

**Contents**

Recent healthcare developments	1
Healthcare in numbers	1
Insight	1-2
Advances in policy and public-private partnerships show promise for healthcare development and pharmaceutical innovation	
Policy & regulatory tracker	3-5

China Healthcare Outlook is a North Head publication. If you have questions or wish to receive in-depth policy analysis, please contact us at info@northheadcomms.com.

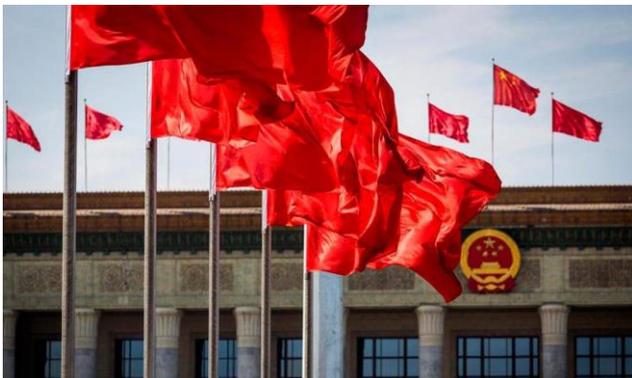
RECENT HEALTHCARE DEVELOPMENTS

March 2017 brought China's annual meetings of the National People's Congress (NPC) and the Chinese People's Political Consultative Conference (CPPCC). These "Two Sessions" mark a season of policy developments and industry advances that have picked up since the Chinese New Year. Other noteworthy policy items were the release of:

- China's Mid-to-Long Term Plan for Chronic Disease Prevention and Treatment
- The State Council's Notice on the 13th Five-Year Promotion of the Equalization of Basic Public Services
- An updated National Reimbursement Drug List (NRDL) for Basic Medical Insurance (BMI), Employment Illness Insurance (EII), and Maternity Insurance (MI) (2017 edition)
- The State Council's 13th Five-Year Plan for National Drug Safety

HEALTHCARE IN NUMBERS: In 2017, the Chinese government increased its per capita subsidy for Basic Medical Insurance (BMI) from RMB 420 to RMB 450.

INSIGHT: Advances in policy and public-private partnerships show promise for healthcare development and pharmaceutical innovation



The season following the Chinese New Year has brought significant progress for the pharmaceutical industry in policies and public-private partnerships.

In early March, the National People's Congress (NPC) and the Chinese People's Political Consultative

Conference (CPPCC) convened in Beijing for their annual meetings, colloquially known as the Lianghui or the "Two Sessions". This year's sessions are especially notable, as they are the last major political meetings in China before Fall 2017, when the 19th Party Congress meets and a new Party leadership will be unveiled for President Xi Jinping's second five-year term.

During this year's Two Sessions, healthcare remained a top concern for the government and public. Healthcare issues were addressed in Premier Li Keqiang's annual government work report and comments to the media from the ministers of the National Health and Family Planning Commission (NHFPCC) and China Food and Drug Administration (CFDA). Guided by the Healthy China 2030 plan, this

year's NPC focused on further developing existing policy to deepen healthcare reform and improve the quality of China's healthcare system. The government announced that it would increase healthcare spending by 6% from 2016 and invest RMB 1.4 trillion to further improve China's basic healthcare system. The annual Basic Medical Insurance (BMI) subsidy for urban and rural residents was increased from RMB 420 to RMB 450 per capita. China Food and Drug Administration (CFDA) Minister Bi Jingquan also said the government will continue to improve the current drug registration mechanism to accelerate the review and approval process for innovative drugs.

Two major pharmaceutical policy developments also occurred around the time of the Two Sessions: 1) Just prior to the Two Sessions, the National Reimbursement Drug List (NRDL) was updated for the first time since 2009. The list adds 339 new drugs, significantly increasing patient access to innovative treatments under China's BMI System. 2) After the NPC, the CFDA released a new multi-regional clinical trial (MRCT) policy that will shorten the drug registration timeline for innovative drugs by allowing pharmaceutical companies to conduct simultaneous clinical trials in China as well as abroad.



In a major advancement for public-private partnerships, the International Pharmaceutical Innovation Forum (IPIF)* was hosted by industry association RDPAC, with the Nanjing Municipal Government and the Industrial Culture Development Center (ICDC) under the Ministry of Industry and Information Technology (MIIT). The Forum was held on March 22-23 in Nanjing, China and attracted 500 Chinese and foreign experts, pharmaceutical industry leaders, and policy makers.

IPIF led to a significant consensus on accelerating China's integration into the global innovation system. Ten leading domestic and foreign trade associations signed and endorsed the *Declaration for Pharmaceutical Innovation*. Signatories of the Declaration have called for a top-down design for innovation from China's central government, incorporating all elements along the innovation chain including basic R&D, clinical research, the regulatory process, and procurement and reimbursement. The design would introduce scientific guiding principles, policies, and mechanisms to advance innovation.

This marks a significant step for the pharmaceutical industry in working with Chinese stakeholders to support the realization Healthy China 2030 goals.

** North Head is proud to have provided consulting services for the IPIF event.*

Business implications

Recent policy and industry developments are a positive trend for foreign pharmaceutical companies. Ongoing healthcare reforms that aim to control medical expenditures have put increasing pressure on drug prices. However, companies have opportunities to improve patient access to drugs through China's growing healthcare market and the government's increasing recognition of innovative drugs, as reflected in the NRDL update and new MRCT policy.

To best position themselves, foreign pharmaceutical companies might readjust their regulatory strategy to take advantage of the new MRCT policy. In addition, as provincial governments are authorized to add or exclude a maximum of 15 percent of the drugs in the NRDL, firms should approach local governments through established communication channels for inclusion of products on provincial drug lists.

Most importantly, recent developments show the increasing importance of government relations in China. Companies may strengthen their connections with central and provincial governments through close work with industry associations and their communication channels, such as RDPAC and the IPIF.

For more details on these or other developments, contact: info@northheadcomms.com

POLICY & REGULATORY TRACKER

Overall policy

- [The 2017 annual sessions of NPC & CPPCC \(Two Sessions\) were held in Beijing](#)
In early March, the 2017 annual sessions of the National People's Congress (NPC) and the Chinese People's Political Consultative Conference (CPPCC) were held in Beijing. This year's NPC is notable as the last major political meeting before the 19th Party Congress in fall 2017, when a new Party leadership will be unveiled for President Xi Jinping's second five-year term.
- [State Council released Notice on the 13th Five-Year Promotion of the Equalization of Basic Public Services](#)
On March 1, the State Council released its Notice on the 13th Five-Year Promotion of the Equalization of Basic Public Services, to improve the quality and fairness of basic public services. The document emphasizes that China will continue establishing a social insurance system with full, basic, and necessary coverage that is also sustainable.
- [State Council released China's Mid-to-Long Term Plan for Chronic Disease Prevention and Treatment](#)
On February 14, the State Council released China's Mid-to-Long Term Plan for Chronic Disease Prevention and Treatment. The goal of the Plan is to lower premature death rates stemming from cardiovascular and respiratory diseases, diabetes, and cancers among the 30-70 age group by 10 and 20 percent by 2020 and 2025 respectively.

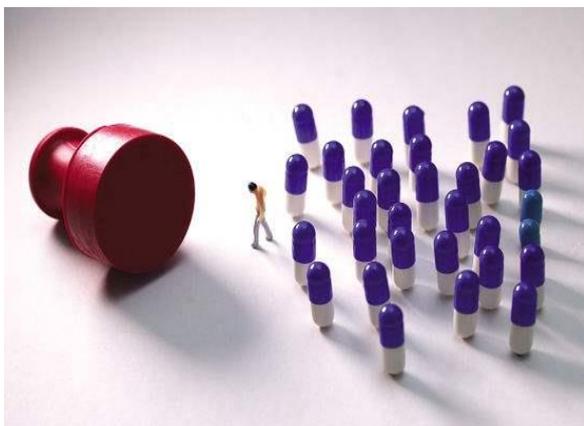
Insurance

- [NHFPC released Notice of the Work Plan for Implementing "Treatment First, Payment Later" for Impoverished Rural Inpatient Care](#)
On March 2, the NHFPC released Notice of the Work Plan for Implementing "Treatment First, Payment Later" for Impoverished Rural Inpatient Care to alleviate financial burdens for impoverished patients in rural areas.

Impoverished patients in rural areas may now receive treatments in certain medical institutions within their county without advance payment.

- [MoHRSS released an updated National Reimbursement Drug List \(NRDL\) for Basic Medical Insurance \(BMI\), Employment Illness Insurance \(EII\), and Maternity Insurance \(MI\) \(2017 edition\)](#)
On February 23, the Ministry of Human Resources and Social Security (MoHRSS) released an updated National Reimbursement Drug List (NRDL) for Basic Medical Insurance (BMI), Employment Illness Insurance (EII), and Maternity Insurance (MI) (2017 edition). Compared to the 2009 edition, the latest NRDL update includes an additional 339 types of drugs.
- [NHFPC, Ministry of Civil Affairs, and State Council released Work Plan for Special Treatment of Critical Illnesses among Impoverished Rural Residents](#)
On February 23, the NHFPC, Ministry of Civil Affairs and State Council released a Work Plan for Special Treatment of Critical Illnesses among Impoverished Rural Residents. The Work Plan calls upon local governments to provide necessary treatment for impoverished rural residents suffering from critical illnesses.
- [NHFPC released Notice on Signing Agreements for Services Related to Trans-Provincial Reimbursement of Urban and Rural Residents' Basic Medical Insurance](#)
On February 15, the National Health and Family Planning Commission (NHFPC) released its Notice on Signing Agreements for Services Related to Trans-Provincial Reimbursement of Urban and Rural Residents' Basic Medical Insurance. The Agreement aims to enable patients to receive reimbursements directly after receiving treatments across provincial borders.
- [State Council released a Circular on Integrating BMI for Urban Employees with Maternity Insurance in Pilot Cities](#)
On February 4, the State Council released a Circular on Integrating Basic Medical Insurance

(BMI) for Urban Employees with Maternity Insurance in Pilot Cities. The document mandates 12 cities to explore the operations and management procedures for the integration of the two insurance schemes.



Pharmaceuticals

- [CDE released Guiding Principles for Non-Clinical Safety Research on Pediatric Medication for public comment](#)

On March 3, the Center for Drug Evaluation (CDE) released Guiding Principles for Non-Clinical Safety Research on Pediatric Medication for public comment. The Guiding Principles primarily cover the effectiveness and timing of non-clinical safety evaluation of drugs for pediatric patients, and provide general considerations and requirements for juvenile animal study.

- [CFDA released Exposure Draft for Drug Re-Registration](#)

On February 23, the China Food and Drug Administration (CFDA) released its Exposure Draft for Drug Re-Registration. The CFDA aims to better manage and regulate drug registration, and ensure effective use of the approval quota.

- [State Council issued 13th Five-Year Plan for National Drug Safety](#)

On February 21, the State Council issued the 13th Five-Year Plan for National Drug Safety (“十三五” 国家药品安全规划) to further improve drug quality and safety. The document outlines plans to improve drug quality, pharmaceutical standards, the evaluation and approval system,

supervision, and services provided by licensed pharmacists.

- [State Council released Opinions to Further Reform the Policy of Circulation and Use of Pharmaceutical Production](#)

On February 9, 2017 the State Council released Opinions to Further Reform the Policy of Circulation and Use of Pharmaceutical Production to deepen healthcare reform, increase quality and efficacy of drugs, regulate drug circulation and fulfill patients' needs. Key points of the policy are to: 1) strengthen examination and approval of drug listings; 2) accelerate the consistency evaluation of generic drugs; 3) implement international pricing comparisons; 4) improve the drug procurement mechanism; 5) rectify the order of drug distribution; 6) promote rational use of drugs; 7) further eliminate the drug compensation mechanism; and 8) strengthen health insurance's role of ensuring compliance and controlling costs.

- [NDRC released a list of key products and services of the national strategic emerging industries](#)

On January 25, the National Development and Reform Commission (NDRC) released a list of key products and services of national strategic emerging industries. In the pharmaceutical industry, the NDRC encourages the development of new vaccines, biopharmaceuticals, chemical drugs, active pharmaceutical ingredients (APIs), and biomedical services.

Medical Devices

- [CFDA released Interpretation on Guiding Principles for Technical Review of Medical Device Safety Registration](#)

On March 2, the CFDA released Interpretation on Guiding Principles for Technical Review of Internet Safety Registration of Medical Devices, to strengthen protection of patient privacy and supervision of innovative medical devices.

Hospitals

- NHFPC and State Administration of Traditional Chinese Medicine released Application and Management Practices for Electronic Medical Records

On February 22, the General Office of the NHFPC and State Administration of Traditional Chinese Medicine released the Application and Management Practices for Electronic Medical Records (Pilot Version). The Practices provides

guidelines on the definition, writing, storage, use, and archiving of electronic medical records.

- NHFPC released three Technical Schemes for Implementing Tiered Diagnosis and Treatment
On February 9, the NHFPC released three Technical Schemes for Implementing Tiered Diagnosis and Treatment to divide responsibilities among hospitals at different levels.

About us

North Head is a strategic communications and public affairs consultancy that tracks developments related to the healthcare sector in China. To receive future issues of this newsletter or obtain more information and analysis on the healthcare policy and regulatory landscape in China, please send an email to info@northheadcomms.com



Strategic counselor to
Shenzhen CCPIT



Strategic counselor to
Global Times



Scan the QR code to
download our iOS
app, "Portal to China"

1105 Full Tower,
No. 9 Dongsanhuan Middle Road,
Chaoyang District, Beijing 100020
Phone: +86 10 8591 0056

E-mail: info@northheadcomms.com