

**Contents**

<b>Recent healthcare developments</b>	1
<b>Healthcare in numbers</b>	1
<b>Insight</b>	1-2
National and Provincial Drug Pricing Moves Point to Developments to Come	
<b>Policy &amp; regulatory tracker</b>	2-4

*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](mailto:info@northheadcomms.com).*

**RECENT HEALTHCARE DEVELOPMENTS**

China is continuing to issue new policies and regulations regarding the healthcare sector. Recent noteworthy policy items are the release of the:

- State Council released Opinions on Supporting Private Medical Institutions to Provide All-Round Medical Services
- NHFPC released Announcement on the Establishment of Health Promotion and Education Expert Guidance Committee
- CDE released Pharmaceutical Electronic Common Technical Document Structure and Chemical Generic Drug Electronic Common Technical Document Application Guidelines for public comment
- CFDA released Circular on the Relevant Work for Consistency Evaluation of Generic Drugs for public comment
- NHFPC released Announcement on Implementing Clinical Pathways

---

**HEALTHCARE IN NUMBERS: ESTIMATES SHOW THAT THE CHINA HEALTHCARE MARKET WILL REACH 8 TRILLION BY 2020.**

---

## INSIGHT: National and Provincial Drug Pricing Moves Point to Developments to Come



Companies are increasingly impacted by China's work to lower drug prices at the national and provincial levels. The government's efforts are driven by concerns over increasing healthcare costs, rising pressure on medical insurance funds, and the need to advance healthcare reforms.

**National Negotiations**

In late June, the Ministry of Human Resources and Social Security (MoHRSS) completed its second national drug negotiation, comprising 44 drugs from 10 pharmaceutical companies. The national negotiations, which first took place in 2016, work to lower prices while promising to cover successfully negotiated drugs under Basic Medical Insurance (BMI). According to media reports, drugs that successfully completed the 2017 negotiations underwent price cuts of 40 to 60 percent, while the three drugs that completed the 2016 negotiations underwent average reductions of 56 percent.

**Provincial Pressure on Prices**

Provinces are continuing to lower prices through policy and procurement. On June 9, Shanghai's drug pricing body announced that it will refer to prices across 15 provinces, calculating average prices before determining the final price for each drug.

Shanghai has also developed a mechanism to prevent generic drug price inflation.

On February 5 of this year, Fujian's drug pricing governing body released a plan for drug price caps based on price comparisons, and BMI payment benchmarks for 16,445 products. Fujian public hospitals will draft a list of drugs to be purchased. A provincial government body will oversee a bidding and price-capping process, with BMI payment benchmarks based on the price caps.

### Ongoing Reforms

These latest developments build on the government's efforts to reduce administrative control over drug prices, with the ultimate goal of increasing patient access to drugs while still managing prices.

In 2015, the National Development and Reform Commission (NRDC) co-signed a document removing price caps on most drugs, in favor of prices based on production costs and market demand. Premier Li Keqiang's 2016 speech to the State Council focused on drug prices as a critical part of China's healthcare reforms. The government has been intensively researching and analyzing pharmaceutical cost-price structures. Authorities have also vowed to investigate drugs with significant price differences across regions, or compared to international markets.

---

### Business implications

This year's MoHRSS negotiations showed an overall increase in the number of drugs up for negotiation.

Fifty-seven percent of the drugs were from foreign pharmaceutical companies, all of which submitted multiple drugs for negotiation. Trends indicate that participating firms may be benefitting from increased revenues, given BMI coverage. Reports indicate that although one foreign drug faced a 50 percent price cut in the 2016 negotiations, it still saw a 354 percent increase in revenue in the next year.

Shanghai and Fujian's new policies are also relevant, as both are pioneers in healthcare reform that may influence other provinces. Fujian's new procurement mechanism will closely link the procurement process with reimbursement policy, putting pressure on public hospitals to lower drug prices through negotiations. Shanghai's provincial price comparison approach means that the lowest bid-winning price at the provincial level could become a universal price for all provinces.

Healthcare companies should plan their strategies around both national and provincial developments moving forward. National negotiations will be the key factor influencing innovative drug prices for pharmaceutical companies. Health insurance, medical providers, and drug companies may also consider offering innovations to address government concerns over the rising costs and pressure on insurance funds, to ensure improved access to innovative care.

*For more details on these or other developments, contact: [info@northheadcomms.com](mailto:info@northheadcomms.com)*

---

## POLICY & REGULATORY TRACKER

### Overall policy

- [State Council released Opinions on Supporting Private Medical Institutions to Provide All-Round Medical Services](#)

On May 23, the State Council released the Opinions on Supporting Private Medical Institutions to Provide All-Round Medical Services to encourage the development of private hospitals. According to the document, three major points highlighted are following: 1) hospitals are required to provide comprehensive services; 2) government simplifies the approval procedure for private hospitals; and 3) State

council provides supportive policy to private medical institutions.

- [MOST released Notice on the Special Plan for the 13th Five-Year Plan for Fundamental Research](#)

On June 8, the Ministry of Science and Technology (MOST) released its Notice on the Special Plan for the 13<sup>th</sup> Five-Year Plan for Fundamental Research to improve China's innovative research ability and global competitiveness. The document outlined the government's technological support for becoming an innovation-oriented country by 2020. Related to healthcare, planning will primarily focus on public research on such topics as prevention of non-communicable chronic diseases (NCDs),

precision medicine, and digital medical equipment.

- [NHFPCC released Announcement on the Establishment of a Health Promotion and Education Expert Guidance Committee](#)

On June 1, the National Health and Family Planning Commission (NHFPCC) released the Announcement on the Establishment of a Health Promotion and Education Expert Guidance Committee, to improve the quality of theoretical research and decision-making. The committee is composed of health experts and it supports work in health promotion and education.



## Pharmaceuticals

- [CDE released Pharmaceutical Electronic Common Technical Document Structure and Chemical Generic Drug Electronic Common Technical Document Application Guidelines for public comment](#)

On May 30, CDE released two documents, including Pharmaceutical Electronic Common Technical Document Structure and Chemical Generic Drug Electronic Common Technical Document Application Guidelines, for public comment to help accelerate the adoption of the Electronic Common Technical Document (eCTD) system.

- [CFDA released four Guiding Principles for consistency evaluation inspections](#)

On May 18, CFDA released four Guiding Principles for consistency evaluation inspections

to improve the safety and quality of generic drugs, covering research lab on-site inspection, manufacturing site on-site inspection, clinical trial data inspection, and inspections for other uncategorized issues. According to the CFDA, all generic drugs will be inspected within five years.

- [CFDA released Technical Guiding Principles for the Extrapolation of Adult clinical trial data to Children](#)

On May 18, the CFDA released the Technical Guiding Principles for the Extrapolation of Adult clinical trial data to Children. According to the CFDA, the document aims to encourage the development of pediatric drugs by reducing unnecessary repetitive research and maximizing the value of existing data. The Principles can be only applied to drugs that already have adult clinical trial data in China.

- [CFDA released a Circular on the Application and Registration Status of Self-Inspection of Clinical Trial Data](#)

On May 19, the CFDA released a Circular on the Application and Registration Status of Self-Inspection of Clinical Trial Data. According to the Circular, the CFDA will launch inspection of the clinical trial data for all 44 newly-registered drugs, which include 35 imported drugs, 4 domestic new drugs, 3 generic drugs, and 2 supplementary applications. The CFDA allows pharmaceutical companies to withdraw their flawed applications within 10 working days after the release of the Circular and will thereafter announce specific on-site inspection dates.

- [CDE signed strategic cooperation agreement with Shandong FDA](#)

On May 26, CDE and Shandong Food and Drug Administration (Shandong FDA) signed a strategic cooperation agreement to carry out multi-level cooperation and resource sharing. The two sides will develop a drug data management platform and establish a training base for evaluation staff.

- CFDA released Circular on the Relevant Work for Consistency Evaluation of Generic Drugs for public comment

On June 9, CFDA released its Circular on the Relevant Work for Consistency Evaluation of Generic Drugs for public comment. According to the document, companies are allowed to procure reference drugs on their own by referring to the 289 brand-name drugs provided by the Administration. The CFDA also suggested that companies choose reference drugs based on certain priorities.

- CDE released the 17<sup>th</sup>, 18<sup>th</sup> and 19<sup>th</sup> list of drugs to be included in priority review in two weeks

On May 23, June 1, and 6, the CDE released the 17th, the 18th, and 19th list of drugs to be included in priority review. The three lists include 38 drugs, including 26 drugs to be granted market access, 9 for clinical trials of new drugs, 1 drug approved for international multicenter clinical trials, and the remaining 2 drugs for indication expansion.

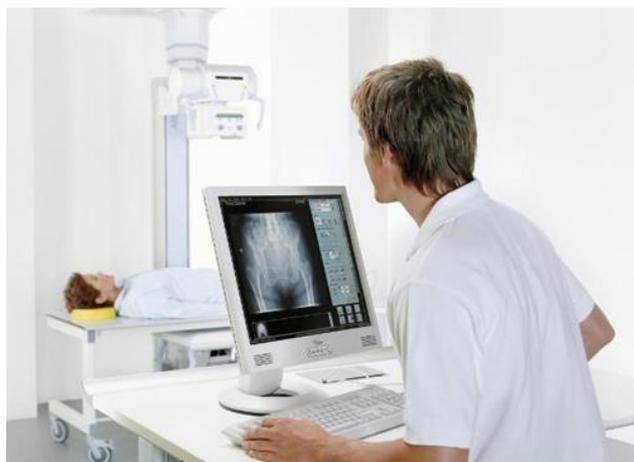
- CFDA released Notice on the 5th and 6th List for Generic Reference Drugs

On June 9, the CFDA released its *Notice on the 5th and 6th List for Generic Reference Drugs*. The two latest catalogs include 84 reference drugs; thus far, a total of 208 reference drugs have been published.

## Medical Device

- MOST released the 13th Five-Year Specialized Plan for Medical Equipment Technology Innovation

On June 14, the MOST released the 13th Five-Year Specialized Plan (13FYSP) for Medical Equipment Technology Innovation to improve Chinese companies' innovation capability and promote the development of domestic medical equipment.



## Hospitals

- NHFPC released Announcement on Implementing Clinical Pathways

On June 1, NHFPC released an Announcement on implementing 202 newly-enacted clinical pathways to standardize treatment activities and ensure the quality and safety of medical services.

---

## 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](mailto: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](mailto:info@northheadcomms.com)