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China Proposes Major Changes to Pharmaceutical Regulations

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On April 20, 2019, the Chinese government submitted a second draft of the *Drug Administration Law of the People's Republic of China (Second Draft for Deliberation)* ("DAL") to the Standing Committee of the National People's Congress of China (the "NPC") for deliberation. The government intends to introduce structural changes to the DAL in order to incentivize innovation and reinforce post-approval compliance obligations. Unlike the first draft, which only modified individual provisions of the DAL, the second draft reorganizes the law according to phases of the product life cycle and contains a dedicated chapter on the statutory duties of Marketing Authorization Holders ("MAHs"). Additionally, the government has drafted dedicated legislation to regulate vaccines. The *Vaccine Administration Law (Second Draft for Deliberation)* ("VAL") was submitted for the NPC's deliberation on April 26, 2019. Comments from interested stakeholders on both drafts must be submitted by May 25, 2019.

Compared with the previous draft amendments to the DAL,[1] the second draft contains some noteworthy additions.

1. The draft states the principle that pharmaceutical innovation should be based on clinical value. New drug research and development should focus on new therapeutic mechanisms, address multiple targets, or involve interventions that systemically affect biological functions.

2. The MAH system will be implemented equally for domestic and imported drugs. Subject to approval by the National Medical Products Administration ("NMPA"), MAHs will be allowed to transfer their marketing authorizations.

3. MAHs and retail pharmacies will be able to establish an online presence on third party portals registered with local drug administrations. Online sales of prescription drugs, however, will continue to be restricted.

Most importantly, penalties for violations will be significantly increased. For example, the first draft of the DAL proposed administrative fines for selling counterfeit drugs up to 10 times the sales value of the affected products, while the second draft of the DAL increases the fines up to 15-30 times. Victims of counterfeit drugs will also be entitled to punitive damages. Likewise, China legal agents of foreign MAHs will also be subject to administrative fines ranging from 100,000-200,000 RMB if found to be in violation of the DAL.

Certain policies proposed in the second draft have triggered fierce discussions among NPC members, including the complete ban on the online distribution of prescription drugs. The industry also has questions about the second draft's unexplained removal of provisions on GMP/GSP certification, which has been mandated on drug manufacturers and distributors for nearly 20 years in China. Lastly, regulatory data protection and patent linkage is not mentioned in the second draft. As a result, it is unclear whether these two important mechanisms will be addressed in the Implementing Regulations of the DAL or Drug Registration Rules.

Much like the second draft of the DAL, the latest draft of the VAL intends to strike a balance between incentivizing innovation and ensuring drug safety. For example, priority review could be granted to vaccines that meet urgent needs for disease prevention and control, and the government would fund the research and development of new multivalent vaccines. As with the draft revised DAL, this draft of the VAL would significantly increase penalties for violations. For example, administrative fines for selling counterfeit vaccines will be increased from 5-10 times to 15-30 times the sales value of affected products. Notably, the second draft of the VAL introduces additional requirements for batch release

[1] The NPC released the first draft for deliberation on November 1, 2018. The former CFDA also released a draft in October 2017 (see Ropes & Gray Alert dated October 10, 2017 for more details).

control of imported vaccines. Manufacturers of imported vaccines will need to submit evidence of their China marketing authorization, a summary of batch production and inspection records, and sample products from the same batch, as well as the marketing authorizations and batch release permits issued by the foreign regulatory authorities in the country of manufacture.

The DAL and the VAL are fundamental to pharmaceutical companies' operations in China. While the proposed draft codifies many reform initiatives that accelerate market access of innovative drugs, it also signals aggressive post-approval enforcement and severe sanctions. We advise that pharmaceutical manufacturers and distributors closely monitor the progress or this legislation and carefully review their operations in China to ensure compliance with the new regulations.

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