appendix

Interpretation of the "Announcement of the National Medical Products Administration on Further Optimizing the Review and Approval of Clinically Urgent Drugs Already Marketed Overseas"

I. What is the background to the introduction of this policy?

Since the implementation of the drug review and approval system reform in 2015, the National Medical Products Administration (NMPA) has continuously optimized the review and approval process and taken multiple measures to facilitate the simultaneous development and market launch of new drugs from overseas. In July 2020, the "Procedures for Priority Review and Approval of Drug Marketing Authorization (Trial)" was released and implemented, improving the priority review and approval system and clarifying that six categories, including innovative drugs and improved new drugs for the prevention and treatment of major infectious diseases and rare diseases, can be

included in the priority review and approval scope. In 2018, the NMPA and the National Health Commission jointly issued the "Announcement on Relevant Matters Concerning the Review and Approval of Clinically Urgent Overseas New Drugs" (Announcement No. 79 of 2018), clarifying that clinically urgent overseas marketed new drugs are included in the priority review and approval scope. Following the issuance of Announcement No. 79, three batches of clinically urgent overseas new drug lists have been released, totaling 81 varieties. Currently, 55 varieties have been approved for market launch through the priority review and approval procedure, effectively promoting the introduction of clinically urgent overseas marketed new drugs and playing a positive role in meeting clinical drug needs. In recent years, with the deepening of reforms and the increasing demand for

medicines from the public, the industry has called for further expanding the scope of the current priority review and approval process, enabling more effective drugs already marketed overseas to be quickly introduced into China. For example, urgently needed drugs for treating chronic diseases and geriatric conditions that are already marketed overseas but not yet available in China could also be included in the priority review process.

Scope of approval.

To further encourage more urgently needed new and effective drugs from overseas to enter the Chinese market and benefit domestic patients, the National Medical Products Administration (NMPA) has drafted the "Announcement on Further Optimizing the Review and Approval of Urgently Needed Overseas Drugs" (hereinafter referred to as the "Announcement"). This announcement adopts a comprehensive set of reform measures, including expanding the scope of priority review and approval, making full use of domestic and international clinical research data, optimizing testing procedures, and streamlining registration verification, to facilitate the entry of more urgently needed overseas drugs into the Chinese market.

II. What is the relationship between this Announcement and Announcement No. 79?

Announcement No. 79 has played a positive role in expediting the introduction of urgently needed new drugs already marketed overseas. Its procedures have been incorporated into the 2020 "Procedures for Priority Review and Approval of Drug Marketing Authorization (Trial Implementation)," and the three batches of selected drug lists remain valid. Applicants continuing to apply for drugs on these lists can still be included in the current priority review and approval scope. For drugs not on the three batches of lists, applicants may submit applications from the date of this Announcement, and those meeting the requirements may be included in the priority review and approval scope. Therefore, this Announcement does not conflict with Announcement No. 79 and they complement each other.

charge.

3. Will a list of urgently needed overseas-marketed drugs be released?

The current method of publishing a list of drug varieties is insufficient to adapt to the rapid changes in drug research and development innovation and clinical needs. Therefore, this "Announcement" adopts a flexible working mechanism, involving enterprise applications, review by the Center for Drug Evaluation of the National Medical Products Administration, and necessary expert assessments, to adapt to the

ever-changing clinical needs. IV. Do generic drugs need to undergo clinical trials?

For generic drugs already marketed overseas, were clinical trials conducted before their overseas market launch?

The circumstances of clinical trials vary. If an application is submitted in accordance with this Announcement and meets the requirements after evaluation, a clinical trial may be exempted.

V. How to optimize the testing of urgently needed overseas-marketed drugs?

In July 2025, the China National Institutes for Food and Drug Control (NIFDC) released the "Specifications for Drug Registration Inspection Procedures and Technical Requirements (2025 Revised Edition)," proposing measures to reduce the batch testing volume for drug registration inspection from three times to two times, and allowing applicants to use samples retained from the initial inspection for supplementary registration inspections during the review process, among other measures to facilitate enterprises. For clinically urgently needed drugs already marketed overseas that are included in the priority review and approval scope, testing institutions will implement priority testing procedures, shortening the testing time by 10 working days.

For imported rare disease drugs with short shelf lives, extremely low batch production, and urgent clinical needs that are already marketed overseas, the inspection agencies will optimize their import inspection strategies. Based on the product's full self-inspection report, and according to the product characteristics, only key quality control items and indicators that may be affected by storage and transportation will be examined, without conducting full-item inspection. The specific quantity and inspection items will be jointly determined by the China National Institutes for Food and Drug Control or the port inspection agency and the applicant.

VI. What are the specific measures to optimize the temporary import channel?

To optimize the temporary import pathway for rare diseases and further accelerate efficiency, the National Medical Products Administration, together with the National Health Commission, has optimized the relevant procedures in the pilot work of the Beijing Rare Disease Drug Security Pilot Zone. Beijing has issued relevant implementation measures, which, by changing the expert evaluation process from sequential to parallel and allowing multiple uses of a single customs clearance, can more quickly meet the urgent clinical drug needs of rare disease patients.