appendix

Interpretation of the "Announcement on Optimizing the Review and Approval of Clinical Trials for Innovative Drugs"

I. Background of the Announcement In recent years,

my country's biopharmaceutical innovation capabilities have continued to strengthen, and innovative achievements have emerged at an accelerated pace. Drug clinical trials are a crucial link in drug development. To further support innovative drug development, the National Medical Products Administration (NMPA) organized a pilot program in July 2024 to optimize the review and approval of innovative drug clinical trials. Through policy guidance and multi-party collaboration, the program aimed to improve the quality and efficiency of clinical research and development, accelerate the review and approval of pilot innovative drug clinical trial applications, and optimize the ecosystem for innovative drug clinical trial development in my country. Currently, the pilot program has been completed. Based on the "Opinions of the General Office of the State Council on Comprehensively Deepening the Reform of Drug and Medical Device Supervision and Promoting the High-Quality Development of the Pharmaceutical Industry" (Guo Ban Fa [2024] No. 53) (hereinafter referred to as the "Opinions"), the NMPA summarized the pilot experience, solicited opinions from relevant departments, and conducted extensive discussions with industry associations, domestic and foreign enterprises, drug clinical trial institutions, and experts. The NMPA then issued the "Announcement on Matters Related to Optimizing the Review and Approval of Innovative Drug Clinical Trials," further optimizing the allocation of review and approval resources and promoting the improvement of the quality and efficiency of innovative drug clinical research and development.

II. Why is an additional 30 days required on top of the 60-day implied consent period for drug clinical trials?

Daily channel?

Since the reform of the drug review and approval system, the National Medical Products Administration (NMPA) has continuously optimized clinical trial management and promoted innovative drug research and development. Following the implementation of the 60-day implied approval process in 2019, the efficiency of drug clinical trial review and approval has significantly improved. Through a series of efforts, my country's drug clinical trial review and approval process has become increasingly efficient.

The average time for clinical trial review and approval has been reduced to about 50 working days, which has effectively accelerated the research and development of innovative drugs, supported the integration of my country's drug research and development industry chain into the global research and development system, and accelerated the pace of new and effective drugs to market.

The implementation of the 60-day implied approval system has effectively met the needs of biopharmaceutical R&D in my country. With the advancement of national policies supporting innovative drugs, breakthroughs in biopharmaceutical technology innovation are constantly being achieved, and some products under development that meet the significant medication needs of the public require further accelerated development. Furthermore, my country possesses abundant clinical R&D resources, and in recent years, the experience and capabilities of Chinese drug clinical trial institutions and professionals have continuously improved, making the conditions for early and in-depth participation in global R&D innovation increasingly mature. Therefore, the National Medical Products Administration (NMPA) has coordinated existing review and approval resources, adding a 30-day channel on top of the 60-day implied approval process. Without affecting the review and approval efficiency of the 60-day implied approval channel, this further expedites some clinical trial applications with a need for accelerated processing.

III. How to coordinate the accelerated review and approval of clinical trials within the 30-day pathway with high-level safety Complete?

High-quality development of biopharmaceutical innovation is inseparable from high-level safety. Drug clinical trials are scientific studies conducted to determine the safety and efficacy of drugs, and since unknown factors exist, risk control is particularly important. my country is a member of the Governing Council of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) and has already implemented all ICH guidelines, achieving alignment of clinical trial technical standards with international standards. The 30-day approval process maintains the same standards, conducting review and approval within the existing international clinical trial technical standard system. Simultaneously, the 30-day approval process promotes stronger collaboration among R&D companies, clinical trial institutions, principal investigators, and ethics review committees to further improve the level of clinical trial risk control. R&D companies should strengthen early communication with principal investigators and clinical trial institutions.

To ensure the smooth progress of clinical trials, potential risks should be identified and addressed in advance, and contingency plans should be developed. Principal investigators should participate in clinical trial risk assessments early and review the clinical trial protocol before submission of the clinical trial application. The ethics review committee should strengthen risk review and assessment throughout the entire process, ensuring the protection of research subjects while accelerating the process. The Center for Drug Evaluation of the National Medical Products Administration has specifically drafted the "Technical Guidelines for Writing Risk Management Plans During Innovative Drug Development (Trial Implementation)" to guide all parties involved in clinical trials in integrating the concept of full life-cycle risk management into the drug development process.

We provide guidance throughout the entire product development process.

IV. The national policy system supporting the development of innovative drugs across the entire supply chain, with significant clinical application potential.

What are the main considerations for including key innovative drugs with significant clinical value in the 30-day support program?

On July 5, 2024, the State Council Executive Meeting reviewed and approved the "Implementation Plan for Supporting the Development of Innovative Drugs Across the Entire Chain," requiring strengthened policy support across the entire chain, optimized review and approval mechanisms, and concerted efforts to promote breakthroughs in the development of innovative drugs. According to the plan, key innovative drug varieties with significant clinical value that have received support from the national policy system for supporting the development of innovative drugs across the entire chain will be included in the 30-day application process.

V. Globally developed products and international multi-center clinical trials are included in the 30-day notification period.

What are the main considerations regarding the scope of support for this route?

The "Opinions" propose supporting drug clinical trial institutions in participating in the early clinical development of innovative drugs, supporting the conduct of international multi-center clinical trials, and promoting the simultaneous development, application, review, and market launch of drugs globally in my country. The National Medical Products Administration (NMPA) is implementing the requirements of the "Opinions" by supporting eligible globally synchronized development products and international multi-center clinical trials to be included in the 30-day pathway. Phase I and Phase II clinical trials are early exploratory clinical trials; globally synchronized development can be conducted either solely in my country or in different countries. Phase III clinical trials must be led by the principal investigator of a Chinese drug clinical trial institution or...

International multicenter clinical trials jointly led by my country, with the early participation of principal investigators in clinical development, help to better adapt innovative drugs for global synchronous development to Chinese clinical practice and better serve Chinese patients. VI. The National Medical Products Administration's Center for Drug Evaluation lists eligible pediatric innovative drugs.

What is the scope of innovative drugs for rare diseases and innovative traditional Chinese medicines?

The list of eligible innovative drugs for children and rare diseases published by the Center for Drug Evaluation of the National Medical Products Administration includes innovative drugs included in special programs such as the Children's Drug Starlight Program and the Rare Disease Care Program. The scope of other eligible innovative traditional Chinese medicine drugs will be formulated and released separately.

VII. Regarding the commitment made by drug clinical trial applicants requesting the 30-day pathway... Consideration for initiating clinical trials within 12 weeks?

The 30-day pathway is a time when the National Medical Products Administration allocates existing review and approval resources to eligible applicants. Reforms favoring innovative drug clinical trial applications. A commitment to complete the process within 12 weeks upon application submission. Initiating clinical trials (first Chinese participant signs informed consent form), explaining the applicant's position. There is a real need to rapidly conduct clinical research and development. Clinical trials require the joint efforts of all parties involved and high-quality clinical trials. Effective collaboration is essential to ensure rapid initiation of clinical trials after approval, which is crucial for accelerating clinical research and development. The process will allow the 30-day channel to function effectively. Applicants should base their decisions on the variety development... Based on actual needs, a reasonable choice should be made between a 30-day pathway or a 60-day implied consent period, and the clinical trial should be included. Information regarding the conduct of clinical trials should be registered on the Drug Clinical Trial Registration and Information Disclosure Platform.