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China Announces New Initiatives to Level the Playing Field for Innovative and Generic Drugs

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China's Government will launch several incentives to enhance accessibility of innovative drugs, especially imported oncology drugs. The State Council, China's cabinet, has decided not to apply any tariff on imported drugs, and will include imported new drugs (especially urgently required oncology drugs) in the government-funded Basic Medical Insurance on a rolling basis. Companies can use their own testing reports to satisfy the import drug testing requirements and reduce time to clear customs. Innovative chemical drugs will enjoy a 6-year data exclusivity period. New drugs to be launched concurrently in China and globally will be entitled to a 5-year patent term extension.

Meanwhile, the government will encourage research and development of generics and enhance generics' quality and efficacy, the State Council announced on April 3, 2018, in its Circular on *Opinions Concerning Reforms of Policies to Improve the Supply and Utilization of Generics* (the "Circular No.20"). Circular No. 20 outlines a series of reforms to bolster generic drug makers, which will have significant impact on the market dynamics between innovative pharmaceutical companies and generic manufacturers.

The Circular No.20 proposes the following key initiatives:

1. Improve market access of high quality generics. China's State Drug Administration (formerly the CFDA) rolled out the Generic Quality Consistency Evaluation in 2015. Generics whose quality and efficacy are deemed equivalent to originator products (*i.e.*, high quality generics) will enjoy preferential treatment in public hospital tenders and prescriptions. Specifically, public hospitals will be required to list high quality generics in their formularies and purchase them through collective tenders. Physicians at public hospitals will be required to prescribe pharmaceuticals using their generic names, and hospitals will be encouraged to fulfill the prescriptions with high quality generics. The government-funded Basic Medical Insurance will reimburse for high quality generics at the same rate as it would for the corresponding brand name drug. This reimbursement policy is designed to encourage medical institutions to switch to and dispense high quality generics.

2. Authorize compulsory license grants to enhance availability of innovative drugs. Patentees will be encouraged to voluntarily grant licenses to Chinese generic manufacturers. In addition, Chinese generic manufacturers that meet the compulsory licensing requirements can apply for compulsory licenses in certain circumstances with the State Intellectual Property Office ("SIPO"). The National Health Commission ("NHC"), the Ministry of Industry and Information Technology ("MIIT"), and the State Drug Administration can request SIPO to grant a compulsory licenses to Chinese generic manufacturers if there is a serious threat to the public health.

3. Balance the interests of innovative and generic drug manufacturers. The government will encourage both the creation of innovative drugs and the development of generic drugs. The initiatives will promote an intellectual property protection system that adapts to China's economic and social development, while balancing the interests of patentees and the public. The government will establish an early-warning patent system in the pharmaceutical industry to mitigate the risk of patent infringement for generic drug makers.

4. Provide policy incentives for the development of generics. The government encourages development of generics that are clinically required, with proven therapeutic benefits, and in high demand (*i.e.*, high priority generics). In

addition, drugs that treat orphan diseases, pandemic diseases, or pediatric illnesses, or that will go off patent protection within one year are also deemed high priority generics. A government research grant will be used to fund the development of high priority generics and the in-licensing/acquisition of related manufacturing and packaging technology. Once a generic drug manufacturer is qualified as a high-tech enterprise, the company will be eligible for tax incentives—the normal 25% corporate income tax rate will be reduced to 15%.

5. Tighten approval standards and accelerate the approval process for generics. Generic drugs will be approved only if their quality and efficacy are proven to be equivalent to the originator products. If a generic drug has been developed based on a compulsory license, listed in the catalog of high priority generics, or supported by the government research grant (*i.e.*, National Science and Technology Major Projects), it can be eligible for expedited review.

These initiatives illustrate the Chinese government's intention to foster an innovation-conducive environment for multinational pharmaceutical companies. On the other hand, the Chinese government is keen to reduce the healthcare burden of Chinese patients by refining the regulatory framework for generics. While many hurdles for regulatory approval of innovator drugs have been eliminated, commercial success will require a sophisticated market access strategy that can fend off pressure from high quality generics. We recommend that multinational pharmaceutical companies carefully assess their competitive advantages and refine their commercialization strategy under these new initiatives.

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