Implementation Measures for Data Protection (Draft for Comments)

Article	Modification Suggestions	Reasons and basis
1		Please explain how these current draft Implementation Measures will align with the Implementation Regulations of the NMPA that are currently in place which state that data exclusivity is 6 years and only applies to new chemical entities.
1		We note that market exclusivity provisions for orphan drugs and pediatric drugs were mentioned in the draft Implementation Guidelines for China's Drug Administration Law in May 2022, but are absent from the current draft Implementation Measures. We still very much wish to express our desire to see these other types of market exclusivities present in China's drug regulatory framework.
3		Please clarify that terms such as "Innovative Drug", "Improved Drug", "Biosimilars" and the like used in these Measures are defined according to the NMPA's regulatory law.
3	During the data protection period, if other applicants submit drug registration applications using <u>legally</u> self-obtained data, their applications shall be approved if they meet the requirements. <u>The other applicants will</u> no longer be granted a data protection period, but the data shall not be relied upon by subsequent other applicants.	The original text is unclear whether "no longer granting data protection period" refers to the data of the holder or other applicants submitting and obtaining data on their own. According to the context, it should refer to other applicants submitting and obtaining data on their own, so it is recommended to be amended to clarify.
3	Data Protection means when drugs containing new chemical ingredients and other qualifying drugs (see the attached Schedules for details) are approved for marketing, NMPA shall protect the trial data and other data submitted by the applicants that are obtained by themselves and have not been disclosed and grant a Data Protection period of ~~up 6 years~~<u>up to 6 years, with the possibility of additional</u>	We recognize and share NMPA's goal of ensuring that patients in China have better access to new medicines. However, adopting longer RDP protection consistent with higher international standards, as well as leaving open the possibility of longer protection (*e.g.,* for pediatric trials), would reinforce China's commitment to promoting an increasingly vibrant and competitive innovative pharmaceutical landscape within the country. Existing regulations in China do not state that the six-year period is a cap. In fact, past proposals have provided for

	protection to be determined later.	a robust period of protection for these innovative therapies: Article 5 of China's 2018 Draft provided for a 12 -year data protection period for innovative biological products. In addition, Article 11.11 of the Sino-Swiss Free Trade Agreement provides that parties shall provide "at least six years" for undisclosed data of pharmaceutical products. Therefore, while the six-year period established in the DALIR and Sino-Swiss FTA may serve as a minimum, they do not preclude China from setting more robust protection periods. Although the Drug Administration Law Implementing Regulation ("DALIR") in China and international agreements propose or establish a minimum six-year protection period, adopting longer periods is essential to incentivize investment and development in the pharmaceutical industry. **(DALIR, Article 34)** As a recent report has recognized, the provision of RDP in China consistent with these higher international standards could boost the innovative pharmaceutical industry and increase the availability of new medicines in China by as much as 66%." (Copenhagen Economics, Regulatory Data Protection for Pharmaceuticals: How Implementing RDP in China Will Benefit Society, Industry and the Chinese Economy, at 2 (July 2024), https://copenhageneconomics.com/publication/regulatory-data-protection-for-pharmaceuticals-in-china/. To more effectively encourage innovation, China should grant RDP commensurate with the greatest period of protection available in other countries for the product type. For Example: The European Union provides a period of eight years of RDP during which a generic or biosimilar applicant cannot refer to the originator's data, and an additional period of two years of market exclusivity during which a generic product cannot be put onto the market. In Switzerland, medicinal products containing a new active substance benefit from a 10-year period of RDP, during which a generic or biosimilar product cannot be approved by reference to the innovative product's data.

		In Japan, a drug with a new active ingredient has a "re-examination period" of eight years, during which no abbreviated application can be submitted. Finally, in the United States, the licensure of an application for a biosimilar or interchangeable product may not be made effective by the U.S. Food and Drug Administration ("FDA") until 12 years after the date on which the reference biologics product is first licensed."
4	Undisclosed trial data and other data refer to the trial data that was never before submitted in a drug marketing authorization application in China regardless of whether it is public or not, and complete application materials. After a drug is approved, test data obtained when subsequent research work is completed in accordance with the requirements of the drug regulatory authorities will ~~no longer be given new data protection~~ be given a protection period that expires at the same time as the data protection period of the originally submitted data.	The original text does not clearly define "undisclosed". We propose clarifying that "undisclosed trial data and other data" refers to data that was never before submitted in a Chinese marketing authorization (MA) application regardless of whether it is public or not. For example, data that was published as part of a foreign trial would still be considered "undisclosed trial data in China" if it was not submitted in China MA application before. Although subsequent test data obtained after a drug is approved cannot be given new data protection, we wish to confirm that such data can enjoy protection during the exclusivity period of the earlier submitted protected data.
5	The time difference between the date on which the drug's application for marketing authorization ~~was accepted~~ meets certain minimum requirements for submission in China and the date on which the drug with the same active ingredient first obtained marketing authorization abroad	Here, "the drug" is presumed to be the same drug, but it is unclear what the definition is, such as whether the determination is based on active ingredients, formula, dosage, strength, etc. According to the spirit of Article 6, it is recommended to be based only on active ingredients to avoid circumvention. The requirements for acceptance of a drug application involve many steps, (some of which could be quite cumbersome and take some time). We propose providing applicants with a submission date for the purposes of this section if the applicant meets certain minimum requirements for submission.
6	The scope of drug data protection in this clause includes new clinical trial data that demonstrates that the drug has significant clinical advantages over drugs with known active ingredients (marketed biological	We think it is too broad to rule out all bioavailability, bioequivalence and immunogenicity data of vaccines. Innovator companies will often invent new formulations of drugs that have significantly improved properties resulting in clinical advantages. Bioequivalence studies may still need to be done to demonstrate that the improved drugs are equally efficacious, yet they may

	products), ~~but does not include bioavailability, bioequivalence and immunogenicity data of vaccines.~~	have other improved properties, such as safety or absorption. Additionally, innovator companies will conduct such studies to ensure safety of a drug candidate as it advances from Phase 1 to 2 to 3. Excluding all data arising from studies relating to bioavailability, bioequivalence and immunogenicity data of vaccines will discourage innovator companies from conducting such types of studies in China, and could potentially discourage foreign companies from entering China, which will ultimate hurt the Chinese people. We recommend leaving out the exclusion and letting the NMPA determine on a case-by-case basis whether the bioavailability, bioequivalence or immunogenicity data of vaccines can still fall under the definition of "new clinical trial data that demonstrates that the drug has significant clinical advantages over drugs with known active ingredients."
6		We do not agree with the deduction rules generally for at least category 5.1 and category 3.1 biologics. An applicant for data protection should not be penalized for delays that may be inherent in the regulatory review process in China versus another jurisdiction. NMPA should provide the full RDP periods to innovative small molecule drugs and biologics without regard to the timing of the submission in China as compared to the time of approval in other jurisdictions. The RDP period for innovative drugs that are first approved overseas should be the same as that for innovative drugs first approved in China without reduction. Article 5 and Article 6 of the Draft Measures indicate that for innovative drugs and biological products that first obtain marketing approval overseas, the RDP period shall be six years, but reduced by the time difference between the date on which the drug's marketing authorization application in China is accepted for filing and the date on which the marketing authorization is obtained for the drug for the first time overseas. This "window period" is inconsistent with international best practices and undermines China's commitment to

		fostering innovation. The proposed "window" approach for drugs first approved overseas would also be inconsistent with China's WTO commitments as TRIPS does not endorse such an approach. TRIPS Article 3.1, which requires China to "accord to the nationals of other Members treatment no less favourable than that it accords to its own nationals with regard to the protection of intellectual property" By conditioning full RDP protection on a requirement that domestic industry is inherently more likely to satisfy, China's proposed RDP rule would disadvantage foreign manufacturers and result in weaker intellectual property protection for foreign innovators, in violation of TRIPS Article 3.1. In addition, in 2020, in the Phase One Economic and Trade Agreement negotiated during President Trump's first term, China has made a bilateral commitment to the United States to "provide for effective protection and enforcement of pharmaceutical-related intellectual property rights, including . . . undisclosed test or other data submitted as a condition of marketing approval." Finally, other members of the International Council for Harmonisation ("ICH") of Technical Requirements for Pharmaceuticals for Human Use ("ICH") all treat molecules that are new to a country as "new drugs" for purposes of RDP and do not tie the provision and extent of RDP to the timing of a marketing application in another country, including the European Union and Japan, as well as South Korea and Switzerland. As such, they do not and would not reduce the RDP term provided to Chinese innovators who secure approval in China before seeking marketing authorizations in their markets. As a permanent member of ICH, China should also adopt this approach.
7	A three-year Data Protection period is granted to the first approved generic drugs (including drugs produced overseas) and biological products of an originator drug that has been marketed overseas but not in China. The Data Protection period is calculated from the date on which the marketing authorization is	Please clarify the following: if a generic drug (cat. 3) application based on a foreign approved drug as reference drug is submitted in China **before** the foreign approved reference drug (cat. 5.1) and obtains 3 year data protection as a first approved generic drug, will the later filed foreign approved reference drug fail to obtain its own data protection due "the generic applicant submission of data acquired by themselves"?

	obtained for the generic drugs or biological products. During the Data Protection period, NMPA will not approve the marketing applications or supplementary applications for chemical generic drugs and biosimilar drugs submitted by other applicants relying on the protected data of an MAH without the consent of the MAH**,** unless such other applicants submit data obtained by themselves.	
8	If the applicant intends to apply for data protection, he/she shall submit ~~an application~~ a request for data protection ~~at the same time as submitting the~~ as part of the application for drug marketing authorization.	To streamline the regulatory application process, we suggest that the NMPA includes the request for data protection as part of the regulatory application process. This will help reduce additional and unnecessary time and cost for the administrative step. However, we don't want any issues in the data protection request to slow down the rest of the normal regulatory process. As such, we propose allowing the regulatory approval process to proceed as normal regardless of the status of the data protection request.

Term	Modification Suggestions	Reasons and basis
3	The applicant must submit documents proving the date on which the drug first obtained marketing authorization overseas, or the information proving submission for marketing authorization application overseas.	It is not uncommon to apply for drug marketing authorization all over the world at the same time. That is, when submitting an application in China, it is possible that no other country/region has approved the marketing authorization. Therefore, it is recommended to increase the information and documents and options for submitting marketing authorization applications abroad.
6	If the requirements are not met, a notice of non-consent will be sent to the applicant, indicating all existing issues. For each issue, the applicant should have at least two chances to overcome the objections/rejections. If the applicant still does not meet the requirements after a maximum of three replies, a proposal will be made not to grant data protection. The applicant is allowed to communicate orally or request an on-line meeting with the centre. The centre should agree to at least one communication to help the applicant understand the rejection(s).	Article 5 allows third parties to submit objections when reviewing whether drug trial data complies with data protection requirements, but Article 6 does not have any mechanism for applicants to make any defense if they do not comply. This violates the principle of fairness, so it is recommended to add a defense mechanism.