May 18, 2025

The General Office of the
National Medical Products Administration
Address: No 1 Beiluyuan Zhanlan Road
Xicheng district, Beijing
100037

Via Email: *yhzcszhc@nmpa.gov.cn and sjbh@cde.org.cn*

Re: Feedback on Drug Trial Data Protection

Dear General Office:

The Intellectual Property Owners Association (IPO) appreciates the opportunity to respond to the solicitation of opinions on the *"Implementation Measures for the Protection of Drug Trial Data (Trial, Draft for Comments)"* ("Measures") and the *"Working Procedures for the Protection of Drug Trial Data (Draft for Comments)"* ("Procedures") published on March 19, 2025.

IPO is an international trade association representing a wide array of stakeholders in all industries and fields of technology that own, or are interested in, intellectual property (IP) rights. IPO membership includes over 125 companies and spans over 30 countries. IPO advocates for effective and affordable IP ownership rights and offers a wide array of services, including supporting member interests relating to legislative and international issues; analyzing current IP issues; providing information and educational services; and disseminating information to the public on the importance of IP rights.

IPO recognizes the importance of the objective of the Measures and Procedures to promote drug innovation and generic drug development and improve the drug trial data protection system. IPO strongly feels that the length of the data protection period set forth in the proposal is insufficient and falls short of global best practice standards. IPO urges NMPA to adopt a period that is better aligned with international best practices and better serves China's pharmaceutical innovation objectives. IPO also strongly encourages NMPA to adopt a model that provides equivalent data protection for innovative drugs that are first approved outside China as those first approved in China. The reduction contemplated in the current proposal is out of step with international best practices and could discourage innovators from launching new drugs in China.

As requested, IPO is submitting its comments on the Measures and Procedures by filling in the feedback forms (Appendix 3, Appendix 4), attached hereto. IPO hopes that our comments will be helpful during the process of finalizing the Measures and Procedures. IPO thanks the General Office for its attention to IPO's comments, and

welcomes further dialogue and opportunity to provide additional comments. IPO has enclosed this letter as translated herewith.

Sincerely,

Krish Gupta

Krish Gupta
President
Enclosures

附件4							
《药品试验数据保护工作程序（征求意见稿）》反馈意见表					**IPO Comments on Procedures (For filing)**		
条款内容	修改意见	理由及依据	企业名称		Article	Suggested modifications	Reason and basis
第三条	**申**请人需提交该药品境外**首次**获得上市许可之日的证明性文件，**或境外提交上市**许可申请的资料和文**件**。	同时在全世界申请药物上市许可并非不普遍，即在中国提交申请时，有可能还没任何其他国家/地区的上市许可被审批。故此建议增加提交境外提交上市许可申请的资料和文件和选项			3	The applicant must submit documents proving the date on which the drug first obtained marketing authorization overseas, or the information and documents submitted 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 add as an option to include the information and documents of marketing authorization applications overseas.
第六条	**不符合要求的，向申**请人发出不同意通知书。申请**人在最多三次回复后**还是**不符合要求的，提出不**给**予数据保**护的建议。	第五条容许第三方在对药品试验数据是否符合数据保护相关要求进行审查时提交异议，但第六条没有任何机制让申请人在不符合的情况下作出任何答辩。此有违公平原则，故此建议增加答辩机制。			6	If the requirements are not met, a notice of non-consent will be sent to the applicant. 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.	Article 5 allows submission of third party opinions when reviewing whether the drug trial data complies with the data protection requirements, but Article 6 does not have any mechanism for an applicant to make any reply if their application does not comply. This violates the principle of fairness, so it is recommended to add a reply mechanism.
请于2025年5月18日前反馈至sjbh@cde.org.cn，邮件标题请注明“药品试验数据保护反馈意见”							

	IPO Comments on Implementation Measures (For Filing)		
	Article	Suggested modification	Reasons and basis
	3	During the data protection period, if other applicants submit drug registration applications using self-obtained data, their applications shall be approved if they meet the requirements. The other applicants will 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 original holder or the other applicant submitting the self-obtained data. According to the context, it is believed that it should refer to the other applicant submitting the self-obtained data, and therefore it is recommended to be amended for clarity.
	4	Undisclosed trial data <u>means data submitted to NMPA in a dossier in support of an application for a drug that has not been previously approved in China.</u>	The original text does not clearly define "undisclosed". The proposed revision is intended to make clear that the previous submission of such data to another health authority outside of China shall not affect the “undisclosed” status of such data.
	4	First <u>successful</u> application for drug marketing authorization	The first application may be rejected based on different original grounds. In order to better encourage drug innovation, it is recommended to change it to the first successful application.
	5	The time difference between the date on which the drug's application for marketing authorization was accepted in China and the date on which the drug <u>with the same active ingredient, in the same form/dosage strength, delivered in the same way and for the same indication</u> first obtained marketing authorization abroad	IPO strongly encourages NMPA to adopt a model that provides equivalent data protection for innovative drugs that are first approved outside China as those first approved in China. The reduction contemplated in the current proposal is out of step with international best practices and could discourage innovators from launching new drugs in China. If NMPA were to the nevertheless maintain a model that treats drugs differently if launched first outside of China, IPO proposes to clarify this provision with the language at left. Here, "the drug" is presumed to be the same drug, but it is unclear what the definition is, such as based on active ingredients, formula, dosage, strength, etc. The regulations should be clear that innovative drugs and original drugs are both entitled to the same sccope of regulatory data protection, including being able to apply for multiple indications. Further, the fourth passage only refers to "innovative drugs" as being eligible for multiple indications. According to the context of Article 6, it is recommended to be based only on the active ingredients, form/dosage strength, delivery, and indication to avoid
	6	Overall comments: The regulations need to provide both a clear distinction and relationship as between modified new drugs and the associated innovative/original drugs.	It is implied from Article 5 that a modified new drug would be a drug substance that does not "share the same approval number", but a clear definition of the modified new drug with the innovative/original drug is needed for recognition of new dosage forms, routes of administration, etc.

	6	The time difference between the date on which the modified new drug's application for marketing authorization was accepted in China and the date on which the modified new drug with the same active ingredient, in the same form/dosage strength, delivered in the same way and for the same indication first obtained marketing authorization abroad	Here, "the modified new drug" should refer to the same modified new drug, but it is unclear what the definition is, such as based on active ingredients, formula, dosage, strength, etc. It is recommended to define the modified new drug as having the same active ingredient, in the same form/dosage strength, delivered in the same way and for the same indication.
	13	Overall comment: The penalty for discovery of incorrect submissions as to first overseas marketing authorization during administrative reviews should be revision, not denial of any grant, and, for discoveries after the grant, should be either correction or revocation (and only if the difference is a significant period of time and evidence of intentional deception).	During the administrative review period, the purpose of an exchange is to ensure accuracy and conformity with regulations so corrections at this time should be permitted without conditions. With regard to post-grant discoveries, there should not be an incentive for challenges to be made based on differences of opinion as to the date of market authorization. Is it measured from conclusion of a final regulatory meeting, the date of correspondence from the regulatory authority, the date of actual first commercialization, measured from the authorization date of a different drug product, i.e. the original rather than modified? Additionally, applicants should be permitted to rely upon guidance of reviewing authorities to provide clear and presumptively accurate guidance so that later challengers can't point to a new standard, a revised regulation or a new administrative case decision that redefines the date of first overseas marketing authorization to cancel a regulatory data period.