

Improving Patient Access to Innovative Medicines for⁺ a Healthier China

November 2017



China Pharmaceutical Enterprises Association
China Pharmaceutical Industry Association
China Chamber of Commerce for Import and Export of Medicines and Health Products
R&D-based Pharmaceutical Association Committee

Preface

On 19th August 2016, President Xi gave a speech at the “National Health and Wellness Conference” and emphasized that “health is the incumbent requirement for all-around development of humankind and the fundamental condition for socio-economic development; people’s health and longevity is the key symbol of national prosperity and rejuvenation, and the common wish of all people across China”. During the conference, top leadership published the *Healthy China 2030* outline and positioned it as one of the priorities of national development in the new period. The Healthy China 2030 outline comprised 5 major systems that need to be established: 1) Tiered Diagnosis and Treatment System; 2) Modern Hospital Management System; 3) National Medical Insurance System; 4) Drug Supply System; 5) Comprehensive Medical Monitoring & Supervision System. The objective is to establish an effective, high-quality and sustainable national healthcare system in order to meet the medical needs of the people; and furthermore, to ensure healthy development of economy and society.

As the Chinese government gradually introduces a more open pricing system and modernizes the medical insurance system, the Chinese medical insurance system has evolved from a simple funding and payment system to one that plays an increasingly central role in health system reform by establishing reimbursement payment standards for medicine, medical equipment, and healthcare services, and increasing effectiveness of funding allocation through payment mechanism reform. Meanwhile, according to the National Innovation-driven Strategy on encouraging development of innovation-based industries and promoting economic growth, promoting the biopharmaceutical industry has become an institutional arrangement as a National Strategic Emerging Industry. Therefore, decision making departments and execution agencies need to establish a more rational overarching design, optimize management system, and streamline roles and responsibilities for the medical security system, to ensure compatibility between its two objectives of sustainable development and promotion of innovation.

The research report *Improving Patient Access to Innovative Medicines for a Healthier China* systematically assessed practical experiences of models from China and around the world to discuss how to both improve patient access to innovative drugs and promote sustainable development of the medical insurance system to achieve a win-win situation. The study took into consideration the diverse needs of a broad set of relevant stakeholders and combined empirical research with the study of global experiences to formulate systematic perspectives and proposals for the reader.

Dr. Gordon Liu

National School of Development at Peking University,
Changjiang Scholar Distinguished Professor of Economics

Introduction

The top leadership of the Chinese People's Congress and State Council published *Healthy China 2030* on Oct 25, 2016, which mandates that “health is the incumbent requirement for all-around development of humankind and the fundamental condition for socio-economic development; people's health and longevity is the key symbol of national prosperity and rejuvenation, and rather the common wish of all nationalities across China.” Improvement of people's health has become the top priority for China's national strategy.

In 2016, China Pharmaceutical Enterprises Association (CPEA), China Pharmaceutical Industry Association (CPIA), and China Chamber of Commerce for Import and Export of Medicines and Health Products (CCCMHPIE), and R&D-based Pharmaceutical Association Committee (RDPAC), jointly published a report titled *Fostering a Sustainable Ecosystem for Drug Innovation in China*. The current report follows this previous work and focuses on pricing and reimbursement (P&R) policies for innovative medicines, which are critical to achieving the goals of *Healthy China 2030*. P&R policies impact patient affordability and access to medicines, and ultimately determine people's well-being. At the same time, they can also help reward and incentivize innovation. While China's P&R policies for innovative medicines have improved in recent years, challenges still exist that limit the development of pharmaceutical innovation.

China has made remarkable progress in building a drug innovation ecosystem. The China Food and Drug Administration (CFDA) has issued a series of policies and measures to enable drug innovation, including building evaluation capabilities, encouraging clinical trials to be conducted simultaneously in China and globally, enhancing drug quality, etc. With remarkable progress being achieved on the regulatory side, P&R will likely become the next target for improvement as part of a systematic effort to drive drug innovation.

Building on the progress made in the healthcare industry and growing demand for high-quality health care, China is facing numerous access challenges, including limited access to innovative medicines and high out-of-pocket expenses for patients. Improving P&R policies that can help address people's common concerns is a top social priority.

Finally, the State Council has defined drug reimbursement and payment mechanism reform as key tasks for deepening the healthcare reform. P&R policies that help drive coordination among medical services, medical insurance and medical products will become high priority for governments across all levels.

In this context, we joined hands to design evidence-based and sustainable P&R policies for innovative medicines, and developed this report to help guide policy making with the aim of improving people's health and well-being.

This report provides an overview of the key achievements of and challenges in China's P&R system; the report then analyzes key elements influencing P&R policies, including greater coordination and consultation among stakeholders, reimbursement listing and payment standard, the payment mechanism, and provincial and hospital level access; finally, it analyzes global P&R practices in other markets and their implications for China. The report reflects the fact that no one system is perfect or wholly appropriate for China,

and that specific policy proposals developed in this report need to consider China's unique characteristics. The authors of this report hope to support China in developing a best-in-class P&R system that facilitates access to innovative medicines.

While conducting research, the project team conducted in-depth interviews with over 60 experts from related fields, including government officials, academic experts, international pricing and reimbursement experts, hospital leaders, representatives of Chinese pharmaceutical companies that value innovation, and representatives of multinational pharmaceutical companies engaged in R&D investment and related activities in China. We would like to acknowledge the invaluable advice and suggestions we received from them.

China Pharmaceutical Enterprises Association

China Pharmaceutical Industry Association

China Chamber of Commerce for Import & Export of Medicines & Health Products

R&D-based Pharmaceutical Association Committee

Acknowledgement

Great contribution to this study was made by experts and researchers from research institutions, universities, as well as the industry, and we would like to thank them for their valuable advice and guidance. We hereby also would like to express our sincere thanks to the officials and experts who showed interest and provided support to this project.

Professor Gordon Liu, Professor Shi Luwen, Peking University

Professor Shen Qunhong, Tsinghua University

Professor Hu Shanlian, Professor Shao Liming, Professor Chen Yingyao, Fudan University

Professor Liu Yuanli, Peking Union Medical College

Professor Shao Rong, Professor Ding Jinxi, China Pharmaceutical University

Professor Sun Lihua, Shenyang Pharmaceutical University

Professor Gu Xijun, Shanghai University of Traditional Chinese Medicine

Dr. Zhang Zhixin, Head of China-Japan Hospital International Department

Dr. Zhao Kun, Director of Center for Health Policy Evaluation and Technology Assessment, CNHDRC, NHFPC

Dr. Dong Zhaohui, Deputy Director of Medical Insurance Research, ISSR, MOHRSS

Executive Chairman Pan Guangcheng, Deputy Chairman Zhang Ziran, China Pharmaceutical Industry Association (CPIA)

Chairman Guo Yunpei, Deputy Chairman Wang Xuegong, Chinese Pharmaceutical Enterprises Association (CPEA)

Deputy Chairman Xu Ming, Director He Chunhong, China Chamber of Commerce for Import & Export of Medicines & Health Products (CCCMHPIE)

Executive Deputy Chairman Zhang Chengxu, Secretary General Wang Ao, China

Nonprescription Medicines Association (CNMA)

Eric Bouteiller, Jean-Christophe Pointeau, Mike Dethick, China Association of Enterprises with Foreign Investment (CAEFI), the R&D-based Pharmaceutical Association Committee (RDPAC)

Jennifer Osika, Linda Distlerath, Kevin Haninger, Ayelet Haran, Pharmaceutical Research and Manufacturers of America (PhRMA)

Meanwhile, this study also received support from domestic and global colleagues of the pharmaceutical industry, as well as assistance in drafting the report from McKinsey & Company.

Table of Contents

Preface	i
Introduction	ii
Acknowledgement	iv
Executive summary	1
Chapter 1 Importance of an effective pricing and reimbursement policy framework for innovative medicines	3
Chapter 2 Challenges in the pricing and reimbursement system for Innovative medicines	5
1. Context and challenges of China's P&R system for innovative medicines.....	5
2. P&R policy principles.....	8
Chapter 3 Policy proposal for an innovative medicine pricing and reimbursement system	9
1. Coordination and consultation process.....	9
1.1 Coordination among government agencies.....	9
1.2 Government-industry consultation.....	11
1.3 Summary of specific policy recommendations on coordination and consultation within the China P&R system.....	12
2. Reimbursement listing and payment standard.....	13
2.1 Key learnings from global practices.....	13
2.2 Proposed approach for reimbursement policy for China.....	16
2.3 Summary of specific policy recommendations on reimbursement listing and payment standard.....	19

3. Payment mechanism.....	20
3.1 Payment method.....	20
3.2 Payer structure.....	23
3.3 Summary of specific policy recommendations on payment mechanism.....	24
4. Provincial and hospital level access.....	25
4.1 Provincial tendering and hospital negotiation.....	25
4.2 Hospital listing and drug usage.....	27
4.3 Summary of specific policy recommendations on provincial and hospital procurement.....	28

Epilogue	29
----------	----

Summary of specific policy recommendations by relevant government agencies	30
---	----

Appendix: Summary of policy recommendations	34
---	----

Executive summary

China has improved healthcare coverage by expanding services for urban and rural populations and introducing new programs to reduce financial burden on patients, including critical disease insurance, universal outpatient Basic Medical Insurance, and an essential drug system.

Even with this significant progress, China continues to face multiple challenges in providing access to innovative medicines. For example, national and provincial formularies are not updated regularly; reimbursement decisions often lack an evidence base, transparency, and efficiency – involving duplicative steps at different levels of government; alternative funding sources are insufficient to meet patient needs; and hospital information technology and clinical pathways are underdeveloped.

This report reflects the joint work of four pharmaceutical manufacturer associations, China Pharmaceutical Enterprises Association (CPEA), China Pharmaceutical Industry Association (CPIA), China Chamber of Commerce for Import & Export of Medicines & Health Products (CCCMHPIE) and R&D-based Pharmaceutical Association Committee (RDPAC), to design a comprehensive pricing and reimbursement policy framework for innovative medicines. These policies would promote a healthier China by achieving the following objectives:

- Improve patient access to innovative and quality medicines and reduce financial burden on patients;
- Optimize allocation and use of medical resources by focusing on patient needs and rewarding value; and
- Develop a sustainable ecosystem for continuous pharmaceutical innovation and enhanced national competitiveness.

The report offers recommendations in four key policy areas:

Coordination and Consultation

Greater coordination among government agencies would improve how policies are developed and implemented. Current roles and responsibilities should be streamlined so that payers can play a central role in reimbursement decisions. To achieve this, the Inter-Ministerial Joint Conference and Coordination Group should be enhanced to ensure policy coordination.

Ongoing consultation between government and stakeholders would help ensure that policies are informed and working as intended. Government agencies should establish a regular mechanism for stakeholders, including industry, physicians and patient groups, to provide input and enhance the dialogue (e.g., a formal liaison group, regular hearings, etc.).

Reimbursement Listing and Payment Standard

Implementing a sound process to regularly update the National Reimbursement Drug List (NRDL) – one based on evidence, clear guidelines, and negotiation – would help

secure timely patient access to innovative medicines. Manufacturers should be allowed to submit applications for reimbursement and pursue negotiation with the Ministry of Human Resources and Social Security (MOHRSS) after drug approval. An evidence-based assessment of clinical benefits, independent of economic and other considerations, should be conducted prior to negotiations. The negotiation would determine the reimbursement payment standard based on clinical and broader value considerations.

Products successfully negotiated for reimbursement by MOHRSS should not have their reimbursement payment standards re-negotiated or otherwise adjusted by provinces and hospitals. However, provincial authorities may determine what percentage of the reimbursement payment standard they would pay and what percentage would be paid by patients, based on certain guidelines.

Finally, an appeal mechanism should be established for both the clinical assessment and negotiation processes. Opportunities for provincial negotiation should be available for products that do not participate in a national negotiation or fail to reach agreement in that process.

Payment Mechanism

Payment reform is a key government priority to ensure sustainability of the health care system. However, transitioning from a fee-for-service model to a comprehensive payment mechanism would require system upgrades and enhanced capabilities. Separate funding for innovative medicines is also needed to facilitate the adoption of innovative medicines under a new payment mechanism.

Supplemental private health insurance is expected to play an important role in closing gaps in public health insurance and addressing diverse patient needs. Specific steps are needed to remove barriers and unlock the potential of private health insurance for Chinese patients.

Provincial & Hospital Level Access

Innovative medicines that have been successfully negotiated with national reimbursement authorities should be accepted by provincial procurement platforms without being subject to tendering or additional negotiations.

Similarly, hospitals should not require additional negotiations. However, in the short term, any hospital negotiations should be regulated to prevent over-reliance on price concessions to fund hospital operations (e.g., by requiring that prices are linked to procured volumes and by redistributing negotiation profits across hospitals). Furthermore, hospitals should not impose additional restrictions on innovative medicines that ultimately harm patient care, including restrictions on the number of products a hospital may list, the share of total hospital revenue from use of medicines, and the amount of prescriptions for a single medicine.

Importance of an effective pricing and reimbursement policy framework for innovative medicines

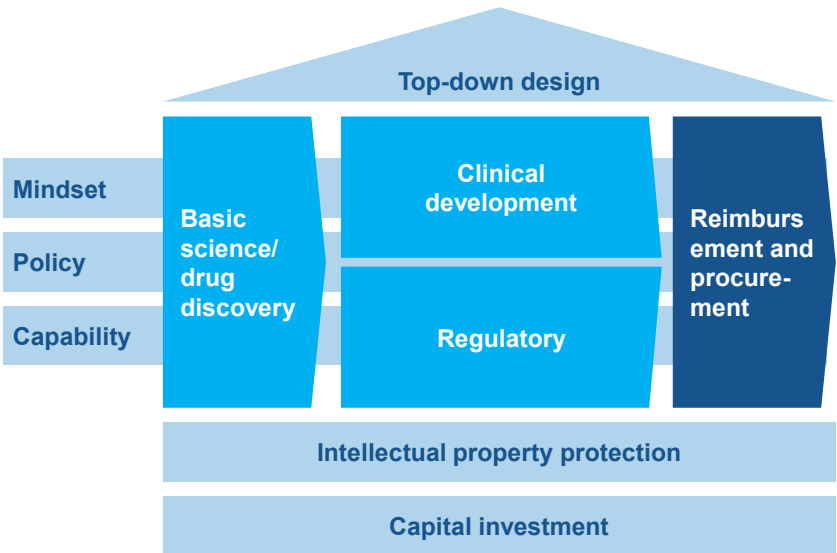
Healthy China 2030 emphasizes “health as a prerequisite for people’s all-around development and a precondition for economic and social development”. As such, building a sound and sustainable pricing and reimbursement (P&R) policy framework that facilitates access to innovative medicines will improve people’s well-being, foster a drug innovation ecosystem, and achieve the ultimate goal of *Healthy China 2030*:

- **An effective P&R policy framework is needed to increase patient access to innovative medicines, reducing the financial burden on patients, and improving the health of the entire nation.** China has made remarkable progress in P&R, with coverage breadth and depth steadily increasing over the past years. At the same time, challenges remain. Patients suffering from certain diseases, especially severe and critical diseases, continue to face a heavy financial burden, while delays in listing a large number of innovative medicines on the Reimbursement Drug List (RDL) create hurdles in addressing the clinical needs of patients. Only by building a sound and sustainable P&R policy framework can China truly increase patient access to innovative medicines that will improve well-being, alleviate out-of-pocket burden, ensure that fewer people become poor or return to poverty because of medical expenditure, and eventually achieve the goal of a healthy nation.
- **An effective P&R policy framework enables efficient use of medical resources and encourages physicians and regulators to focus on patients’ clinical needs.** By building a sound and sustainable P&R policy framework, China will encourage physicians to improve clinical outcomes and the efficiency of reimbursement funds (e.g., through payment reform), incentivize healthy competition among medical institutions, address patients’ clinical needs, and eventually create a lasting impact on the health system.
- **An effective P&R framework is a driving force in stimulating continuous innovation, building capabilities, and enhancing national competitiveness.** In 2016, R&D-based Pharmaceutical Association Committee (RDPAC), China Pharmaceutical Enterprises Association (CPEA), China Pharmaceutical Industry Association (CPIA), and China Chamber of Commerce for Import and Export of Medicines and Health Products (CCCMHPIE) jointly published a report titled *Fostering a Sustainable Ecosystem for Drug Innovation in China*. The report proposed a drug innovation ecosystem framework (Figure 1). All elements along the innovation chain – including basic research and drug discovery, clinical research, regulatory, and patient access – need to be supported by scientific guiding principles, sound policies and mechanisms, and strong capabilities from all parties. Patient access in particular is

an indispensable element of the innovation ecosystem but remains a hurdle. Only by building a sound and sustainable P&R policy framework for innovative medicines can China maintain its momentum towards the sustained development of its drug innovation ecosystem.

The importance of a P&R policy framework for innovative medicines lies in its ability to address fundamental healthcare needs of patients, improve the efficiency of the healthcare system, increase returns on innovation and, by extension, sustainability of the drug innovation ecosystem. Therefore, building an effective P&R policy framework for innovative medicines should be seen as a key priority for China’s healthcare system reform.

Figure 1
Key elements for drug innovation ecosystem



SOURCE: Innovation Ecosystem Report, RDPAC, 2016

Chapter 2

Challenges in the pricing and reimbursement system for innovative medicines

1 Context and challenges of China's P&R system for innovative medicines

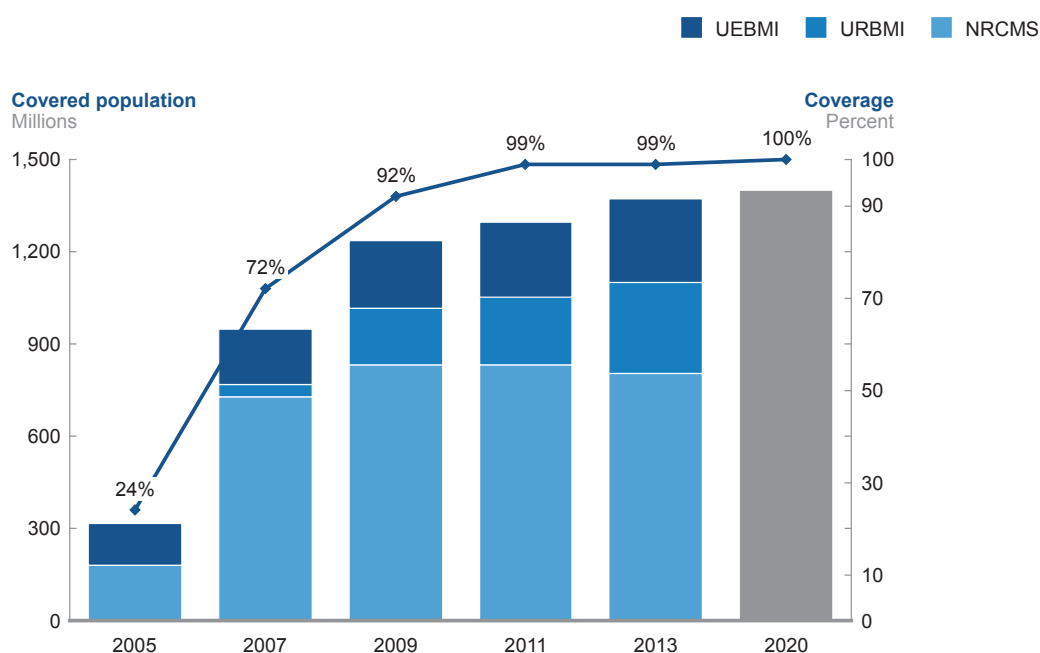
China has made meaningful progress in recent years in developing its P&R system as it works towards achieving universal health coverage.

The breadth of basic medical insurance (BMI) has significantly improved.

China has extended coverage of BMI, including the Urban Employee Basic Medical Insurance (UEBMI), the Urban Resident Basic Medical Insurance (URBMI), and the New Rural Cooperative Medical System (NRCMS), from 25 percent in 2005 to over 95 percent in 2013, providing medical insurance for nearly the entire nation (Figure 2). The national insurance schemes focus on broad and basic coverage, continuously making improvements in coverage breadth. China's progress towards universal health coverage has been widely recognized, including by the World Health Organization.

Figure 2

China has made progress towards achieving universal coverage



SOURCE: MOHRSS; NHFPC Statistics Book

BMI funding levels have been rising steadily. For example, per capita funds raised for NRCMS have increased from 42 RMB in 2005 to 490 RMB in 2015. Elevated funding levels facilitate improved affordability and support expanded coverage of drug reimbursement under BMI. In addition, the establishment of critical disease insurance and the convergence of URBMI and NRCMS, among other policies, have helped address the patient burden resulting from medical expenditures. Yet despite this progress, numerous challenges remain. BMI funding is increasingly under pressure, and depth of coverage remains lacking. For instance, patient co-pays remain high and only a small number of innovative medicines are reimbursed.

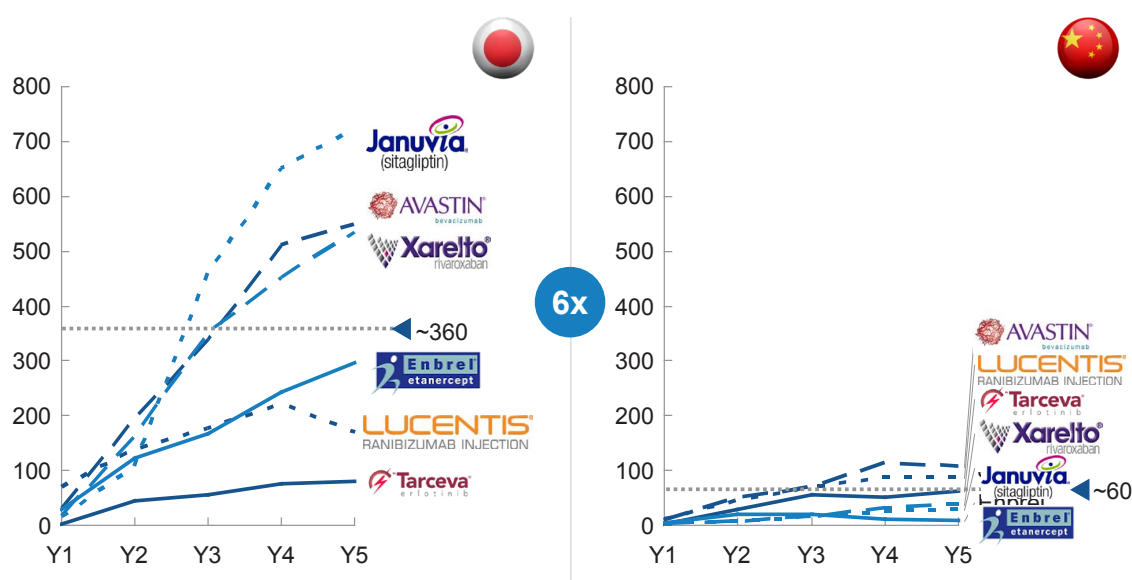
A well-functioning P&R system can have a significant impact on innovative medicines reaching patients at scale. Figure 3 shows the performance of six innovative medicines in China and Japan following market launch. Despite Japan's population being one tenth that of China, the average sales of selected new products in Japan five years after launch is six times that of China. While much of this difference can be explained by Japan's more developed economy –per capita GDP is USD 39,000 in Japan vs. USD 8,100 in China – and greater healthcare spending as a percentage of GDP (10.2% in Japan vs. 6.2% in China), Japan's drug reimbursement system reimburses new medicines shortly after launch (generally within 3 months) ensuring that new medicines reach patients more quickly at scale.

Figure 3

New drugs take longer to reach patients at scale in China

Selected products 5- year sales performance after launch

Mn USD¹



¹ USD/RMB=6.5; USD/JPY=102

SOURCE: Company reports; Prospectus; Testa Marketing; Fuji Keizai; WHO (2014); Industry association, team analysis

In addition to reimbursement and coverage challenges, many other policies in China also affect patient access to innovative medicines. The perception that drug prices in China are too high is driven by numerous factors in the Chinese market that are outside of the manufacturer's control, including distribution markups, VAT, and tariffs. For example, China imposes a 5% tariff on imported medicines, while parties to the WTO Pharmaceutical Agreement (including the USA, EU, and Japan) have reciprocally eliminated tariffs on prescription medicines. China's VAT on medicines is among the highest in the world at 17%, as compared to 10% in South Korea, 3% in Taiwan, 2% in France, and 0% in Australia, Hong Kong, Korea, and other markets.

Several additional challenges can be observed in China's P&R system:

1. The central government has a clear vision to improve people's health and promote innovation; however, specific approaches to achieve this vision may differ.

2. Infrequent updates to the national and provincial reimbursement drug lists lead to insufficient reimbursement for innovative medicines. In many developed markets, new medicines are reimbursed shortly after receiving regulatory approval. However, the interval between the last two NRDL updates in China was eight years. Reimbursement of innovative medicines added to the 2017 NRDL was delayed on average by nearly six years. To address this challenge, MOHRSS recently initiated efforts to explore options for regularly updating the NRDL.

3. Lack of sound, scientific evidence-based decision making. The reimbursement list is decided by expert who vote based on unclear criteria. Good practices for making reimbursement decisions in developed markets are based on objective and consistent evidence-based clinical assessments with clear criteria.

4. The link between price negotiation results and reimbursement remains inconsistent at the local level. Drug prices are largely decided by tendering at the local level, which is not linked to the reimbursement status. Meanwhile, medicines negotiated at the national level also experience challenges being included on the provincial reimbursement list (PRDL).

5. Provincial tendering processes and negotiations follow unclear timelines at different levels. Such uncertainty hinders drug accessibility and the efficiency of drug delivery to patients.

6. Multi-layer negotiations are required across provincial, municipal and hospital levels, reflecting system inefficiencies.

7. Alternative funding sources for innovative medicines remain suboptimal. For example, private health insurance (PHI) growth is restrained by limited access to healthcare data and weak controls over provision of health services.

8. Tendering processes reference each other and call for implementing the "national lowest price" in every province and municipality, without adoption of evidence-based methods or consideration of economic variation among regions.

9. Underdeveloped hospital IT infrastructure and clinical pathways limit the adoption of measures to improve hospital management and drive science-based physician behavior. For example, the adoption of electronic medical records (EMR) by Chinese hospitals is far lower than that of primary care physicians in developed markets.

2 P&R policy principles

The Chinese government aims to set healthcare policy that generally centers around three fundamental priorities: 1) improving access to quality care for patients; 2) fostering a sustainable innovation ecosystem; and 3) building an economically viable healthcare system.

China's future P&R policy framework for innovative medicines should follow a set of guiding principles that closely align with the government's healthcare priorities and effectively address current challenges. An efficient system that provides access to innovative medicines for Chinese patients is composed of three indispensable parts:

- A timely reimbursement listing process to determine which medicines are reimbursed and at what level;
- A payment mechanism for how payments between payer and provider are settled; and
- Distribution channels serving as the “last mile” for patient access to innovative medicines, including hospital procurement (including hospital negotiation and listing) as well as pharmacies or community medical institutions linked with reimbursement systems.

While China has made significant progress in improving the P&R environment for innovative medicines, many challenges remain. An effective P&R policy framework for innovative medicines will be necessary to fundamentally improve China's patient access barriers. The remainder of the report discusses specific policy recommendations on reimbursement listing and payment standard, payment mechanism, and provincial and hospital access.

Chapter 3

Policy proposal for an innovative medicine pricing and reimbursement system

Building a P&R policy framework is a system-level undertaking, which involves multiple government agencies at the central and local levels. As a result, an overarching design is required to ensure aligned and consistent policy development.

This chapter discusses policy proposals in four key policy areas: coordination and consultation, reimbursement listing and payment standard, payment mechanism, and provincial and hospital level access. The proposals are supported by analysis drawn from global and China case studies.

1 Coordination and consultation process

The regulation of innovative medicines involves multiple ministries and entities at the national, provincial and local levels. Therefore, developing a coherent overarching design is of critical importance.

China's P&R system can improve in two important aspects: coordination among government agencies and government-industry communication.

1.1 Coordination among government agencies

(1) Enhance the role of the inter-ministerial joint conference or set up a permanent inter-ministerial coordination group to enhance government coordination

China, like many other countries, faces complex challenges in medical and pharmaceutical development. Tackling problems and making decisions often involves multiple government agencies, including the NHFPC, MOHRSS, NDRC, CFDA, MOF and CIRC at the central level, and many other agencies at the provincial and local levels. Multiple government agencies at the central and local levels that share responsibilities over P&R policies without clear coordination has resulted in inconsistencies among the different policies applied.

In many countries roles and responsibilities over P&R policy are consolidated under one governing body. For instance, the Ministry of Health in France together with its branches and committees play a central role in the French P&R system; in England, the National Health Service consolidates most of the roles and responsibilities for P&R policy; in Japan, the Ministry of Health, Labour and Welfare leads P&R policy.

Better coordination among Chinese government agencies at the central level can be enabled by establishing a formal inter-ministerial joint conference or a permanent inter-ministerial coordination group to ensure successful implementation of P&R policies.

Meanwhile, ministries at the central level should establish dedicated functions to guide policy making at the local level, which will help ensure smooth and thorough implementation of national policies across the country. Furthermore, given that departmental silos and lack of coordination is also prevalent in local governments, improved mechanisms to enhance collaboration among local governmental departments is also required.

(2) Streamline roles and responsibilities to allow payers to play a central role in the future P&R system

In mature markets, government agencies that administer P&R policies are typically under the supervision of one government body. Healthcare reform in these markets generally resulted in the establishment of a central government agency that integrated duplicate responsibilities and functions.

China has begun to streamline roles and responsibilities of different government agencies to allow the payer to play a central role in the P&R system. Such a consolidated role for the payer will allow for greater policy consistency and help develop stronger links between pricing and reimbursement. To further deepen the consolidation of responsibilities, the payer can lead a cross-departmental agency to negotiate with industry, define the criteria for reimbursement listing and payment methods, and ensure policies are ready for implementation. In addition, the payer can work as the administrative body for all insurance schemes under BMI, and regulate hospital behavior through the payment method (see Figure 4). We recommend that changes in agency responsibilities be conducted gradually and in a transparent way, with consultation from broad stakeholders including physicians, academia, industry, and more.

Figure 4

In China, a payor-centric governance model for pricing and reimbursement is emerging

✓ Leading role ✗ Supplementary role

Policy areas	Current responsibilities								Future responsibilities							
	MOHRSS	BOHRSS	NHFPC	BHFPC	CFDA	NDRC	CIRC	MOF	MOHRSS	BOHRSS	NHFPC	BHFPC	CFDA	NDRC	CIRC	MOF
Inter-ministerial coordination			✓ ¹						Permanent inter-ministerial coordination group							
Price monitoring						✓									✓	
Tendering		✗		✓						✗	✗	✓				
Reimbursement payment standard																
Negotiation	✓		✓							✓	✓					
Clinical assessment									Separate step for clinical assessment is needed prior to reimbursement decisions							
RDL / EDL	✓	✓	✗	✗					✓	✓	✗	✗				✓
Payment method	✓	✓							✓	✓						
PHI								✓		✗	✗	✗	✗			✓
Hospital procurement			✓	✓							✓					

MOHRSS in charge of urban BMI RDL and NHFPC in charge of NRCMS RDL and EDL

MOHRSS/BOHRSS expected to lead national negotiation for innovative drugs

Tendering process become simpler for innovative drugs

Single agency shall be in charge of all medical insurances after convergence of insurance schemes

Support of MOHRSS and NHFPC required to debottleneck PHI growth

¹ Health reform office of the State Council in charge of the overall policy coordination, is currently setup in NHFPC

SOURCE: Expert interviews; team analysis

1.2 Government-industry consultation

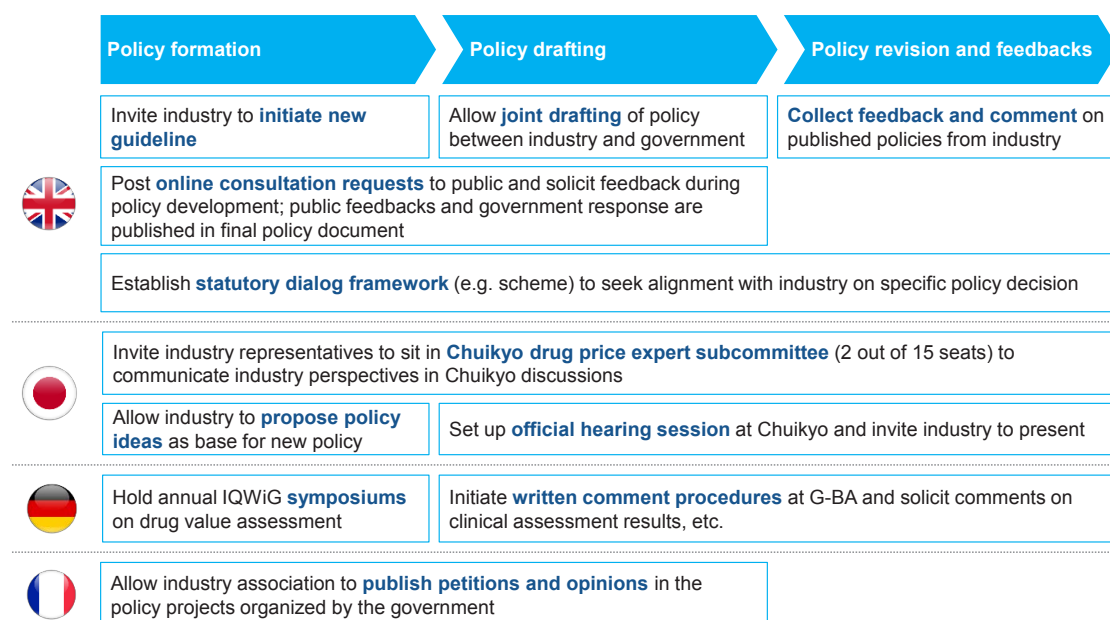
Another challenge in China's P&R policy system is the lack of policy predictability and a mechanism for stakeholders to provide input on policy development. Industry views are important to consider when developing P&R policies to ensure they are practical and implementable, promote patient access to innovative medicines, and foster innovation.

In developed countries, governments adopt various government-industry consultation mechanisms that allow industry to engage in different stages of policy making (such as policy formulation, policy drafting and policy revision). Such regular engagements enhance the transparency of policy making and the ease of implementation.

The UK, for example, has established a robust approach to enable government and industry interaction throughout the policy development cycle. In the policy formation stage, the UK allows industry to initiate new guidelines for evaluation. In the policy drafting stage, the UK engages industry to jointly draft policies with the government. After the policy is released, the UK proactively seeks opinions and feedback from the industry for further improvement and revision. Examples of effective government and industry communication are also observed in other developed markets such as Japan, Germany, and France. (Figure 5)

Figure 5

In many countries, industry is involved throughout the policy development cycle



SOURCE: Expert interviews; team analysis

In China, central and local governments have improved efforts to seek industry input in policy development (e.g., MOHRSS sought public feedback on the NRDL dynamic update). A more robust government-industry consultation mechanism that allows for industry involvement throughout the policy development cycle will help ensure that policies are predictable and sound. Consultation can be held with a range of stakeholders, including manufacturers, physicians, patient groups, etc., to ensure views are collected from all relevant parties. Sufficient time should be allowed for stakeholders to submit comments, and responses to comments and how they will be addressed should also be made available.

1.3 Summary of specific policy recommendations on coordination and consultation within the China P&R system

- Increase coordination amongst government agencies:
 - Enhance the role of the inter-ministerial joint conference or set up a permanent inter-ministerial coordination group to resolve policy inconsistencies and ensure smooth cross-ministerial policy implementation at the provincial and municipal level.
 - Streamline roles and responsibilities to allow payers to play a central role in future P&R decisions.

- Government-industry communication:
 - Establish government-industry consultation mechanisms (e.g., formal industry liaison group, regular hearing sessions, etc.), to facilitate industry's involvement throughout the policy development process, and improve policy predictability, feasibility, and overall success.
 - Consult with a broad set of stakeholders, including manufacturers, physicians, patient groups, etc.

2 Reimbursement listing and payment standard

China's BMI system is close to achieving universal health coverage, with the three BMI schemes covering over 95% of the population. The depth of insurance benefits has been extended as well, as the number of pharmaceutical products included in NRDL is now 1 297 after the 2017 update, in addition to 1,238 traditional Chinese medicine products. BMI funds have seen almost a tenfold growth in the past decade. Policies and programs like the critical disease insurance scheme have further reduced the financial burden on patients.

Despite this remarkable progress, China's BMI system still faces multiple challenges: infrequent NRDL updates; lack of an evidence-based, sustained evaluation system to support reimbursement decisions; inconsistency between national negotiations and provincial implementation, and more.

This section will discuss the challenges in managing reimbursement listing (whether a drug is eligible for reimbursement) and the reimbursement payment standard (the amount the government may pay for a reimbursed drug; the actual amount will be determined by individual provinces depending on their reimbursement percentage), and offer recommendations on how to improve them.

2.1 Key learnings from global practices

Generally, the prices of medicines are negotiated with payers as part of a reimbursement decision, while medicines not reimbursed are priced at market rates. A public payer has the expertise and scale to conduct an objective clinical assessment of a drug, and is rendered the collective bargaining power in negotiations with a manufacturer or wholesaler. This negotiation model has been widely adopted around the world.

For example, in Germany, a drug automatically becomes reimbursed at market prices upon its launch, and then the reimbursement amount is subsequently negotiated between the payer and manufacturer based on additional clinical benefits. In France, manufacturers may initiate a process to assess a drug for reimbursement shortly after launch, and once negotiation is successfully concluded, the drug will be reimbursed. Japan and South Korea adopt a similar approach, with public payers directly in charge of negotiations that determine the reimbursement amount for new drugs.

In China, the link between pricing and reimbursement has not been established. Typically, drug prices are determined by provincial tendering which is led by the bidding office under NHFPC. Separately, the NRDL is developed based on expert voting led by MOHRSS. While the 2017 NRDL reimbursement negotiation of 44 medicines provided important experience, forging such a link between pricing and reimbursement will require a key set of policies and enabling conditions: an evidence-based framework for reimbursement and pricing decisions, a separate step for drug clinical assessment, dynamic updates of reimbursement listing following regular timelines, and transparent processes for implementation at the provincial level.

(1) Evidence-based evaluation framework for reimbursement decisions

Updates to the NRDL are primarily based on expert opinions today. While experts have started to incorporate factors such as clinical benefits and economic considerations into their decisions, an open and transparent reimbursement framework based on clinical benefits does not yet exist.

Most major developed countries, however, have developed evidence-based frameworks for reimbursement decisions. For example, Germany and France are similar in making the added therapeutic benefit of the drug the primary criterion in reimbursement decisions. Both countries conduct a separate assessment of added therapeutic benefit based on manufacturer submissions of clinical trial and other clinical outcomes data. This clinical assessment is used to inform subsequent reimbursement negotiations along with other economic and budgetary considerations.

The UK adopts drug cost-effectiveness as the primary criterion. The UK conducts separate assessment of the cost-effectiveness of a new product based on manufacturer submission of clinical and economic data. The incremental cost-effectiveness ratio and other appraisal factors are used to inform reimbursement decisions.

Japan adopts a more comprehensive approach involving a separate assessment of added therapeutic benefit, market size, and other factors based on a manufacturer submission of clinical and economic data. This information is used to establish a price premium over the comparator, or to establish the price based on production and other costs when a comparator does not exist.

(2) Separate step for drug clinical assessment prior to reimbursement decisions

The process for determining reimbursement of a new medicine should begin with a separate assessment of clinical benefits that meets the following recognized standards:

- Describes a sound process that is open and transparent, with regular opportunity for input by manufacturers and a strong role for patients and physicians.
- Supports patient-centered care by considering patient preferences and heterogeneity, appropriately communicating results, and avoiding misuse.
- Delivers reliable, relevant information by using rigorous, transparent methods that rely on the full range of evidence and prioritize longer-term and broader outcomes.

- Values continued scientific and medical progress by accounting for personalized medicine, the step-wise nature of progress, and the inherent value of innovation.
- Takes a system-wide perspective on value by examining the full range of tests, treatments, care management approaches and health care services.





The clinical assessment should be conducted separately from economic and other considerations to avoid any potential for distorting the clinical science and evidence. Accordingly, the clinical assessment should be conducted by clinical experts familiar with the drug and its particular pharmacology. This underscores why the existing voting process does not result in the best clinical decisions for patients.

Many countries have set up independent clinical assessment organizations to support reimbursement decisions. (Figure 6)

Figure 6

Independent drug assessment organizations can lend strong support to reimbursement decisions

EXAMPLE

Organization for clinical assessment	Organization for reimbursement decision
 <ul style="list-style-type: none"> ▪ IQWiG¹ – examine objectively the advantages and disadvantages of medical interventions to inform reimbursement decisions 	<ul style="list-style-type: none"> ▪ G-BA² – makes the reimbursement decision based on results from IQWiG ▪ GKV-SV³ – price negotiation with pharmacos based on IQWiG assessment
 <ul style="list-style-type: none"> ▪ HAS⁴ – performs benefit assessment (in the format of SMR and ASMR rating) and economic evaluation (as needed) 	<ul style="list-style-type: none"> ▪ CEPS⁵ – makes reimbursement decision and negotiates price with pharmacos, based on the assessment of HAS
 <ul style="list-style-type: none"> ▪ Chuikyo⁶ – DPO⁷ within Chuikyo leads price negotiation with Pharmacos 	<ul style="list-style-type: none"> ▪ MHLW⁸ – reimburses drugs via NHI, based on price negotiation results between Chuikyo and pharmacos
 <ul style="list-style-type: none"> ▪ N/A 	<ul style="list-style-type: none"> ▪ MoHRSS, based on expert opinions

1 Institute for Quality and Efficiency in Health Care; 2 Joint Federal Committee; 3 National Association of Public Payors; 4 French National Authority for Health; 5 Economic Committee on healthcare products; 6 The Central Social Insurance Medical Council; 7 Drug Pricing Organization; 8 Ministry of Health Labor and Welfare

SOURCE: Expert interviews; team analysis

Establishing an independent clinical assessment organization in China will take time. Therefore, it will be important to allow a period of transition during which the development of clinical assessment capabilities will not delay dynamic reimbursement.

(3) Dynamic update of reimbursement listing following regular timelines

Infrequent updates of the reimbursement drug list (e.g., an 8-year interval between the last two NRDL updates in 2009 to 2017) poses another major challenge for patient access to

innovative medicines. MOHRSS has articulated in several policy documents that future NRDL updates will be regular.

Based on global practices, one key element of regular listing updates is the application process, i.e., manufacturers are allowed to submit applications for reimbursement at any time and responsible government agencies respond within a certain timeframe. For example, in France, manufacturers can submit an application at any time, and the Transparency Committee completes a clinical assessment within 3 months. Following this clinical assessment, the French Economic Committee (CEPS) negotiates prices.

Germany also stipulates the time for each step of the reimbursement process. Manufacturers submit applications at the time of launch, and G-BA passes a resolution after 3 months to decide whether the product offers additional therapeutic benefit, and whether a price negotiation is needed. The National Association of SHI Funds (GKV) then completes the price negotiation with manufacturers within 6 months.

For China, the current approach of a centrally organized NRDL update needs to shift towards a dynamic application system, in which manufacturers may submit a request for reimbursement at any time, drug clinical assessment, following a transparent process and clear evaluation criteria, needs to be completed within a pre-defined period (e.g., within 90 days) following the application, and negotiations between manufacturers and the responsible government agency (led by MOHRSS) take place periodically (e.g., semi-annually). The regular NRDL update process may be managed by MOHRSS, with support from multiple agencies and committees.

2.2 Proposed approach for reimbursement policy for China

In light of global practices and the current Chinese context, we propose the following approach for China's reimbursement policy, in which P&R negotiations at the national level will be closely tied to local implementation. (Figure 7)

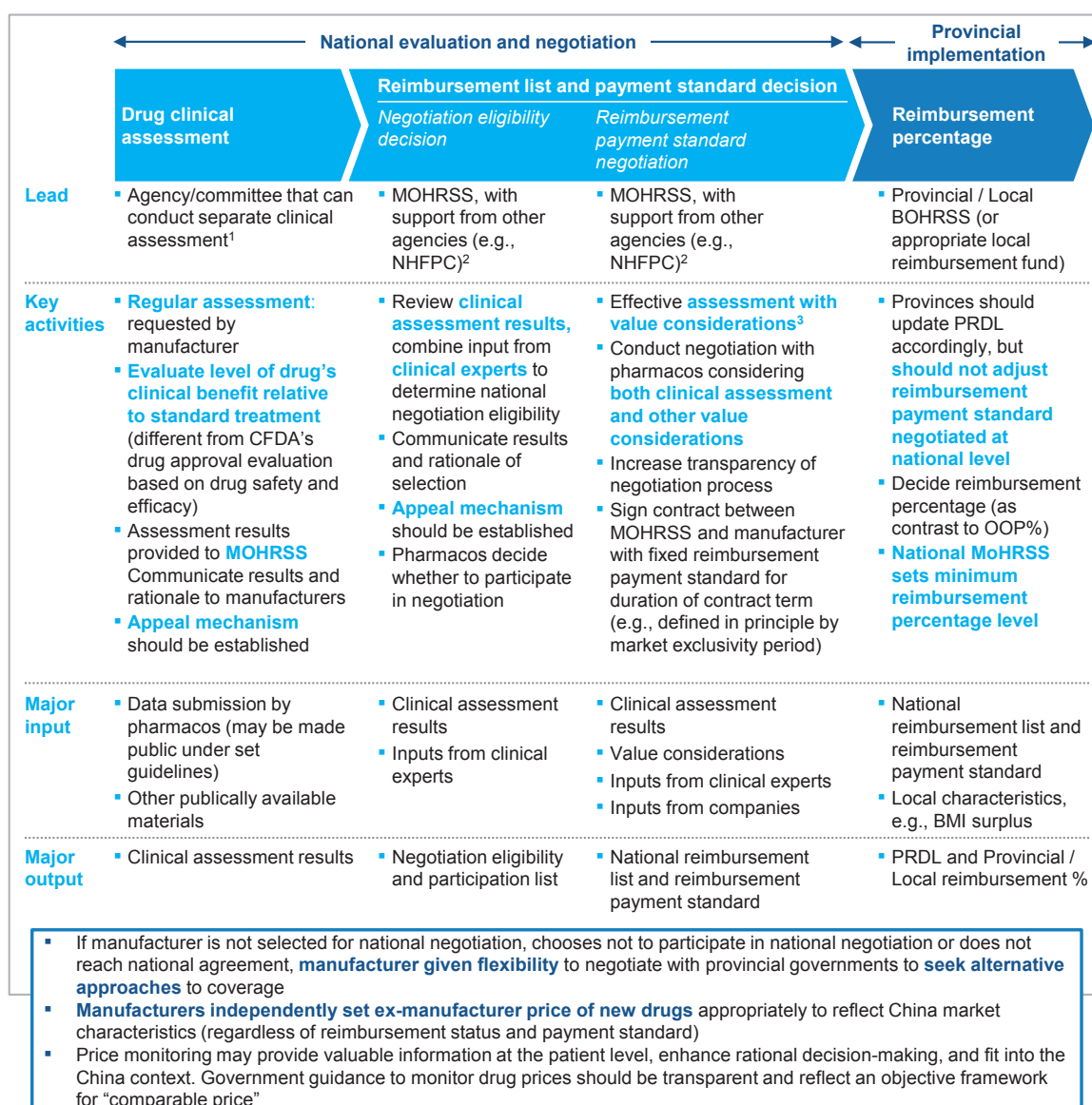
MOHRSS will serve as the primary national body for P&R negotiation, with support from other agencies (e.g., NHFPC). MOHRSS will negotiate with manufacturers to determine reimbursement listing and the reimbursement payment standard. The reimbursement payment standard will be fixed for the duration of contract term (e.g., defined in principle by the market exclusivity period).

Provincial BOHRSS (or another appropriate local reimbursement fund) will not re-negotiate the reimbursement payment standard, but can decide on the local reimbursement percentage subject to central government issued guidelines (e.g., a minimum reimbursement percentage).

A fair and transparent reimbursement decision-making process should be mandated, and an appeal mechanism should be established for both the clinical assessment and negotiation.

Figure 7

Process for national reimbursement negotiation and local implementation



¹ Clinical assessment may be conducted by MOHRSS, independently, or by other ministries (NHFPC, State Council HR Office);

² Support from clinical expert panel; funding may be provided by manufacturers through standard assessment fees to ensure neutrality

³ Including health outcomes; quality of life; impacts on health care and non-health care costs; productivity; other societal benefits such as disease severity, unmet medical needs, and scientific spillovers; and other treatment-related benefits compared to current standards of care in China

SOURCE: Expert interviews; team analysis

The proposed negotiation and implementation process includes three steps:

- Step 1: Manufacturers submit a clinical assessment request to the responsible agency or committee, which conducts an independent evaluation of the drug's clinical benefit relative to the standard of care. This assessment differs from CFDA's drug approval evaluation based on drug safety and efficacy. Clinical assessment should be conducted through a transparent process with pre-defined timelines, results are provided to the relevant government agencies in MOHRSS to determine eligibility for national reimbursement negotiation. Assessment results and rationales should be communicated to manufacturers and an appeal mechanism should also be established.
- Step 2: MOHRSS, with support from other agencies, reviews clinical assessment results and combines input from clinical experts to determine the drug's national negotiation eligibility. If the manufacturer decides to participate in the national negotiation, MOHRSS, with support from other agencies, conducts an appraisal of broader value considerations (including health outcomes, quality of life, impacts on health care and non-health care costs, productivity, budget impact, etc.). MOHRSS and manufacturers will use this information in negotiations to determine a national reimbursement payment standard. Following a successful negotiation, a contract is signed between MOHRSS and the manufacturer with a fixed reimbursement payment standard for the duration of the contract term.
- Step 3: Provincial BOHRSS (or the appropriate local reimbursement fund) updates the PRDL accordingly and decides the patient co-pay percentage based on pre-determined factors and a minimum reimbursement level set by MOHRSS. The reimbursement payment standard negotiated at the national level should not be adjusted. Products that are successfully negotiated for reimbursement should not be subject to provincial tendering or secondary negotiations at the hospital level.

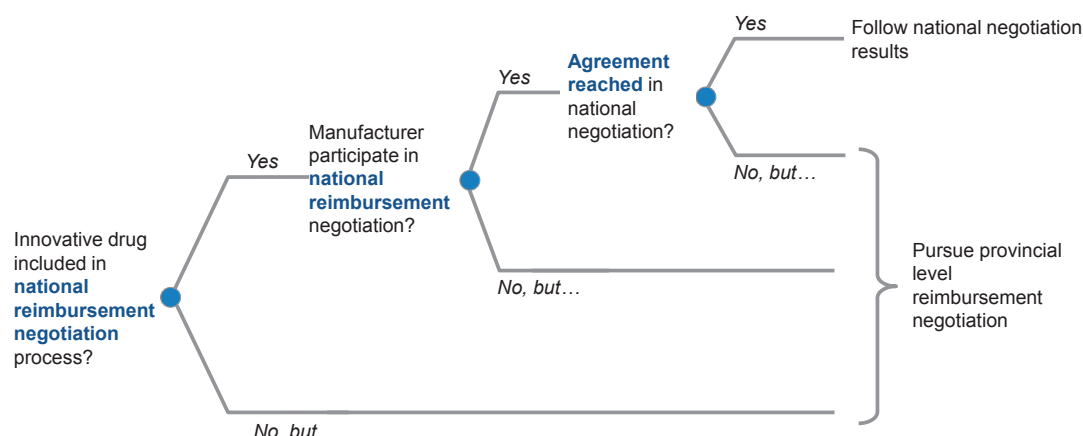
While manufacturers and the government will negotiate the reimbursement payment standard for innovative medicines, manufacturers may independently set the ex-manufacturer price of new medicines to reflect China market characteristics, regardless of reimbursement status and amount. Price monitoring should engage all stakeholders, be goal-driven, and have the right context to help healthcare providers make sound clinical decisions and patients understand their out-of-pocket payments. Government monitoring of drug prices should be transparent and reflect an objective framework for "comparable price".

If a product is not selected for national negotiation, or if a manufacturer chooses not to participate in national negotiation or does not reach national agreement, then the manufacturer should have the flexibility to enter into provincial or local negotiations for reimbursement. (Figure 8)

Figure 8

For innovative drugs, provincial level negotiation may be an alternative approach to reimbursement beyond national negotiation

National evaluation and negotiation with flexibility for provincial negotiation



SOURCE: Expert interviews; team analysis

Manufacturers may pursue reimbursement at the provincial or local level on a regular basis prior to or following national negotiation (for the latter, if national negotiation is unsuccessful). Flexibility should be given for manufacturers to pursue multiple reimbursement paths to increase patient access to innovative medicines. Provincial governments may decide whether to enter into alternative reimbursement arrangements outside of the national negotiation framework, and may conduct economic assessments at the local level. However, additional clinical assessments should not be necessary if such an assessment was conducted at the national level.

2.3 Summary of specific policy recommendations on reimbursement listing and payment standard

- Link reimbursement listing and payment standard through a negotiation process between manufacturers and payers. Given confidentiality and capacity challenges at the provincial level, national negotiations are preferred in the near future.
- Manufacturers shall be allowed to submit reimbursement applications and pursue negotiation on a regular basis.
- A transparent, evidence-based assessment, focused on clinical benefits and independent from economic considerations, should take place within a set timeframe prior to negotiations to ensure timely updates to the NRDL.
- Following the clinical assessment, a fair negotiation based on clear conditions and open communication should be conducted between the national reimbursement

authority and the manufacturer. The negotiation will determine the reimbursement payment standard based on broader value considerations.

- Products successfully negotiated for reimbursement at the national level should not be subject to provincial tendering or secondary negotiations of the reimbursement payment standard. However, the provincial authority may decide the reimbursement percentage based on certain guidelines (e.g., a minimum reimbursement percentage for negotiated medicines can be set to better ensure patient affordability). Opportunities for provincial access may be available for products that do not participate in national negotiation or fail to reach agreement at the national level.
- It is essential that criteria for clinical assessment submissions are specified, and that manufacturers are allowed to seek clarification to ensure accuracy and objectivity. Similarly, an appeals mechanism should be established for both the clinical assessment and negotiation processes.

3 Payment mechanism

3.1 Payment method










Despite the remarkable progress in increasing health coverage, China still faces challenges in optimizing resources and reducing waste in the healthcare system. The current fee-for-service payment method in most Chinese hospitals does not incentivize efficiency due to lack of appropriate utilization management and can lead to system waste. To achieve sustainable growth of the healthcare system, payment reform has become a critical topic on the government's agenda. This section discusses policy proposals and capabilities required to further payment reform in China.

Different payment methods are adopted across countries (see Figure 9). A country may adopt a composite payment model by combining multiple payment methods. In China, a comprehensive payment mechanism would provide greater incentives to drive efficiency and reduce waste. However, no payment method is perfect, and in adopting a more sophisticated and treatment-based payment method, China needs to build a solid foundation of system capabilities, to ensure the payment method benefits both patients and the healthcare system while also enabling access to innovation.

Figure 9

Most developed countries adopt comprehensive payment methods

✓ Hospital payment ✓ Outpatient payment

Major payment methods of different countries						
Countries	Global budget control	Fee-for-service	Capitation based	Episode based ¹	DRG based	Pay-for-performance
Australia 	✓	✓			✓	
England 		✓	✓		✓	✓
France 		✓	✓		✓	✓
Germany 		✓			✓	
Japan 		✓✓			✓	
Netherlands 		✓	✓		✓	✓
Singapore 	✓	✓			✓	
Sweden 	✓	✓	✓		✓	✓
US 		✓✓	✓	✓✓	✓	✓✓

¹ Also known as bundled payment

SOURCE: 2015 International Profiles of Health Care Systems; expert interviews; team analysis

A. Separate injection of reimbursement funding for innovative medicines

Comprehensive payment methods may offer providers a fixed amount per case treated, which would cover various costs including medical supplies and medicines. A separate injection of reimbursement funding for innovative medicines is important to ensure that patients receive needed innovative medicines. Without such a subsidy, a comprehensive payment system would discourage physicians and hospitals from prescribing and dispensing innovative medicines.

Many countries subsidize innovative medicines separately under comprehensive payment methods (Figure X). In France, for example, expenditure for most medicines is covered under the diagnosis-related group (DRG) payment mechanism. These medicines are called “T2A medicines”, and their full expenditure is counted as a cost for providers. At the same time, the French government also maintains a “non T2A drug list”, mainly including high-value innovative medicines. The cost of such medicines is separately reimbursed by health insurance rather than included in the DRG so as to not discourage appropriate patient access to innovative medicines.








In China, a separate allocation of reimbursement funding for innovative medicines is needed as part of a comprehensive payment mechanism. The allocation of national and

provincial health budgets should be assessed regularly to ensure sufficient funding is allocated to sustain and encourage innovation.

Innovative medicines should be funded primarily through more efficient use of reimbursement funding and to a limited extent through increased funding levels. Rational use of medicines based on clinical benefit will help to reduce system waste and help meet the demand of patients in the long run. Medicines with little clinical value may see their reimbursement levels reduced, usage restricted, or they may even be delisted from hospitals.

Figure 10

Comprehensive payment methods should include separate payment for innovative medicines

Countries	% of hospital revenue from DRG payment	Items covered by separate payment funding			
		High-value drugs	Teaching	Research	Capital costs
France 	80%	✓	✓	✓	
Germany 	80%	✓	✓	✓	✓
Netherlands 	84%	✓	✓	✓	
Poland 	>60%	✓	✓	✓	
Sweden 	Varies by hospital	✓	✓	✓	
England 	60%		✓	✓	
Portugal 	80%		✓	✓	

SOURCE: DRG systems in Europe; expert interviews; team analysis

B. Close capability gaps to transition toward comprehensive payment methods

Apart from establishing a separate payment method for innovative medicines, China cannot successfully transition towards comprehensive payment methods without significant upgrades in its capabilities and mechanisms. The following recommendations will support China's capacity-building goals:

(a) Unify and periodically update diagnosis and treatment categorizations by creating common activity categorizations across the nation, and increasing transparency to enable practitioners to offer suggestions for improvement.

(b) Develop coding capabilities in hospitals by standardizing case reports through physician training, recruiting coding specialists to help with case coding and coding review, and developing automatic IT systems to increase efficiency.

(c) Conduct cost accounting studies in representative hospitals with sufficient sample size and provider archetype representation.

(d) Systematically review case-level cost data and provider behavior; enhance clinical capability of BOHRSS to identify and monitor risks.

(e) Adopt quality-related adjustments to final payment, e.g., link a portion of the payment to service quality to deter provision of inadequate care.

(f) Based on the evidence gathered, **adopt a multi-ministerial solution to ensure hospitals and physicians are adequately financed and incentivized** to provide high-quality care and make meaningful clinical decisions for their patients.

3.2 Payer structure

Today, a major healthcare funding source in China is basic medical insurance (BMI). With increasing pressures on BMI funds to expand coverage, and ongoing concerns over the suboptimal management of the funds, private health insurance (PHI) may be able to help increase the overall efficiency of the healthcare system. Currently, PHI is nascent in China, unable to sufficiently supplement BMI and satisfy diversified patient needs.

PHI only accounts for 10 percent of overall private healthcare expenditures, far below other countries where public insurance also plays the major role, such as Germany (Figure 11).

China currently faces major barriers to expand PHI. First, PHI companies lack oversight mechanisms over healthcare providers. PHIs have not yet developed capabilities to monitor hospital behavior effectively; the 22,000 hospitals in China are mostly standalone institutions, making it even more difficult to manage provider networks. In addition, large hospitals are often overburdened; therefore, private payers have limited negotiation power. Second, China's healthcare system lacks comprehensive and robust data on disease incidence, prevalence, treatment standards and costs, which creates challenges for PHI companies to effectively develop plans and calculate premiums. Third, public awareness of and willingness to pay for PHI is not yet developed; many push-sales models are far from customer-centric and hurt the reputation of the PHI industry.

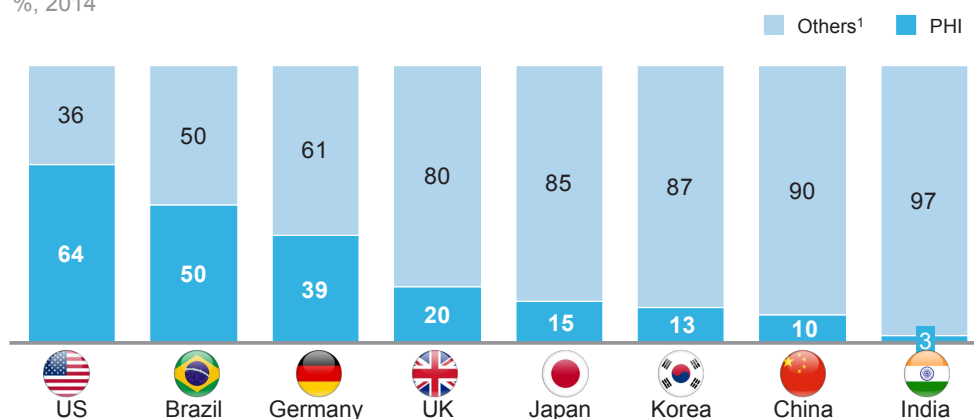
Figure 11

Low PHI share in China healthcare expenditure

Private health insurance in China is still nascent

Private health insurance as % of private expenditure on health

%, 2014



- The coverage of private health insurance in China is lower than developed countries where public insurance also plays the major role
- PHI in China will primarily serve as a supplement to the government insurance programs

¹ Predominantly out of pocket expenditure, also includes non-profit institutions serving households (e.g. NGOs) and other private funding sources
SOURCE: WHO; expert interviews; team analysis

To supplement the BMI coverage gaps and address the diverse needs of patients, China can encourage the rapid development of PHI by improving data availability, reducing PHI market access hurdles, facilitating better PHI-provider links, establishing a preferable tax system for PHI, and enhancing coordination among NHFPC, MOHRSS and CIRC.

3.3 Summary of specific policy recommendations on payment mechanism

- Payment method:
 - Build a solid foundation of capabilities and conduct thorough analysis before gradually moving from simple fee-for-service model to comprehensive payment mechanism;
 - Provide separate injection of reimbursement funding for innovative medicines under a new payment mechanism;
 - Close capability gaps to move to a more sophisticated and treatment-based payment method.

- Payer structure:
 - Improve effectiveness of the public payer by leveraging private payer fund management capabilities;
 - Empower private payers: unleash the potential of PHI to supplement BMI by improving data availability, reduce PHI market access hurdles, and improve PHI-company links.

4 Provincial and hospital level access

As the “last mile” in the value chain of the pharmaceutical industry, provincial and hospital level access has a direct impact on timely delivery of high-quality medicines to patients. Currently, medicines must go through multiple layers of negotiation (e.g., national, provincial, hospital) before patients gain access. Compared to other markets, hospitals in China play a particularly important role in the P&R system. However, efforts to fill the budget shortfall from the “zero markup policy” through negotiations continue, and limitations on hospital listing remain a challenge for patient access.












4.1 Provincial tendering and hospital negotiation

Multiple layers of negotiation at national, provincial, municipal and hospital levels reflect system inefficiency in China. In order to increase patient access to innovative medicines, products successfully negotiated with national reimbursement authorities should be directly accepted by the provincial procurement platform without provincial tendering or secondary negotiation.

Hospital negotiation is a common practice in many countries. However, given the differences across healthcare systems, negotiations have to be conducted using different methods and at different levels (Figure 12). For example, in France and Germany, negotiations take place at the hospital level with each individual hospital connecting to a group purchasing organization (GPO) to gain better bargaining power with manufacturers and wholesalers. In the UK, after tendering by the Commercial Medicines Unit (CMU), NHS allows hospitals to procure medicines directly from wholesalers at a lower price.

Figure 12

Hospital negotiation is a common practice in different countries

<div>  Central level  Provincial level  Local level (Individual, hospital / GPO) </div>					
Country	Procurement/ negotiation level	GPO's drug share at hospital %	Volume-based tender/rebate	Confidential procurement price	Remarks
 France		▪ ~80%	✓	✓	▪ ONCAM and PHARE programmes are exerting considerable pressure on the hospital to reduce drug prices
 Germany		▪ ~80%	✓	✓	▪ Hospitals use tendering to reduce drug price and control overall cost
 UK		▪ ~0%	✓	✓	▪ After tendering by CMU ¹ , NHS allows hospitals to procure the drugs directly from wholesalers at a lower price
 Japan		▪ ~0%	✓	✓	▪ High pressure for cost reduction as hospitals rely on margin obtained from negotiation with wholesalers

¹ In charge of the procurement platform

SOURCE: Expert interviews; team analysis

A recent China State Council document emphasized the important role of hospitals in drug procurement. China could improve reimbursement coverage across multiple channels (e.g., retail pharmacy) and expand dispensing channels by promoting the establishment of independent pharmacies (e.g., a direct-to-patient pharmacy system) and gradually transition dispensing out of hospitals. These actions would maximize patient access to reimbursed medicines in parallel to hospitals.

In the medium term, China can progressively increase funding for public hospitals to compensate for the funding gap caused by the “zero mark-up” policy.

In the context of current funding levels for public hospitals, mechanisms to regulate hospital negotiation should be in place to prevent hospitals from being overly focused on obtaining price discounts at the expense of drug quality and clinical efficacy.

If the hospital procurement price is lower than the reimbursement payment standard, the difference can be retained by the hospitals. To prevent hospitals from overly focusing on price discounts, the government may consider the following recommendations, based on both domestic and global experiences:

- Follow an evidence-based approach and thoroughly assess the necessity and effectiveness of hospital negotiation practice in the short and long terms.

- Newly launched medicines or medicines that have successfully conducted reimbursement negotiations at the national level should be made available on the provincial procurement platform without tendering and in principle should not be subject to hospital negotiation.
- For areas allowing hospital negotiation, any negotiation profits should not be given directly to hospitals, so as to avoid overly incentivizing hospitals to obtain additional funding through drug sales.
- Hospital negotiations should be well-regulated, e.g., negotiated prices can be linked to procurement volume.

4.2 Hospital listing and drug usage

Hospital formulary listing is another essential step to ensure patient access to innovative medicines. However, infrequent listing updates and rigid listing requirements have delayed clinical use. For example, formulary updates in western European countries generally occur within 6 months, while in China this has required one to two years, or more.

Developed markets typically have clear guidelines on how to conduct the hospital listing process. In the UK, public hospitals are supposed to complete the listing process within 3 months following a positive reimbursement decision. In France, guidelines require frequent updates of hospital formularies to ensure adherence to clinical pathways. Moreover, hospitals typically have a fixed-term formulary committee to ensure timely management. Formulary committees are staffed with senior physicians on fixed terms, with frequent meetings and decision-making cycles. The committee is often chaired by a pharmacist and other clinical professionals, e.g., physicians, nurses and pharmacists.

China has not published national guidelines on hospital listing. Each hospital determines its own formulary listing process, listing review cycle and drug selection criteria. The setup of the drug formulary committees also significantly differs from one hospital to another.

To accelerate hospital listing, China can publish nation-wide guidelines to regulate the listing process, encourage hospitals to adopt innovation, and improve hospital formulary committee practices (e.g., regular and predictable meeting frequency, decision making process and criteria for formulary updates).

Two more factors regarding listing requirements are causing delays in hospital listing. First, listing requirements of “1 molecule, 2 products” and total hospital product limits create extra hurdles for new medicines to enter the hospital formulary. The total hospital drug limit (e.g., some hospitals are restricted from listing more than 1,200 medicines) leads to long delays as old medicines need to be removed before new medicines are added, which requires alignment among different clinical departments. While drug listing restrictions will continue to exist, listing cap restrictions (e.g., total hospital drug limit) for innovative medicines should be removed to encourage faster patient access.

Second, hospitals are restricted by the percentage of hospital revenue attributed to medicines. Even if innovative medicines enter the formulary list, hospitals would still be

conservative in clinical usage of innovative medicines to control the drug contribution to hospital revenue, posing a new challenge to patient access. While the drug contribution to hospital revenue and single prescription amount limits remain a hospital key performance indicator (KPI), excluding innovative medicines from the calculation of drug contribution to hospital revenues and removing single prescription amount limits will give physicians greater flexibility to meet the diverse needs of their patients. Gradually, drug listing restrictions and drug contribution to hospital revenue as a hospital KPI should be phased out.

4.3 Summary of specific policy recommendations on provincial and hospital procurement

- Innovative medicines successfully negotiated with the national reimbursement authority should be directly accepted by the provincial procurement platform without provincial tendering or secondary negotiation.
- Hospitals should not conduct negotiations for innovative medicines. Given that in the near term some regional hospitals or hospital groups are allowed to re-negotiate, hospital negotiations should be regulated to:
 - Allow negotiated prices to be linked to procurement volume.
 - Limit profits gained from hospital re-negotiation to prevent hospital reliance on pharmaceutical price concessions.
- Progressively increase funding for hospitals to compensate for the funding gap created by the “zero mark-up” policy.
- Expand dispensing channels for reimbursed products to improve patient access to innovative medicines by promoting the establishment of independent pharmacies (e.g. a direct-to-patient pharmacy system).
- Remove restrictions on listing caps for innovative medicines, drug revenue percentage, and single prescription amount limits for innovative medicines.
- Publish hospital formulary listing guidelines (e.g., formulary committee meeting frequency, decision making process and criteria for formulary updates).

Epilogue

China has built universal medical insurance system from scratch, achieving nearly universal coverage that improves people's health and reduces the burden of medical expenditures.

Healthy China 2030 proposed more ambitious targets: improve healthcare services, broaden the coverage, and strengthen the health of the industry to improve the health of the population.

China's healthcare system has already come into a critical stage of development, and the P&R system is integral to successful healthcare system reform. Achieving the goals of *Healthy China 2030* will require efforts on several fronts: coordination between government bodies and sufficient consultation between government and industry; creation of a timely, transparent and predictable clinical assessment and reimbursement negotiation process; payment mechanism reform that increases efficient use of healthcare resources while ensuring high quality care, and development of PHI; removal of hospital listing limits for innovative medicines and standardization of hospital procurement processes to improve timely patient access to innovative medicines.

Summary of specific policy recommendations by relevant government agencies

Policy Recommendations	Relevant government agencies							
	MOHRSS	BOHRSS	NHFPC	BHFPC	CFDA	NDRC	CIRC	MOF
1. Coordination and Consultation								
1.1 Coordination among government agencies								
<ul style="list-style-type: none"> Enhance role of the inter-ministerial joint conference or set up an inter-ministerial coordination group to facilitate cross-ministerial policy development and implementation at the central and local level 	✓	✓	✓	✓	✓	✓	✓	✓
<ul style="list-style-type: none"> Gradually shift towards a payer-centric governance model for P&R 	✓	✓	✓	✓		✓	✓	
1.2 Government-industry communication								
<ul style="list-style-type: none"> Establish government-industry consultation mechanisms to facilitate industry's involvement throughout the policy development process, and improve policy predictability, feasibility, and overall success 	✓		✓		✓	✓	✓	✓
2. Reimbursement listing and payment standard								
<ul style="list-style-type: none"> Link national reimbursement listing and payment standard through a negotiation process between manufacturers and payers 	✓		✓					
<ul style="list-style-type: none"> Manufacturers shall be allowed to submit reimbursement listing applications and pursue negotiation at any time 	✓	✓						

Policy Recommendations	Relevant government agencies							
	MOHRSS	BOHRSS	NHFPC	BHFPC	CFDA	NDRC	CIRC	MOF
<ul style="list-style-type: none"> A transparent, evidence-based assessment, focused on clinical benefits and independent from economic considerations, should take place within a set timeframe prior to negotiations to ensure timely updates to the NRDL 	✓		✓					
<ul style="list-style-type: none"> National negotiation will determine the reimbursement payment standard based on broader value considerations 	✓							
<ul style="list-style-type: none"> Provincial BOHRSS (or appropriate local reimbursement fund) should adopt national negotiation results and can decide local reimbursement percentage under central government issued guidelines (e.g., minimum reimbursement percentage) 	✓	✓						
<ul style="list-style-type: none"> If manufacturer chooses not to participate in national negotiation or does not reach national agreement, they should have the flexibility to negotiate with provincial governments to seek alternative approaches to coverage 	✓	✓						
<ul style="list-style-type: none"> It is essential that criteria for clinical assessment submissions are specified, and that manufacturers are allowed to seek clarification to ensure accuracy and objectivity. Similarly, an appeals mechanism should be established for both the clinical assessment and negotiation processes. 	✓		✓					

Policy Recommendations	Relevant government agencies							
	MOHRSS	BOHRSS	NHFPC	BHFPC	CFDA	NDRC	CIRC	MOF
3. Payment mechanism								
3.1 Payment method								
<ul style="list-style-type: none"> Gradually move from simple fee-for-service model to comprehensive payment mechanism based on sufficient data , analysis, and capability building across hospitals and medical institutions 	✓	✓	✓	✓				
<ul style="list-style-type: none"> Provide separate injection of reimbursement funding for innovative medicines under a new payment mechanism 	✓	✓	✓	✓				✓
3.2 Payer structure								
<ul style="list-style-type: none"> Improve effectiveness of the public payer by leveraging private payer fund management capabilities 	✓	✓					✓	
<ul style="list-style-type: none"> Empower private payers: unleash the potential of PHI to supplement BMI by improving data availability, reduce PHI market access hurdles, and improve PHI-company links 	✓	✓	✓	✓		✓	✓	
4. Provincial and hospital level access								
4.1 Provincial tendering and hospital negotiation								
<ul style="list-style-type: none"> New medicines and medicines successfully negotiated with the national reimbursement authority should be directly accepted by the provincial procurement platform without provincial tendering or secondary negotiation 	✓	✓	✓	✓				

Policy Recommendations	Relevant government agencies							
	MOHRSS	BOHRSS	NHFPC	BHFPC	CFDA	NDRC	CIRC	MOF
<ul style="list-style-type: none"> Progressively increase funding for hospitals to compensate for the funding gap created by the “zero mark-up” policy 			✓	✓				✓
<ul style="list-style-type: none"> Regulate hospital negotiation by assessing necessity, removing profit incentives, and linking negotiation to volume 			✓	✓				
4.2 Hospital listing and drug usage								
<ul style="list-style-type: none"> Remove restrictions on listing caps for innovative medicines, drug revenue percentage, and single prescription amount limits for innovative medicines 			✓	✓				
<ul style="list-style-type: none"> Publish hospital formulary listing guidelines (e.g., formulary committee meeting frequency, decision making process and criteria for formulary updates) 			✓	✓				

Appendix: Summary of policy recommendations

Sound pricing and reimbursement policies are critical to improve patient access to innovative medicines in China, foster a pharmaceutical innovation ecosystem, and achieve the goals of Healthy China 2030. Such policies would:

- Improve patient access to innovative and quality medicines, reduce the financial burden on patients, and thus improve the health of the nation;
- Optimize allocation and use of medical resources, encourage physicians and regulators to refocus on patient needs and reward clinical value; and
- Encourage development of an ecosystem with lasting capabilities for continuous innovation and enhance national competitiveness.

Recent Progress Made in China's Healthcare System

In the past few years, China has made meaningful progress in improving healthcare coverage for Chinese patients. Both the depth and breadth of basic medical insurance (BMI) have been improved¹, and coverage has increased with the integration of the urban (URBMI) and rural (NRCMS) programs². The recent update to the National Reimbursement Drug List (NRDL) expanded coverage of chemical and biological medicines, including 36 high-value medicines. Moreover, MOHRSS is considering a dynamic adjustment of the NRDL³. In addition, numerous programs such as critical disease insurance, universal outpatient BMI, and an essential drug system are helping to address the out-of-pocket burden faced by patients⁴.

Continued Challenges in the Pricing and Reimbursement System

However, despite this progress, China continues to face multiple challenges in providing access to innovative medicines:

- Central government has clear direction to improve people's health and promote innovation, however lack common understanding on specific approach to deliver aspiration.
- Infrequent updates to national and provincial reimbursement drug lists.
- Lack of a sound, transparent, and science-based pricing and reimbursement decision-making process.
- Linkage of price negotiation results to reimbursement remains inconsistent at a local level.

1 http://www.mohrss.gov.cn/gkml/xxgk/201607/t20160713_243491.html

2 http://www.mohrss.gov.cn/SYrlzyhshbzb/dongtaixinwen/buneiyaowen/201705/t20170525_271399.html

3 http://www.mohrss.gov.cn/yiliaobxs/YILIAOBXSzhengcewenjian/201704/t20170419_269695.html

4 http://www.gov.cn/zhengce/content/2015-08/02/content_10041.htm

- Unclear timelines for provincial tendering and negotiations.
- Multi-layer negotiations required across provincial, municipal and hospital levels.
- Sub-optimal alternative funding sources for innovative medicines.
- Tendering processes require “national lowest price” in every province and municipality.
- Underdeveloped hospital IT infrastructure and clinical pathways.

China Pricing and Reimbursement Policy Framework for Innovative Medicines

Building a sustainable pricing and reimbursement policy framework, a scientific overarching design requires aligned and consistent policy development.

An efficient system that successfully provides access to medicines for Chinese patients is composed of three indispensable parts:

1. A timely reimbursement listing process that determines which medicines are reimbursed and at what level;
2. A payment mechanism that determines how payment should be settled between payer and provider; and
3. Access channels serving as the “last mile” to patient access to innovative medicines, including hospital procurement (including hospital negotiation and listing) as well as pharmacies or community medical institutions linked with reimbursement system.

Industry’s recommendations for improving China’s pricing and reimbursement policies for innovative medicines covers four key policy areas – coordination and consultation, reimbursement listing and payment standard, payment mechanism, and provincial and hospital level access.

Coordination and consultation process:

- Increase coordination amongst government agencies
 - Enhance the role of the inter-ministerial joint conference or set up a permanent inter-ministerial coordination group to resolve policy inconsistency and ensure smooth cross-ministerial policy implementation at the provincial or municipal level.
 - Streamline roles and responsibilities to allow payers to play a central role in future P&R decisions.

- Government-industry communication
 - Establish government-industry consultation mechanisms (e.g., formal industry liaison group, regular hearing session) to facilitate industry's involvement throughout the policy development process, and improve policy predictability and feasibility.
 - Consult with a broad set of stakeholders, including manufacturers, physicians, patient groups, etc.

Reimbursement Listing and Payment Standard:

A regular and evidence based NRDL listing process through negotiation would enhance links between reimbursement and pricing, and consequently secure timely and greater patient access to innovative medicines.

- Link reimbursement listing and payment standard through a negotiation process between pharmaceutical manufacturers and payers. Given confidentiality and capacity challenges at the provincial level in the short term, national negotiations are preferred in the near future.
- Manufacturers shall be allowed to submit reimbursement listing applications and pursue negotiation at any time of year.
- A transparent, evidence-based assessment, focusing on clinical benefits and independent from economic considerations, shall take place within a set time frame prior to negotiations to ensure timely updates to the NRDL.
- Following clinical assessment, a fair negotiation based on clear conditions and open communication shall be conducted between the national reimbursement authority and manufacturers. The negotiation will determine the reimbursement payment standard, based on factors including clinical efficacy and safety improvement, public health benefits, improvement on patient life quality, and contribution to medical and pharmaceutical fields.
- Medicines successfully negotiated at national level shall not be subject to provincial re-negotiation on the reimbursement payment standard. However, the provincial authority may decide the reimbursement percentage based on certain guidelines (e.g., a minimal reimbursement percentage for negotiated medicines can be set in principle to ensure patient affordability). Opportunities for provincial level negotiation may be available for products that do not participate or fail to reach agreement on the national level.
- An appeal mechanism should be established for both the clinical assessment and negotiation processes.

Payment Mechanism:

Payment reform to ensure sustainable growth in the healthcare system is a critical issue for the government. The transition from fee-for-service to a comprehensive payment mechanism should be implemented gradually and in coordination with the build-up of system capabilities (e.g., the implementation of clinical pathways to address treatment costs). Supplemental health insurance may play a role in closing BMI coverage gaps and addressing diverse needs of patients.

- I. Move from a fee-for-service model to comprehensive payment mechanism based on sufficient data and analysis system established across hospitals and medical institutions.
- II. Provide separate funding for innovative medicines.
- III. Close capability gaps that will facilitate the use of more sophisticated and treatment-based payment methods:
 - Unify activity categorizations and update periodically.
 - Develop coding capabilities in hospitals; establish highly automatic IT tools.
 - Conduct cost accounting studies to increase hospital cost transparency and inform payment tariff setting.
 - Set up a systematic review process of case-level cost data, and provider behavior; enhance clinical capability of BOHRSS; adopt quality adjustment for final payment.
 - Develop HR capability for conducting comprehensive payment mechanism.
- IV. Unleash the potential of private health insurance (PHI) to supplement BMI by improving data availability, reduce PHI market access hurdles, and improve PHI influence over providers.
- V. Improve effectiveness of public payers.

Provincial & Hospital Level Access:

Numerous barriers at the provincial and hospital level, including additional negotiations, hospital listing and drug usage restrictions, continue to delay patient access

- I. Innovative medicines successfully negotiated with reimbursement authorities shall be directly accepted by the provincial procurement platform without provincial tendering or price negotiation.
- II. Hospitals should not conduct negotiations for innovative medicines for the same reason. Given that in the near term some regional hospitals or hospital groups are allowed to re-negotiate, hospital negotiations shall be regulated by

- Enforcing transparent volume-linked rebate criteria.
 - Regulating profits gained from hospital re-negotiation to prevent hospital reliance on pharmaceutical price concessions.
- III. Progressively increase funding for hospitals to compensate funding gap due to “zero mark-up” policy.
- IV. Remove restrictions on listing caps for innovative medicines, drug revenue percentage, and single prescription amount limits for innovative medicines.
- V. Expand dispensing channels for reimbursed products to improve patient access to innovative medicines through promoting the establishment of independent pharmacies (e.g. Direct To Patient pharmacy system) to maximize patient access to reimbursable medicines as a parallel channel to hospitals.

