NORTH HEAD | 诺恒

CHINA HEALTHCARE OUTLOOK

A newsletter on regulatory and policy developments of China's healthcare sector

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Contents

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.

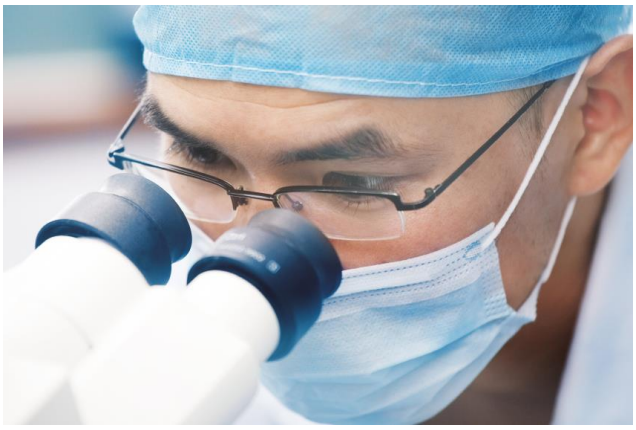
RECENT HEALTHCARE DEVELOPMENTS

Recent policy developments show the government's concern over controlling medical expenditure, enhancing drug safety, and increasing international participation. Recent noteworthy policy items include:

- NHFPC released 2016 China Health and Family Planning Development Report
- State Council released Measures to Promote Foreign Investment
- CFDA released the Circular on the Consistency Evaluation of Generic Drugs (No.100)
- CFDA released the Good Drug Data Management Practice for Public Comment
- CFDA released the Circular for Pilot Work of Marketing Authorization Holder System
- State Council released the Guiding Opinions on Establishing the Modern Hospitals Management System

HEALTHCARE IN NUMBERS: IN 2016, THE SIZE OF TERMINAL SALES IN THE CHINESE PHARMACEUTICAL MARKET WAS 1.286 TRILLION RMB. THE MARKET SHARE OF THIRD TERMINAL HAS SEEN AN INCREASE OF 8.2%

INSIGHT: Clinical trials as significant steps toward innovation



Given the Chinese government's determination to support domestic pharmaceutical innovation, recent policies and government reports illustrate the government's focus on developing early stage R&D, specifically, improving the capacity of clinical trials.

The policies are triggered by China's currently limited capacity to conduct clinical trials. According to the records on the China Drugs Clinical Trials Registration Platform (www.chinadrugtrials.org.cn), by August 4, 2017, only 6,831 clinical trials are registered, which is far lower than the 251,206 studies registered in the US. Moreover, there were 35,845, 51,210, and 32,104 studies for Stage I, II, and III respectively in the U.S, but only 2,523, 1,297, and 1,308 for each of those stages in China. Besides limited quantity, the data fraud issues found in the clinical trial data verification process reveal the quality problems that China faces in its quest to facilitate clinical trials. In the Interim Report for Verification of Drugs Clinical Data for the period from July 2015 to June 2017, the Center for Food and Drug Inspection (CFDI) found 38 cases of data fraud among 313 verified drugs. The data fraud ratios for

innovative drugs, generic drugs, and imported drugs are 17.0%, 45.95%, and 2.74% respectively. The generic drugs have the highest rate of data fraud while the imported drugs have the lowest rate. The fraud issue demands consistency evaluation of generic drugs to ensure their quality, which further necessitates solid clinical trials as the foundation.

On the quantity side, the policy support to accelerate the growth of clinical trials is demonstrated by the Five-Year Plan of the National Clinical Medical Research Center, which was released by the Ministry of Science and Technology (MOST) in late July. The Plan calls for building approximately 100 centers for critical disease and clinical specialties, enhancing international cooperation, and establishing several platforms for data analysis. During the past five years, China has built 32 National Clinical Medical Research Centers in 11 critical disease areas, including cardiovascular disease, chronic disease, and respiratory disease. The ambition outlined in the Plan to establish 100 centers in five years indicates the government's diligent pursuit of developing more clinical studies in the future.

As for the quality of clinical trials, on July 3, the Center for Drug Evaluation (CDE) released Innovative Drugs (Chemical Drugs) Stage III Clinical Trial Pharmaceutical Research Information Guidelines for public comment. The document specifies general requirements for active pharmaceutical ingredients (API), preparations, placebos, and control drugs to provide necessary information, including fundamental information, quality and stability information, and manufacturing information. Together with other related regulations and guidelines, Guidelines will navigate complexities in the management of clinical trials to enhance their overall effect.

Business implications

In the past decades, the Chinese government has declared its intention to transform China into a world leader in science and technology, and accelerate the translation of innovation into actual products that generate market value. Clinical trials are useful for commercializing new ideas, thus the Chinese government has invested considerable effort in improving clinical trial capacity, through approaches including shortening the review and approval period. The recent decisions to establish 100 National Clinical Medical Centers and regulate information provided in Stage III clinical trials support the policy, and highlight the government's concerns regarding clinical trials.

MNCs that are known for having experience with clinical trials may leverage their expertise on clinical trial data to seek opportunities to cooperate with the CFDA, in order to enhance Chinese clinical trial capacity-building and build potential for further communication with the CFDA.

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

POLICY & REGULATORY TRACKER

Overall policy

- NHFPC released 2016 China Health and Family Planning Development Report

  On August 18, the National Health and Family Planning Commission (NHFPC) released the 2016 China Health and Family Planning Development Report. The report summarized the development of major indicators in medical sector during last year. In 2016, the total healthcare expenditure increased by 13.11% to reach RMB 4634.5 billion, accounting for 6.2% of China's GDP, an increase of 0.2% compared to 6.0% in 2015. Moreover, during 2016, 3.27 billion patients went to hospitals for medical services, which increased by 190 million compared with 2015.

- State Council released Measures to Promote Foreign Investment

  On August 16, the State Council released Measures to Promote Foreign Investment to stimulate an increase in foreign investment. According to the document, China will lower the entry threshold for foreign investment through nationwide implementation of the negative list, enact preferential tax policies to encourage MNCs to set up regional headquarters in China, improve the investment climate in the national-level development zones by granting more autonomy to the administrators, and enhance

the attraction of foreign talent through expanding the scope of the visas issued.

Pharmaceuticals

- CFDA released the Circular on the Consistency Evaluation of Generic Drugs (No.100)

  On August 25, the China Food and Drug Administration (CFDA) released the Circular on the Relevant Work for Consistency Evaluation of Generic Drugs (No.100). The document is a finalized and comprehensive regulation for consistency evaluation, regulating the selection of reference drugs, the principles of exemption, the review timetable, and preferential policies. Drugs that have successfully completed the evaluation will be identified with a sign on the drug package. If more than three companies that produce the same type of generic drugs are qualified through evaluation, the government will not select other drugs that failed the evaluation in the centralized procurement of drugs.

- CFDA released the Good Drug Data Management Practice for Public Comment

  On August 25, the CFDA released the Good Drug Data Management Practice for public comment. All feedback shall be submitted to yhjgs@cfda.gov.cn by October 1, 2017. The document outlined comprehensive regulations of all-life-cycle data, especially quality control, basic requirements of data, and computerized system. The guiding principle of the Practice is to enhance the integrity and reliability of drug data.

- CFDA released the Circular for Pilot Work of Marketing Authorization Holder System

  On August 21, the CFDA released the Circular for Pilot Work of Marketing Authorization Holder (MAH) System to accelerate the promotion of pilot work of MAH and regulate relevant activities in 10 pilot provinces (municipalities).The Circular outlined the regulations on authorized production and selling, and clarified legal liabilities of participants.

- CFDI released the Interim Report for Verification of Drugs Clinical Data (July 2015 to June 2017)

  On July 21, the Center for Food and Drug Inspection (CFDI) released the Interim Report for Verification of Drugs Clinical Data from July 2015 to June 2017, summarizing the achievements and problems found during that time period. According to the document, by the end of June 2017, the CFDA had released seven Notices on clinical data verification for 2033 drugs applying for production and import registration. Since some applications were voluntarily withdrawn by companies, the total number of applications for CFDI on-site verification was 313. According to the verification results, there were 38 cases of data fraud found, including 16 innovative drugs, 17 generic drugs, and five imported drugs.

- CFDA released Notice on the 7th and 8th List for Generic Reference Drugs

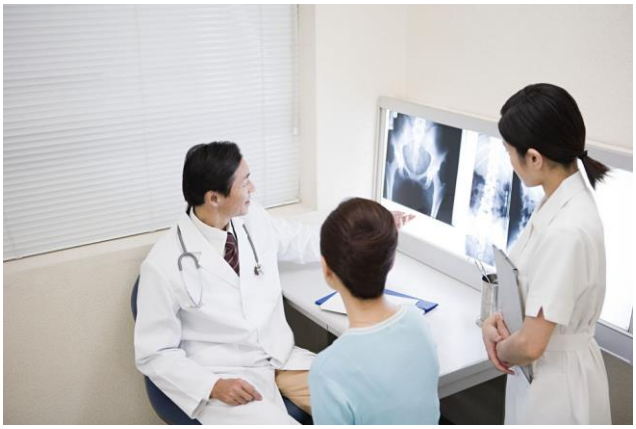
  On July 21, the CFDA released its Notice on the 7th and 8th List for Generic Reference Drugs. The two latest catalogs include 382 reference drugs. Thus far, a total of 610 reference drugs have been published.

Medical Device

- CFDA released the Qualifications and Filing Mechanism of Medical Equipment Clinical Trials Institutions for Public Comment

  On August 4, the CFDA released the Qualifications and Filing Mechanism of Medical Equipment Clinical Trials Institutions soliciting public comment. All feedback of Medical

institutions and companies shall be submitted collectively by the food and drug administrations of provinces (municipalities) through paper or digital versions. Other institutions or individuals can send comment by email (mdct@cfda.gov.cn) or by fax (010-88331443). Institutions that are qualified to conduct clinical trials of medical equipment can file by themselves and submit self-inspection reports as required.



Hospitals

- State Council released the Guiding Opinions on Establishing the Modern Hospitals Management System

  On July 25, the State Council released the Guiding Opinions on Establishing a Modern Management System of Public Hospitals to improve the quality of medical services provided. The overall goal is to achieve a publicly beneficial and supply-sustainable public hospital system by 2020. Moreover, public hospitals will be authorized to operate with autonomy when making decisions in human resources management.

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

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