



US-China Business Council Comments on China Food and Drug Administration's Draft Decision on Adjusting Administrative Management for Drug Import Registrations

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The US-China Business Council (USCBC) represents approximately 200 member companies engaged in business across all industries and sectors in China, including manufacturers and marketers of pharmaceutical products. Our companies appreciate efforts by the China Food and Drug Administration (CFDA) to ensure the availability of high-quality, innovative drugs in China, and appreciate the opportunity to provide comments on the CFDA draft Decision on Adjusting Administrative Management for Drug Import Registrations (“draft for comment”), as published on March 17, 2017.

We welcome the CFDA's faithful implementation of China's commitments at the Joint Commission on Commerce and Trade and largely support the measures listed in the draft Decision, as these changes will provide an increasingly streamlined regulatory review process that helps to improve patient access to necessary drugs. Furthermore, by expediting and simplifying the process for pharmaceutical companies to obtain market access approval, the proposed policy will contribute to an increasingly product quality-focused competitive drug market in China. In particular, there are several aspects of the new regulations we would like to commend:

- Foreign drugs that have already concluded the international multi-center trial in China may directly apply for market approval with CFDA;
- Foreign drug manufacturers may apply for the importation of a chemical drug or therapeutic biological product before the product has been approved in its home country or region; and
- The new regulations waive the requirement for registration trials for imported drugs whose registrations are based on data from international multi-center trials.

However, while these measures reflect important progress for China's drug review processes, USCBC would like to also highlight certain details that limit the full potential of China's

pharmaceutical market. We respectfully submit the following comments on the draft Decision for clarification and revision prior to issuing the final version.

Although these measures will undoubtedly contribute to significantly reduced timelines for a number of pharmaceutical product regulatory approvals, the clinical trial application period for products requiring longer wait times remains 12-24 months. This wait period is still ten times that of major regulatory authorities such as the US Food and Drug Administration, European Medicines Agency, and Pharmaceuticals and Medical Devices Agency—each of which are members of the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH). USCBC encourages CFDA to guarantee a maximum review time of 30-60 days for these products, which will ensure that China’s clinical review times are consistent with those of ICH member regulatory authorities and, therefore, are aligned with international practices. Maintaining this 30-60 day review time standard assures that Chinese patients can benefit quickly from the full range of high-quality, innovative drugs available on the international market.

Moreover, while Article 1 states that CFDA no longer requires drugs used for clinical testing to be approved in another country or to have been in Phase II or Phase III trials elsewhere before an international multi-center trial can be conducted in China for that drug, it also includes an explicit exemption for vaccines. This exemption means that top-quality vaccines produced by foreign companies will continue to encounter heavy delays during the review and approval process, limiting Chinese patient access to these treatments. Given the importance of ensuring that Chinese patients have access to these top-quality vaccine products, USCBC strongly recommends that CFDA does not exempt vaccines from this group of drugs.

USCBC greatly appreciates the opportunity to provide comments on this important policy. Our companies look forward to the implementation of this draft Decision, including further clarification on key details. We hope that these comments are constructive and useful to CFDA as it reviews the draft measures, and we welcome opportunities for further dialogue on these issues.

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