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China's State Council Announces Major Policies to Reform the Pharmaceutical Industry

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China will launch further reforms in the pharmaceutical sector as part of the healthcare reform initiatives announced by the State Council in its February 9, 2017 Circular on *Several Opinions Concerning Further Reforms of the Policies Governing Drug Production, Circulation and Usage* (the "Circular No.13"). The Circular No. 13 sets forth general principles of the reform. Detailed implementation measures are expected from relevant ministries, including the CFDA, National Health and Family Planning Commission (NHFPC), the Ministry of Human Resources and Social Security (MOHRSS), the Ministry of Commerce (MOC), National Development and Reform Commission (NDRC), State Administration of Industry and Commerce (SAIC), and the Ministry of Public Security (MPS).

The Circular No. 13 reinforces the government's determination to expedite approvals for new drugs and urges generics to pass the quality consistency tests.

- Generics that are consistent with the quality of originator drugs ("high quality generics") will be deemed interchangeable with the originator drugs. These high quality generics will be prioritized for hospital procurement. In addition, only the first three high quality generics passing the consistency test will be eligible for collective tenders for public hospitals.

- The Marketing Authorization Holder ("MAH") system will be applicable to both new drugs and high quality generics if they are developed or manufactured in China.

- Compulsory license can be granted and enforced for any patented drugs that prevent or treat critical illness. This practice, if widely implemented, will significantly impact the competitive landscape for innovative products.

Healthcare affordability is another major theme in the Circular No. 13.

- Prices of patented and off-patent drugs must not be higher than those in the country of origin or in China's neighboring countries. The government expects manufacturers of patented or off-patent drugs to offer price commitment when applying for marketing authorizations, and will further leverage price-volume negotiations at collective tenders to exercise its control over drug prices.

- The CFDA is responsible for establishing an ex-factory price database for pharmaceuticals to enhance surveillance and provide better intelligence for antitrust enforcement.

- Public hospitals must prioritize their use of essential drugs. The NHFPC will organize health economic studies to evaluate clinical outcomes and further rationalize the use of drugs. The performance review of public hospitals will be closely tied to the change in healthcare costs.

- Reimbursement by Basic Medical Insurance funds will be calculated based on Disease Related Groups, number of patients, or number of days in hospital. The costs for drugs and consumables will not be separately reimbursed.

- Sales of pharmaceuticals on the Internet will be promoted. Consumers can order pharmaceuticals online, with either pickup or delivery from brick-and-mortar retail pharmacies.

Last but not least, anti-bribery and anti-corruption enforcement remains high on the Chinese government's agenda. The Circular No. 13 asks the CFDA to strengthen the administration of medical representatives. All medical representatives will have to register with the CFDA (or its local counterpart), and their registration will be timely published. More notably, medical representatives can engage only in academic promotion and technical consulting activities; they will be prohibited from selling pharmaceuticals. Failures to comply with these requirements will impact the individual credit ratings.

The Circular No. 13 will considerably impact the China strategy of multinational pharmaceutical companies. We recommend that companies carefully review and study the policies, and monitor the progress of any implementing rules associated therewith.

If you would like to discuss the foregoing or any other related matter, please contact Katherine Wang or your usual Ropes & Gray advisor.