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# China Drug Administration publishes a key Draft Guidance on data exclusivity

May 8, 2018

On April 26, 2018, China Drug Administration or CDA (formerly China Food and Drug Administration or CFDA) published a draft guidance titled *Measures for the Implementation of Data Protection for Pharmaceutical Tests (Interim)* (Draft Guidance). This is the first time CDA has provided details on how the data exclusivity applies to pre-clinical and clinical data submitted to the agency. Companies with plans to launch pharmaceutical products in China should carefully review the Draft Guidance and assess its implications. Comments are due on the Draft Guidance by May 31, 2018.

By way of brief background, before the publication of the Draft Guidance, China already has in place limited data exclusivity for pharmaceuticals. In particular, as part of its obligations undertaken with its accession to the World Trade Organization (WTO), China agreed to implement data exclusivity with a term of protection of six years for pharmaceuticals that utilize new chemical entities. The current Draft Guidance has expanded the scope of the data exclusivity to cover more products including innovative drugs, orphan drugs, pediatric drugs and innovative biological treatment products, as well as drug applications that have successfully challenged a patent. Notably, the Draft Guidance limits the type of data covered to those pre-clinical and clinical trial data related to drug efficacy, and explicitly excludes data related to drug safety. The Draft Guidance further states that to be protected, the data must meet the following requirements:

1. the data are required by the agency as part of the application for obtaining the market authorization
2. the data are not otherwise disclosed to the public prior to the application
3. the data are independently developed without relying on data developed by others or publicly available studies

Under the Draft Guidance, the data exclusivity periods are six years for innovative drugs approved in China and 12 years for innovative biological treatment products. The Draft Guidance further provides detailed guidance on how the data exclusive periods are calculated for innovative drugs.

- If the drug application uses data from clinical trials conducted in China, or data developed with multicenter clinical trial in China and the application is either submitted in China (first)

or submitted in China concurrently with other countries/regions, six years for innovative drugs and 12 years innovative biological treatment products.

- If the drug application uses data from multicenter clinical trial in China and the drug is already approved in other countries or regions first, the data exclusivity is one to five years depending on the delay. If the time lapse between the drug's first approval outside of China and application in China is more than six years, there is no data exclusivity.
- If the drug application uses data from clinical trials conducted outside of China with no Chinese patients, the data exclusivity periods are 25 percent of the above; if the application is supplemented with clinical trial data in China, 50 percent of the above.

For orphan drugs and pediatric drugs, the data exclusivity periods are six years.

Under the Draft Guidance, the data exclusivity starts from the date of application approval. To invoke the data exclusivity, the drug applicants are required to prepare a separate application to CDA along with the new drug application. While during the data exclusivity periods CDA cannot approve another drug that contains the same active ingredient and the same indications using the protected data, the Draft Guidance also provides a dispute resolution mechanism through which generic drug applicants can challenge the data exclusivity. The data exclusivity is also revoked if the companies fail to market the products in China within one year after obtaining regulatory approval.

In summary, the Draft Guidance on data exclusivity is clearly aimed at encouraging more global companies to launch innovative drugs in China and also provides incentives for companies to conduct clinical trials in China. It is somewhat concerning, however, that the Draft Guidance seems to be inconsistent with China's previous commitment with a term of protection of six years for pharmaceuticals that utilize new chemical entities. In particular, for an innovative drug with clinical trial data outside of China with no Chinese patients, the Draft Guidance would only grant 25 percent of the six years exclusivity period. Further, the Draft Guidance fails to clearly define the exceptions to the data exclusivity and the language might be subjected to different interpretations that favor generic drug companies. For example, the requirement that the data protected must be required by the agency as part of the drug application may overly restrict the scope of the data that are protected. It is counterintuitive that a drug applicant will submit irrelevant data. As such, it is our view that CDA should either provide further clarification or simply delete this requirement.

We will continue to monitor these and other developments related to life sciences regulatory framework in China. With team members based both in Washington D.C. and Beijing, we are uniquely positioned to help you navigate the ever-changing regulatory requirements in China and advocate for policy changes on your behalf. Please contact us if you would like assistance with drafting comments or have any questions.

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