Implementation Measures for Drug Trial Data Protection [1]

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Article 1

These Measures are formulated in accordance with the Drug Administration Law of the People's Republic of China, the Regulations for the Implementation of the Drug Administration Law of the People's Republic of China, the Administrative Measures for Drug Registration, and other relevant provisions, for the purposes of encouraging pharmaceutical innovation and meeting public demand for medicines.

Article 2

The National Medical Products Administration ("NMPA") shall be responsible for the administration of drug trial data protection ("Data Protection"), and, in accordance with the principles of fairness, openness, and impartiality, shall establish and administer the Data Protection system. The Center for Drug Evaluation of the NMPA ("CDE") shall be responsible for the specific implementation of Data Protection.

Article 3

Data Protection refers to the protection granted by the NMPA, upon approval for marketing, to independently obtained and undisclosed trial data and other data submitted by applicants for eligible chemical drugs and biologics, for a protection period of up to 6 years. The Data Protection period shall commence on the date the relevant drug registration application is approved within the territory of China.

During the Data Protection period, where another applicant seeks marketing authorization or submits a supplemental application by relying on the protected data described in the preceding paragraph without the consent of the drug marketing authorization holder ("MAH"), the NMPA shall not grant approval; provided, however, that this restriction shall not apply where such

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applicant has independently obtained the relevant data without reliance on another party's protected data.

Where, during the Data Protection period, another applicant submits a drug registration application supported by data independently obtained by such applicant, approval may be granted if the applicable requirements are satisfied; however, no separate Data Protection period shall be granted in respect of such data, and such data may not subsequently be relied upon by any other applicant.

In the event of a public health emergency in the State, or where required for the public interest, the relevant provisions shall apply.

Article 4

The term "undisclosed test data and other data" as used in these Measures refers to complete, unpublished application data that is submitted for the first time within the territory of China in connection with a drug marketing authorization application.

Article 5

A data protection period of 6 years shall be granted from the date of the first marketing authorization within the territory of China for an innovative drug. For an original drug that has been approved for marketing outside China but not yet within China, a data protection period of 6 years shall be granted from the date of its first marketing authorization within China.

The scope of data protection under this Article includes all test data contained in the drug marketing authorization application dossier that demonstrates the safety, efficacy, and quality control of the drug.

Where a single innovative drug obtains approval for multiple indications under the same approval number, each indication shall be granted data protection separately according to its respective registration category. For a newly added indication, the scope of data protection shall be limited to the clinical trial data supporting its approval.

During the data protection period, without the consent of the right holder, the NMPA not grant approval to any other applicant's marketing authorization application or supplementary application for a modified new drug, chemical generic drug, or biosimilar that relies on the protected data of the said right holder; this shall not apply where the other applicant submits data independently generated without reliance on the protected data of others.

Article 6

A data protection period of 4 years shall be granted from the date of the first marketing authorization within the territory of China for a modified drug. For a modified drug that has been approved for marketing outside China but not yet within China, a data protection period of 4 years shall be granted from the date of its first marketing authorization within China.

The scope of data protection under this Article includes new clinical trial data demonstrating a significant clinical advantage over the known active ingredient drug (or approved biologic product), but excludes bioavailability data, bioequivalence data, and vaccine immunogenicity data.

During the data protection period, without the consent of the right holder, the NMPA shall not grant approval to any other applicant's marketing authorization application or supplementary application for a chemical generic drug or biosimilar that relies on the protected data of the said right holder; this shall not apply where the other applicant submits data independently generated without reliance on the protected data of others.

Article 7

Where an original drug that has been approved for marketing outside China but not yet within China submits a registration application for a new indication that has not yet been approved either inside or outside China, and submits all test data demonstrating the safety, efficacy, and quality control of the drug as specified in paragraph 3 of Article 5 of these Measures, the provisions of Article 5 shall apply, and a data protection period of 6 years shall be granted for all such test data. For subsequent additions of indications to the same drug, the provisions of Article 6 shall apply, and a data protection period of 4 years shall be granted for the corresponding data within the scope of protection.

Article 8

A data protection period of 3 years shall be granted to the first generic drug and biologic product that obtains approval for an original drug already approved for marketing outside China but not yet within China. The data protection period shall be calculated from the date of marketing authorization of such generic drug or biologic product. The scope of data protection under this Article includes the necessary clinical trial data supporting approval, but excludes bioavailability data, bioequivalence data, and vaccine immunogenicity data. During the data protection period, without the consent of the right holder, the NMPA shall not grant approval to any other applicant's marketing authorization application or supplementary application for a chemical generic drug or biosimilar that relies on the protected data of the said right holder; this shall not apply where the other applicant submits data independently generated without reliance on the protected data of others.

Article 9

Where an applicant intends to apply for data protection, it shall file a data protection application simultaneously with the submission of the drug marketing authorization application. If the applicant has any questions concerning data protection-related matters, it may request a communication meeting.

Article 10

When conducting technical review of a drug registration application, the CDE shall determine the scope and duration of data protection to be granted in accordance with the provisions of these Measures.

Article 11

For a drug that meets the data protection conditions, the NMPA shall indicate the data protection information for such drug on the drug approval document. The CDE shall establish a data protection column on its website and publish relevant information concerning drug data protection.

Article 12

After a drug has been granted data protection, other applicants may submit a drug marketing authorization application or supplementary application relying on such protected data within 1 year prior to the expiration of the data protection period. The CDE shall suspend the review clock upon completion of the technical review, and approve the marketing of the relevant drug after the expiration of the data protection period. Where an applicant claims, when submitting a drug marketing authorization application or supplementary application, that the data have been independently generated, but it is discovered during the technical review process that the application relies on protected data of another applicant, such application shall not be approved.

Article 13

Data protection shall terminate under any of the following circumstances: the drug approval document is revoked, withdrawn, or cancelled; the right holder voluntarily waives data protection; or as otherwise provided by laws or regulations. In the event of termination of data protection, the NMPA shall issue an announcement on the termination of data protection. The CDE shall update the relevant information in the data protection column based on the announcement. From the date of issuance of the announcement on termination of data

protection by the NMPA, drug registration applications submitted by other applicants relying on such protected data may be accepted or approved.

Article 14

The specific working procedures for data protection shall be separately formulated by the CDE.

Article 15

These Measures shall take effect as of May 15, 2026.

I. How to Understand the Terms "Undisclosed," "Obtained Independently," and "Reliance" as Defined in the Implementation Measures?

Undisclosed: With industrial development and the need to protect public access to information, drug regulatory authorities in major countries and regions generally require the public disclosure of clinical trial summaries or reports. "Undisclosed" as defined in these Measures means that the relevant trial data have not been fully disclosed. Specifically, if only a portion of the trial data has been disclosed, the complete set of trial data shall still be considered undisclosed.

Obtained Independently: This includes drug trial data that are: (a) generated from research conducted independently by the drug registration applicant; (b) generated from research commissioned by the applicant; or (c) obtained by the applicant through purchase or exclusive licensing arrangements.

Reliance: Under normal circumstances, the approval of a new drug requires the submission of complete data on pharmaceutical chemistry, nonclinical studies, and clinical trials. For improved new drugs and generic drugs, however, repeat clinical trials are generally not required. Instead, these drugs are developed by conducting comparative studies against the reference listed drug (innovator product) to provide supplementary evidence of safety and efficacy demonstrating clinical advantage, or by using bioequivalence (BE) studies as indirect evidence of pharmaceutical equivalence and therapeutic equivalence to the reference listed drug.

Reliance as defined in these Measures refers to the situation where an applicant, in seeking approval for market authorization of an improved new drug or a generic drug, references or relies upon the trial data already submitted by the marketing authorization holder of an approved reference listed drug to demonstrate the safety and efficacy of the latter, without repeating the same studies.

II. Why Is the Data Protection System Not Applicable to Traditional Chinese Medicines (TCMs)?

Traditional Chinese medicines are subject to the Regulations on the Protection of Traditional Chinese Medicine Varieties and their implementing rules.

III. Article 5 of the Implementation Measures Mentions "All Trial Data Used to Demonstrate the Safety, Efficacy, and Quality Control of a Drug." What Does This Include?

Pursuant to the Drug Registration Regulation and the ICH guidelines, trial data used to demonstrate the safety, efficacy, and quality control of a drug generally include the following categories:

(1)Pharmaceutical (CMC) Data: including but not limited to studies on active pharmaceutical ingredients (API)/drug product formulation, manufacturing processes, quality standards and methodology validation, stability studies, and packaging material compatibility studies.

(2) Nonclinical Study Data: including but not limited to pharmacodynamics studies, pharmacokinetic studies, toxicology studies, and safety pharmacology studies.

(3) Clinical Study Data: including early-phase (Phase I/II) clinical data and pivotal (Phase III) clinical data.

IV. For a drug already granted data protection, will new data protection be granted for new indications, new patient populations, or combination use? Will bioavailability (BA), bioequivalence (BE), or vaccine immunogenicity data be granted data protection?

The core purpose of drug clinical trial data protection is to protect the original trial data generated to demonstrate the safety and efficacy of a drug. Therefore, new data protection may only be granted where new data demonstrating drug safety and efficacy are generated.

For a drug already granted data protection, if the addition of a new indication or patient population is supported by new, original clinical trial data, data protection may be granted for such clinical trial data. However, the addition of new combination regimens shall be assessed on a case-by-case basis, and data protection may be granted only where entirely new data are required.

Data relating to bioavailability (BA) and bioequivalence (BE) do not generate new evidence of safety or efficacy and therefore fall outside the scope of data protection.

Given that the objective of data protection is to encourage drug innovation, and that efficacy clinical trials constitute the gold standard for evaluating innovative vaccines, whereas immunogenicity serves only as a surrogate endpoint for vaccine efficacy evaluation, immunogenicity data shall not be protected.

V. If the active pharmaceutical ingredient (API) of a drug has been approved outside China but not yet in China, and the indication for which the drug is first submitted for approval in China has not been approved either inside or outside China, how will trial data protection be provided in such a case?

For a reference listed drug that has been approved outside China but not in China, if the indication for which it is first submitted for approval in China has not been approved for marketing either inside or outside China, although such a drug is classified as an improved new

drug under the drug registration classification system, the applicant is required to submit not only the clinical trial data related to that indication, but also all trial data used to demonstrate the safety, efficacy, and quality control of the drug. In other words, the data requirements for such a drug registration application are identical to those for an innovative drug or a reference listed drug approved outside China but not in China.

To encourage simultaneous global development of new indications, and taking into account the basic principles governing the scope of drug trial data protection, the *Implementation Measures* provide that in such circumstances, the provisions of Article 5 shall apply, granting 6 years of data protection. The scope of data protection shall cover all trial data contained in the drug market authorization application dossier used to demonstrate the safety, efficacy, and quality control of the drug.

However, if such a drug subsequently adds further indications, the applicant is required only to submit the data necessary for approval of the new indication. Such applications are not different from other applications for additional indications. Therefore, Article 6 of the *Implementation Measures* shall apply, granting 4 years of data protection, the scope of which shall include the new clinical trial data demonstrating a clear clinical advantage over the known API drug (or approved biological product), but shall not include bioavailability, bioequivalence, or vaccine immunogenicity data.

VI. If a drug manufactured outside China is transferred to be manufactured inside China, may the data protection term previously granted to the foreign-manufactured drug be carried over?

Yes. To improve drug accessibility, meet clinical needs, and encourage overseas enterprises to transfer the manufacturing of reference listed drugs already approved in China to domestic manufacturing sites, if such a reference listed drug has already been granted drug trial data protection, then during the data protection term of the reference listed drug, the NMPA shall not approve any other applicant's application for market authorization or supplementary application that relies, without the holder's consent, upon the trial data of either the imported reference listed drug or the domestically-manufactured reference listed drug. The aforementioned holder includes both the holder of the imported reference listed drug and the holder of the domestically-manufactured reference listed drug. To obtain such protection, the holder of the domestically-manufactured drug shall obtain the consent of the holder of the reference listed drug.

VII. For a conditionally approved drug that has been granted data protection, will new clinical trial data generated in the post-approval period be granted new data protection?

A drug that receives conditional approval and meets the criteria for data protection has already been granted a data protection term at the time of approval. The new clinical trial data obtained

from post-approval studies conducted to fulfill the conditions attached to the approval serve as supplementary support for the conclusions reached at the time of initial approval. Such data do not constitute new data demonstrating clinical safety and efficacy and shall therefore not be granted a new data protection term. However, during the data protection term of such drug, other applicants may not, without the holder's consent, rely on these new clinical trial data to obtain drug market authorization.

VIII. How shall the data protection terms be handled for chemical drugs classified under Category 5.1, Category 5.2, and Category 3?

To encourage reference listed drugs approved outside China but not in China to enter the Chinese market as early as possible and to meet the clinical needs of Chinese patients, once a chemical drug classified under Category 5.1 has been granted a data protection term, the data protection terms already granted to chemical drugs under Category 5.2 and Category 3 shall remain valid. For chemical drug applications under Category 5.2 and Category 3 that have already been accepted, the review and approval process shall continue if they meet the relevant requirements, but no data protection term shall be granted. For any new drug market authorization applications or supplementary applications that rely on such data, the provisions of Article 12 of the *Implementation Measures* shall apply.

IX. After the promulgation of the *Implementation Measures*, how will the regulatory requirements for clinical trials of generic drugs referencing a reference listed drug that has been approved outside China but not in China (where the same generic drug product is already available on the market) be optimized and adjusted?

The phrase "the first generic drug that has been approved and references a reference listed drug approved outside China but not in China" in Article 8 of the *Implementation Measures* refers to the first generic drug of the same product category to receive approval. For a generic drug referencing a reference listed drug approved outside China but not in China, where the same generic drug product has already been approved and is on the market prior to the promulgation of the *Implementation Measures*, and where the first generic drug has been on the market for 2 years or more, other newly submitted applications for the same generic drug product shall not be required to repeat the clinical trials for safety and efficacy.