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CHINA HEALTHCARE OUTLOOK

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

2017 Issue 3

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

The Chinese government made significant progresses regarding market access of pharmaceutical and medical devices. Both the Ministry of Human Resources and Social Security (MOHRSS) and the China Food and Drug Administration (CFDA) released important exposure drafts on reimbursement and registration, marking a milestone of the Chinese healthcare reform. Noteworthy policy items were the release of:

- State Council released 2017 Work Foci to Deepen Healthcare Reform
- MOST released the Special Plan for the 13th Five-Year Plan for Biotechnology Innovation
- MOHRSS seeks public opinions on how to establish a dynamic adjustment mechanism for NRDL
- CFDA released new regulations on clinical trial, registration, administration and intellectual property of pharmaceutical and medical devices (exposure drafts)
- CFDA released Administrative Measures of Medical Devices Standards

HEALTHCARE IN NUMBERS: China's biotechnology industry has maintained an average annual growth rate of approximately 20 percent.

INSIGHT: Unlocking China's Healthcare Opportunities

Author: Robert Magyar (Executive Director), Jennifer Pearl (Senior Consultant)

Improving the quality of healthcare and deepening ongoing healthcare reform remain top priorities for the Chinese government. This was clearly stated during the recent annual full session of China's National People's Congress. The government's active shaping of and participation in the sector can complicate the work of corporations that are manufacturing drugs and medical devices and providing healthcare services.

Innovation and healthcare system development are government priorities, as demonstrated in China's annual legislative meetings, the 13th Five-Year Plan, and Healthy China initiative. In August 2016, President Xi Jinping named health as a strategic national priority, calling to develop the healthcare system and ensure food and drug safety. Healthcare was also amply covered at China's March 2017 Two Sessions, during which Premier Li announced to

increase government expenditures on healthcare by 6% from 2016 and invest RMB 1.4 trillion in 2017.

In addition, Premier Li Keqiang's annual government work report called for accelerating R&D and commercialization of strategic industries such as biopharmaceuticals. China will develop industrial clusters in these fields and the government will establish a National Strategic Industry Development fund to promote research and commercialization of these and other technologies. The State Administration for Industry and Commerce (SAIC) also announced some new measures to protect IPR.

Business implications

There are opportunities for healthcare companies in China, if they can navigate the economic and healthcare reform policies affecting the market.

Most importantly, companies need to prove their value to the government and position themselves as partners to the government by aligning their business objectives with the government's plans and supporting innovation and by creating platforms for engagement with government and potential business partners. In addition, companies may work to advance healthcare professionals' training, while sharing expertise on innovative therapies and treatment safety to help China to improve healthcare quality.

As the government plays the most important role in the industry, government relations and positioning with stakeholders can heavily impact business outcomes. Companies can only successfully navigate the complexities of this market by developing robust policy monitoring, government relations, stakeholder engagement, and strategic communications that are aligned with business development strategies.

Full article is available on publicaffairsasia.com.

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

POLICY & REGULATORY TRACKER

Overall policy

- State Council released 2017 Work Foci to Deepen Healthcare Reform

  May 5, the State Council released the 2017 Work Foci to Deepen Healthcare Reform (Document 37), to detail plans, assign timelines, and allot tasks to different parts of government for healthcare reform in 2017. Document 37 focuses on how government can develop five systems through China's healthcare reform efforts: 1) tiered diagnosis and treatment, 2) modern hospital management, 3) universal health insurance, 4) protection of the drug supply, and 5) comprehensive supervision.

- MOST released the Special Plan for the 13th Five-Year Plan for Biotechnology Innovation

  On May 10, the Ministry of Science and Technology (MOST) released the Special Plan for the 13th Five-Year Plan for Biotechnology Innovation. According to the Plan, China's biotechnology industry has maintained an average annual growth rate of approximately 20 percent. Key tasks of the Special Plan are to: 1) develop common key technologies; 2) support the development of biomedical sector; 3) advance technology innovation centers; and 4) promote strategic resource platform.

Insurance

- MOHRSS seeks public opinions on how to establish a dynamic adjustment mechanism for NRDL

  On April 18, the Ministry of Human Resources and Social Security (MOHRSS) released a document for collecting public opinions on how to establish a dynamic adjustment mechanism for the National Reimbursement Drug List (NRDL). MOHRSS released six questions on its website and expect the public to provide feedback accordingly.

- MOHRSS released a Notice on the Negotiation of the 2017 Reimbursement Drug List for BMI, EII and MI

  On April 14, MOHRSS released its Notice on the Negotiation of the 2017 Reimbursement Drug

List for Basic Medical Insurance (BMI), Employment Illness Insurance (EII) and Maternity Insurance (MI). According to the Notice, among the 44 selected varieties of drugs, 25 varieties are from foreign pharmaceutical enterprises and 19 from domestic pharmaceutical enterprises, accounting for 57% and 43% of the list respectively. A total of 32 enterprises were selected.

Pharmaceuticals

- CFDA released new regulations on clinical trial, registration, administration and intellectual property of pharmaceutical and medical devices (exposure drafts)

  On May 11, the CFDA released four documents for public comment: 1) Policies on Reforming Clinical Trial Management for Encouraging Pharmaceutical and Medical Device Innovation; 2) Policies on Accelerating Review and Approval Process for Encouraging Pharmaceutical and Medical Device Innovation; 3) Polices on Implementing Full Life-Cycle Management for Encouraging Pharmaceutical and Medical Device Innovation; and 4) Policies on Protecting Innovator's Interests for Encouraging Pharmaceutical and Medical Device Innovation. According to the CFDA, these four documents aim to further deepen registration reform, promote industrial upgrade and innovation in the pharmaceutical and medical device sector, and meet increasing clinical needs. All feedback shall be sent to yhzcszhc@cfda.gov.cn preferably by May 25 and no later than June 10.

- CFDA released Opinion on Managing Problems Found during Clinical Trial Data Inspection (revised draft) for public comment

  On April 10, the Center for Food and Drug Administration (CFDA) released its Opinion on Managing Problems Found during Clinical Trial Data Inspection (revised draft) for public comment. This is the second time that the CFDA released an exposure draft for this document. The CFDA adopted six public suggestions received during the last round of feedback.

- CFDA released Guiding Opinions on Drug Classification for Consistency Evaluation

  On April 5, the CFDA released its updated Guiding Opinions on Drug Classification for Consistency Evaluation. The policy no longer requests companies to conduct consistency evaluation for domestically-made original products and allows these products to be used as reference drugs. In addition, the CFDA also cancelled on-site inspections of research institutions, manufacturing sites, and clinical trial institutions for generic drugs on the market that have filed applications based on consistency principles.

- CDE released the 15th list of drugs to be included in priority review

  On April 14, the Center for Drug Evaluation (CDE) released the 15th list of drugs to be included in priority review. The list includes seven drugs, including products from Boehringer Ingelheim and GSK. Notably, the CDE for the first time gave priority review to generic drugs that had been approved by the FDA but had not been approved by the China Food and Drug Administration (CFDA).

Medical Devices

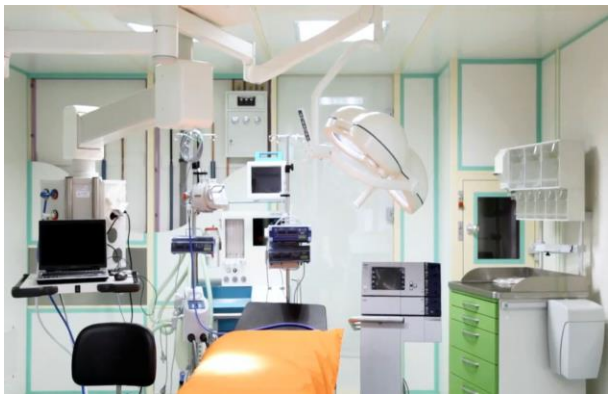
- CFDA released Administrative Measures of Medical Devices Recall

  On April 28, the CFDA released the Administrative Measures of Medical Devices Recall to strengthen supervision and ensure the safety of medical devices. This document applies to both domestic and foreign manufacturers. According to the Measures, when companies decide to recall their products, they are required

to send a notice to their local FDA or/and CFDA immediately and submit a detailed evaluation report within five days.

- CFDA released Administrative Measures of Medical Devices Standards

  On April 26, the CFDA released the Administrative Measures of Medical Devices Standards to provide guidance for the establishment of technical standards for different medical device categories. According to the document, the National Institute for Food and Drug Control (NIFDC) will in charge of the general formulation of medical devices standards; an expert commission affiliated to NIFDC will be responsible for conducting technical review and research. The CFDA also encouraged companies to participate in the formulation of medical devices standards and help NIFDC improve its review capacity. The Administrative Measures will go into effect on July 1.



Hospitals

- China to cancel drug mark-ups at all public hospitals by the end of September

  On April 11, National Development and Reform Commission (NDRC) Vice Minister Hu Zucai announced that drug mark-ups at all public hospitals would be cancelled by the end of September. Similar to practices being implemented in Beijing, to compensate for public hospitals' revenue losses, provincial governments are allowed to increase prices for medical services.

- State Council released the Guiding Opinions on Promoting the Construction and Development of Partnerships across Medical Institutions

  On April 26, the State Council released the Guiding Opinions on Promoting the Construction and Development of Partnerships across Medical Institutions to further promote the reform of public hospitals. According to the State Council's plan, by the end of 2017, every municipality of the pilot provinces conducting comprehensive healthcare reform will have at least one influential partnership across medical institutions. The Opinions emphasize that the development of these partnerships will increase grassroots hospitals' capacity through their partnership with tiered hospitals in talent training, physician multi-site licensing, and other means.

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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