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Registration of Imported Drugs

CFDA Issues Draft Incentives to Encourage Registration of Imported Innovative Drugs

On March 17, 2017, the China Food and Drug Administration (the "CFDA") released a draft policy, *the Decision to Adjust Certain Matters related to the Administration of Imported Drug Registration* (the "Draft Policy"), soliciting public comments until April 20, 2017. The industry expects that, once the Draft Policy becomes effective, the registration of imported innovative drugs with the CFDA will be significantly expedited.

I. Background

Due to the CFDA lengthy review process, innovative drugs take a much longer time to complete registration in China than in other countries. The CFDA has been receiving a lot of complaints and pressure from the public. In August 2015, the PRC State Council indicated a clear intention to improve the review and approval process of clinical trials, by (a) synchronizing clinical trials in China for imported drugs before obtaining NDAs in other jurisdictions and (b) encouraging Chinese medical institutions to participate in international multi-center clinical trials ("IMCTs") and the direct use of data gained from IMCTs for the purpose of imported drugs registration in China. In furtherance to the State Council's opinions, the CFDA has proposed the Draft Policy with an aim to substantially accelerate the introduction of imported innovative drugs into China.

II. Overview

The only four articles in the Draft Policy are simple and straightforward:

i. For an IMCT to be initiated in China, the drugs (excluding vaccines) for the IMCT are no longer required to have been registered or

entered into phase II or III clinical trials in another jurisdiction.

ii. Where the IMCT for an imported drug is completed in China, the application for the imported drug registration in China can be submitted directly in accordance with the requirements under the Measures for the Administration of Drug Registration.

iii. The pre-existing NDA in another jurisdiction may be no longer required for the import of new chemical drugs or innovative biologics for therapeutic purposes.

iv. If, before the CFDA regulations go into effect, an applicant has submitted an application for an exemption from the PRC clinical trials for an imported drug, and such application is accepted for review based on the IMCT data, the import of such drug will be approved where the application meets the relevant requirements.

III. Implications

It is expected that the Draft Policy will boost the IMCT in China and the registration of imported drugs.

The simultaneous initiation of clinical trials in both China and other countries may substantively increase the chance of achieving the proof of concept (POC) for a new drug under development, specifically to types of diseases displaying a high prevalence in China. The large number of patients of China with highly prevalent diseases (e.g., lung cancer) offers a large patient pool for clinical trials and faster trial enrollment. By carrying out early-stage clinical trials in China, foreign pharmaceutical companies may find opportunities to more quickly test the POC for drugs at R&D stages in a variety of potentially applicable symptoms, and substantially shorten the time needed to demonstrate the POC through global drug development pipelines.

With the current language of the Draft Policy, the step of applying for the exemption from the PRC clinical trials for imported drugs may be removed after the completion of an IMCT, and the registration of imported innovative drugs may no longer be subject to the NDA in other jurisdictions. This will definitely accelerate the commercial launch of imported drugs in China and narrow the gap between when new drugs can be introduced in the US/EU and the PRC. Theoretically there may be new drugs developed by foreign pharmaceutical companies specially tailored for the Chinese market and launched here first. On the other hand, without the endorsement of foreign NDAs, it may be more challenging for the CFDA to consider green-lighting new imported drugs and in the near future their decision-making process may need to be closely reviewed.

With the booming of IMCTs and the commercial launch of new imported drugs, we can foresee a strong need for clinical trials in China which may give rise to prosperous growth of CROs, hospitals and other medical institutions actively involved in clinical trial activities and ultimately benefit the cultivation of talent in the related sectors. Further, we can anticipate very robust product licensing transactions between foreign drug developers and Chinese GSP holders, which will also create dynamic for cross-border equity investments between industry players.

FENG Rui	Partner	Tel: 86 10 8519 1389	Email: fengr@junhe.com
YANG Fan	Partner	Tel: 86 21 2208 6371	Email: yangfan@junhe.com
LIU Yiyi	Associate	Tel: 86 21 2208 6196	Email: liuyy@junhe.com

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