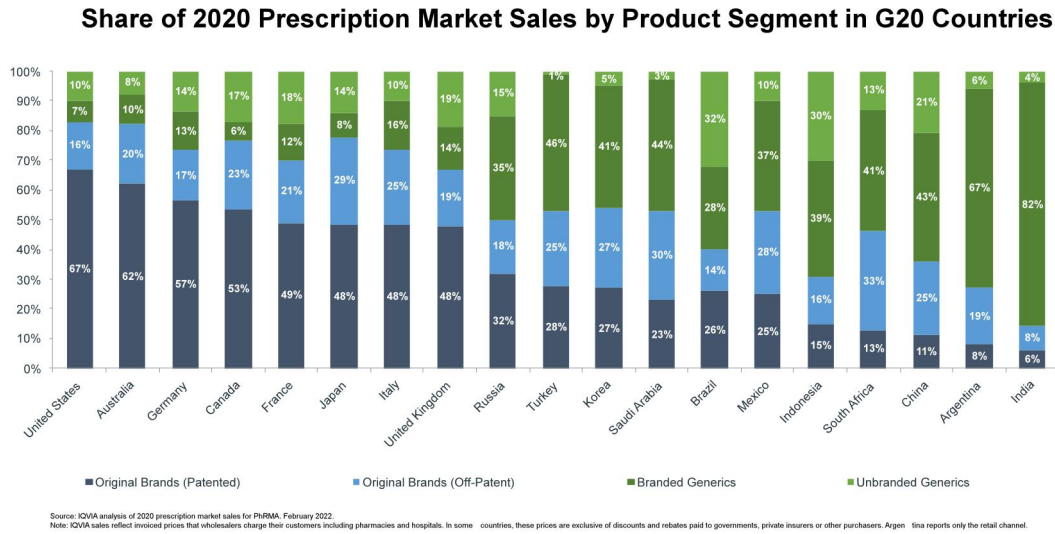
The final component of an innovation ecosystem is a timely, transparent, predictable and evidence-based system for pricing and reimbursement of medicines. Such a system should reflect the holistic value that innovative medicines provide to patients and society and enable companies to continue to invest in the next generation of treatments and cures.

China has made great progress strengthening its health care system and providing health insurance to its vast population, including access to medicines. Annual updates to the NRDL have increased the number of new medicines covered and the introduction of the company-initiated application system and the simplification of the contract renewal process in 2020 and 2021, have led to greater administrative ease.

However, the negotiation process for new medicines continues to lack sufficient transparency and diverge from global best practices. For example, previous rounds of negotiations have significantly varied in process, timelines and requirements, ultimately resulting in a lack of predictability and timely reimbursement for new medicines. The product selection and assessment criteria appear to be based on narrowly defined dimensions of value and budget impact, without clarity on how these criteria are determined and applied. Furthermore, even when prices are established, there remain major implementation challenges, such as low reimbursement percentages, hospital listing restrictions and additional cost control regulations that continue to restrict patient access to innovative and life-saving medicines. Moreover, contract renewal and price renegotiation are required two years after listing, which result in irreversible price reductions without any mechanism for price maintenance or positive adjustment based on the demonstrated benefits of the product.

China currently lags other major economies in the availability of innovative medicines, as shown above in Section II. In addition, innovative medicines accounted for only 11 percent of China's prescription medicine market in 2020, far below other economies such as the United States and Europe, both of which had percentages at least equal to 50 percent. Even in countries with a per capita GDP comparable to that of China, such as Brazil, Mexico, Russia and Turkey,

innovative medicines account for approximately 25 percent of total prescription medicine expenditure. Thus, there is significant room for improving access to innovative medicines in China.



Source: IQVIA analysis of 2020 prescription market sales for PhRMA. February 2022.
Note: IQVIA sales reflect invoiced prices that wholesalers charge their customers including pharmacies and hospitals. In some countries, these prices are exclusive of discounts and rebates paid to governments, private insurers or other purchasers. Argentina reports only the retail channel.

1. Public Pricing and Reimbursement

As China's health care system continues to evolve, its success in delivering world-class medicines to patients in a timely manner will depend on appropriate value assessment, reimbursement and funding policies. The following recommendations reflect our support for Healthy China 2030 and what is needed to foster a more innovative, value-based and transparent health care system for Chinese patients.

Value Assessment

To help ensure scientific objectivity and balance in the valuation of medicines, we recommend the establishment of a value assessment process that is independent from reimbursement authorities. Assessments should use rigorous methods and the full range of available evidence to support reimbursement negotiations. The assessment framework should be holistic and recognize multiple domains of value, including therapeutic benefit, unmet need, broader socioeconomic benefits and contribution to medical innovation. Assessments should focus on the outcomes that matter to patients, recognizing individual patient needs and varying responses

to treatments. The assessment process should also regularly and meaningfully engage relevant stakeholders (e.g., patients, physicians and manufacturers) and integrate their perspectives into key procedures and decisions.

Pricing and Reimbursement

The negotiated reimbursement price should recognize assessed value through premium pricing over the appropriate comparator products. The reimbursement price should be maintained during the period of IP protection with predictable rules for price adjustment that creates incentives for early access and continued innovation (e.g., new indications and formulations). Novel pricing and payment models should be permitted to accelerate patient access while managing uncertainty with regard to real-world clinical outcomes and budget impact. Pricing and reimbursement policies should be tailored to meet the objectives of different stages of the biopharmaceutical lifecycle, with separate policies for innovative medicines versus off-patent and generic medicines.

Funding

To address demographic and epidemiological trends and to ensure the uninterrupted provision of health care driven by patient outcomes and quality of care, health care finance mechanisms should be appropriately funded. Products without evidence of safety and efficacy should be delisted from the NRDL to free up budget for clinically-proven innovative medicines. Supplemental funding should be allocated to expand access to negotiated products and reduce cost-sharing for patients. Furthermore, we support the adoption of policies that diversify health care financing and further promote a multi-layered medical security system, including supplemental CHI, to improve patient access to innovative medicines and reduce out-of-pocket burden (see below).

Process

Proposed laws, regulations and procedures concerning how medicines are selected, assessed, priced and reimbursed should be published with timely opportunities for comment prior to adoption. Specific determinations and decisions should be fair, evidence-based, reasonable and consistent, with meaningful engagement of stakeholders and supported by written rationales. Procedures, rules and criteria should provide non-discriminatory treatment of pharmaceutical products and a level playing field for manufacturers regardless of their geographic location.

Product appraisals and pricing and reimbursement decisions should be subject to an appeals process with independent review of evidence.

2. Supplemental Commercial Health Insurance

In 2020, China's out-of-pocket personal health care expenditure reached RMB 2 trillion, accounting for approximately 28 percent of total health care expenditure and vastly exceeding the OECD country average of 14 percent.[13], [14]Adopting policies that diversify health care financing will improve patient access to innovative medicines and reduce their out-of-pocket burden. Therefore, PhRMA supports China's goal to establish a multi-layered medical security system to reduce personal health care expenditure, ensure effective use of government and private funding sources to advance health outcomes, and expand access to innovative medicines for Chinese patients. In particular, we support the development of a robust multi-payer system in China, which includes government and CHI payers.

China has taken many steps in recent years to support the growth of CHI, including issuing key policies that have created an environment conducive to CHI's development and led to accelerated growth of the CHI market. The size of CHI market in China based on premium income has grown from RMB 70 billion in 2011 to RMB 844.7 billion by end of 2021 (approximately a 28 percent compound annual growth rate).[15] City Supplementary CHI (CSCHI), a relatively new type of CHI product, had more than 70 million participants across the country in 2021.[16]

To further advance a healthy, sustainable CHI system in China, we recommend:

- The relationship between BMI and CHI is clearly defined and that systems can interact seamlessly. Coverage of CHI plans should be able to extend existing BMI coverage as well as offer coverage for an increased number of innovative medicines that are not covered by BMI.

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13 National Health Commission, "2020 China Healthcare Development Statistics".

14 World Bank "Out-of-pocket expenditure (% of current health expenditure)- OECD members", available at https://data.worldbank.org/indicator/SH.XPD.OOPC.CH.ZS?locations=OE.

15 China Banking and Insurance Regulatory Commission, "December 2021 China's Insurance Business Situation", available at https://www.cbirc.gov.cn/cn/view/pages/ItemDetail.html?docId=1034665&itemId=954.

16 Chinese Medical Information and Big Data Association, Insurance Association of China "CSCHI Development Pattern Research Report" (Jan. 2022).

- Regulating CHI products so that they best meet public needs, including through coverage of pre-existing conditions and consumer protection mechanisms. We encourage the development of a diverse range of indemnity CHI products, which provide coverage based on a patient's medical need, rather than fixed-payment policies, which may fall short of adequate coverage.
- Addressing data availability and management limitations that can hamper actuarial modeling and ability to create targeted, viable products. This could be achieved through universal data coding, data privacy and sharing standards and development of data platforms.
- Improving the integration of CHI with the health management industry, medical service industry and the insurance industry, which would allow CHI to offer better health management services, increase the efficiency of hospital-based medical services and leverage the knowledge of CHI companies.

Conclusion

PhRMA and its member companies believe in the importance of public policies that encourage the discovery of and access to important, new medicines to the benefit of patients and society. As China continues to implement the 14th Five-year Plan and Long-Range Objectives for 2035 and Healthy China 2030 Blueprint, there are numerous opportunities to enhance the vitality of the biopharmaceutical industry and patient access to innovative medicines. PhRMA stands ready to share the experience of the multinational industry in markets around the world to support the advancement of the biopharmaceutical innovation ecosystem in China.