Announcement of National Medical Product Administration on Further Optimizing the Review and Approval of Clinically Urgently Needed Overseas Marketed Drugs [1]

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To accelerate the marketing authorization in China of overseas-approved drugs that are urgently needed for clinical use and to meet patients' urgent clinical medication needs, the National Medical Products Administration (NMPA) has decided to further optimize the review and approval mechanism for such urgently needed overseas-marketed drugs. The relevant matters are hereby announced as follows.

1-Adhere to a clinical value–oriented approach and encourage applicants to conduct global synchronized research and development and submit marketing authorization applications simultaneously in China. Encourage the domestic application for marketing authorization of urgently needed overseas-marketed originator drugs and generic drugs; those meeting the relevant requirements may be included in the priority review and approval process.

2-Optimize the review mechanism and accelerate the review process. Applicants may apply for Class I communication meetings regarding the utilization of domestic and overseas clinical data for urgently needed overseas-marketed drugs, matters related to priority review and approval, and applications for conditional approval.

Applicants shall submit supporting materials demonstrating the urgent clinical need, including research data supporting overseas marketing authorization (including complete clinical data as well as necessary pharmaceutical, non-clinical and other research data), post-marketing clinical use and safety monitoring reports from overseas markets, benefit-risk assessment analyses for cross-ethnic or cross-regional use, and risk control plans following import and marketing in China (including post-marketing clinical study plans). Submission of research data from international multicenter clinical trials conducted in China is encouraged. After communication and consultation with the Center for Drug Evaluation of the National Medical Products Administration (hereinafter referred to as the "CDE") and once a consensus has been reached,

[1] Translated by Health Law Asia – Pharmaceutical, Medical Device, and Cosmetics Law

for products requiring the conduct of drug clinical trials, the applicant shall submit a clinical trial application, and the CDE shall decide within 30 days from the date of acceptance whether to approve the conduct of the clinical trial.

For products eligible for exemption from drug clinical trials, the applicant may directly submit an application for marketing authorization.

For products applying for inclusion in the priority review and approval procedure, the Center for Drug Evaluation shall conduct a procedural review. Upon expert assessment confirming that the relevant requirements are met, the product may be included within the scope of priority review and approval.

The Center for Drug Evaluation shall manage registration applications for urgently needed overseas-marketed drugs included in the priority review and approval process separately and shall strengthen communication and guidance with applicants.

3-Improve the testing system to reflect the characteristics of individual products. For urgently needed overseas-marketed drugs for rare diseases that are not yet marketed in China, applicants are encouraged to submit registration applications using a pre-testing approach. For products undergoing sample testing only, the registration testing timeline shall be shortened from 60 days to 40 days. For products undergoing both standard verification and sample testing, the registration testing timeline shall be shortened from 90 days to 70 days. The quantity of samples required for registration testing shall correspond to one batch produced at commercial scale, with each batch providing twice the amount needed for quality standard testing. For rare disease drugs with extremely low single-batch yields, applicants may collaborate with the testing institution to determine the minimum sample quantity necessary for registration testing.

4-Optimize registration verification with an emphasis on risk-based management. For products included in the priority review and approval process, the initiation of overseas registration verification shall be optimized. Registration verification and post-marketing overseas inspections may be organically integrated and coordinated according to risk, and the method of inspection, whether on-site or remote, shall be determined based on the level of risk.

5-Maintain continuous access to temporary import channels for urgently needed drugs. Optimize the temporary import pathway for rare disease drugs to further accelerate the process and improve efficiency, in order to meet the clinical needs of medical institutions for urgently needed rare disease medications.