

May 8, 2018

The China Drug Administration Proposes a Working Procedure for Pharmaceutical Study Data Protection

Attorneys
Katherine Wang

In response to the central government’s calling for a data protection mechanism,¹ the China Drug Administration (the “CDA”) published a draft on Implementing Measures for Pharmaceutical Study Data Protection (the “Draft”) on April 25, 2018 for public comments.

This Draft specifies data protection scope, extends the data protection period, and, for the first time, proposes a working procedure for applying for and granting a data protection right.

To Redefine Protection Scope

Since China’s entry to the WTO in 2002, drugs containing innovative chemical entities have been entitled to six years of data exclusivity protection.² The Draft expands the protection scope to cover both innovative drugs and generic drugs. Specifically, eligible drugs include (i) innovative drugs, (ii) innovative therapeutic biologics, (iii) orphan drugs, (iv) pediatric drugs, and (v) generic drugs to which pertinent patents have been invalidated.

The current data protection mechanism protects independently generated and undisclosed study data and other data. The Draft narrows the scope of protected data to those independently generated and undisclosed non-clinical and clinical study data that is submitted for marketing authorization purposes only if they are related to product efficacy. Product safety data in the regulatory submissions is excluded from protection.

To Extend Protection Period

The Draft offers a variety of protection periods up to 12 years (for details, please see the table below). The level of protection is on par with what the USFDA offers³ and surpasses what the EMEA provides.⁴

| Drugs | Protection Period |
|----------------------------------|---|
| Innovative drugs | 6 years from the date of marketing authorization in China |
| Innovative therapeutic biologics | 12 years from the date of marketing authorization in China |
| Orphan drugs | 6 years from the date of the first approval of the relevant indication in China |

¹ See the General Office of the CPC Central Committee and the General Office of the State Council’s Opinions on Deepening the Reform of the Evaluation and Approval Systems and Encouraging Innovation on Drugs and Medical Devices dated October 2017.

² See Article 34 of the Implementing Regulation of the Drug Administration Law (2016) and Article 20 of the Drug Registration Administration Measures (2007).

³ The U.S. grants a maximum 12 years of data protection period to biologics.

⁴ The EU grants a maximum 10 years of data protection period to innovative drugs.

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|---|---|
| Pediatric drugs | 6 years from the date of the first approval of the relevant indication in China |
| Generic drugs to which pertinent patents have been invalidated (i.e., first-to-market generics) | Unclear |

To incentivize early launches of new drugs in China, the protection period for an innovative drug will be reduced by one to five years if the New Drug Approval (NDA) application is first filed outside China in reliance of data from multi-regional clinical studies on Chinese patients. No protection will be granted if such NDA application is filed six years later than the first foreign filing. Further, a protection period will be reduced (i) by 75% if a NDA application is solely based on overseas clinical data or (ii) by 50% if such NDA application is based on supplemental studies on Chinese subjects.

To Provide an Implementing Mechanism

The Draft introduces a working procedure for pharmaceutical companies to apply for and exercise its data protection right. An NDA applicant can apply for a study data protection right in the NDA application with the CDA. The CDA may grant a data protection right together with the relevant NDA. Information about the rationale for data protection and its exclusivity term will be publically available in China's Orange Book.

If any subsequent application concerns a drug having the same active ingredient and indication as that of a protected drug during the exclusivity term, the CDA will notify the relevant data protection right owner within 30 days after its receipt of the application. The right owner can oppose this application within 30 days after receiving the notification. If the right owner opposes, the CDA will verify and decide on the authenticity of the data submitted by the other applicant, e.g., whether this data is truly independently generated by the applicant or from properly authorized sources. Either the right owner or the applicant can appeal to the CDA's decision by administrative appeals or litigations.

To Prevent Abuse of Right

The Draft requires a data protection right owner to voluntarily disclose its protected data after the right is conferred. However, it is unclear whether the right owner is obligated to disclose any protected data that contains trade secrets or personal data.

In addition, an approved data protection right can be revoked by the CDA upon a third-party request if the relevant right owner fails to market and sell the protected drug within one year after receiving the NDA.

The updated regulatory data protection mechanism is encouraging, but several questions remain unclarified, for example, how an innovative drug is defined; which types of patents, if being successfully challenged, can render a generic drug eligible for data protection; the exclusivity term of first to market generics; and the definition of "independently generated data," etc. We advise that pharmaceutical companies submit comments to the CDA by May 31, 2018.

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