Announcement of the National Medical Products Administration Regarding Matters Related to the Importation of Commercial-Scale Batches of Drugs Already Marketed Abroad Prior to Approval in China[1]

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In order to implement the relevant requirements of 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" (Guobanfa [2024] No. 53), and to support the early clinical use of innovative and urgently needed drugs for the benefit of patients, the following matters regarding the importation of commercial-scale batches of drugs already marketed abroad prior to approval in China are hereby announced.

1. Applicable Categories of Drugs

Following approval for marketing in China of drugs already marketed abroad (including the issuance of a drug approval certificate or a supplemental application approval certificate, hereinafter referred to collectively), the importation and commercialization of commercial-scale batches meeting the relevant requirements shall be permitted. Such products must fall into one of the following categories:

1-Original or improved drugs.

2- Drugs listed in the "National List of Shortage Drugs," the "National Key Monitoring List of Clinically Essential Drugs Subject to Shortage," the "Catalog of Encouraged Generic Drugs," or the "List of Pediatric Drugs Encouraged for Research and Registration."

3- Drugs whose indications include diseases listed in the "Catalogue of Rare Diseases."

4- Drugs temporarily imported prior to approval in China in accordance with the "Work Plan for the Temporary Import of Clinically Urgent Drugs."

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

5- Drugs approved in China through the accelerated registration pathway in accordance with the "Measures for the Administration of Drug Registration."

6- Other drugs as specified by the drug regulatory authorities of the State Counc

2. Conditions and Requirements

Applicants seeking to file for the importation of commercial-scale batches of drugs already marketed abroad prior to approval in China, in addition to complying with the requirements of the "Measures for the Administration of Drug Importation," must also satisfy the following conditions:

1-The drug has been authorized for marketing by the regulatory authority in the foreign country. In the case of post-marketing changes, such changes must have been approved by the foreign regulatory authority or completed in accordance with the applicable laws and regulations of the foreign country.

2-The product quality standards comply with the drug registration standards approved by the drug regulatory authorities in China; the manufacturing site and production process are consistent with the content of the drug approval certificate in China or with the filed content as required; the package insert and labeling are consistent with the content approved by the Chinese drug regulatory authorities or with the filed content as required.

3-The drug has been manufactured in compliance with Good Manufacturing Practice (GMP) inspections conducted by China, the country (or region) of production, or the country (or region) of registration/market authorization, and subsequent production adheres to these standards.

4-A release document is signed after the drug is approved for marketing in China.

3. Other Matters

1-The marketing authorization holder of the drug and its designated domestic responsible party shall submit an application letter (template provided in Annex 1) and relevant materials (submission requirements provided in Annex 2) in accordance with the requirements set out in the attachments. The port-level drug regulatory authority accepting the import filing application shall conduct the relevant inspection work (inspection items are set out in Annex 3).

2-For imported drugs that have been approved for marketing both abroad and in China and are already being sold in China, if post-marketing changes occur, the importation of commercial-scale batches produced prior to approval may follow the procedures set out in this Announcement after such changes are approved in China. For changes classified as filing-type changes under the "Measures for the Administration of Post-Marketing Changes of Drugs (Trial)" and relevant guidelines, commercial-scale batches produced prior to filing that are

consistent with the filed information may complete import filing under the "Measures for the Administration of Drug Importation" without the need to submit materials according to the requirements of this Announcement.

3-For innovative drugs and improved new drugs produced abroad, once approved for marketing in China, the importation of commercial-scale batches produced prior to approval may follow the procedures set out in this Announcement. When applying for import filing, submission of documentation issued by the foreign drug regulatory authority certifying that the drug is authorized for marketing abroad is not required.

4-The marketing authorization holder of the drug and its designated domestic responsible party shall strengthen risk management for commercial-scale batches produced prior to approval. For sales of such batches in violation of this Announcement, the provincial-level drug regulatory authority where the domestic responsible party is located shall investigate and handle the matter in accordance with applicable laws and regulations.

Requirements for Submitted Materials

Applicants seeking to file for the importation of commercial-scale batches of drugs already marketed abroad prior to approval in China, in addition to complying with the "Measures for the Administration of Drug Importation," shall submit, via the “Other Supporting Documents” field on the “Import Drug Clearance Form” interface within the “Regulatory Certificates” module of the international trade “Single Window,” the application letter and scanned copies of the following materials (if the materials are in a foreign language, a Chinese translation must also be submitted):

1-Documentation issued by the foreign drug regulatory authority certifying that the drug is authorized for marketing (e.g., Certificate of Pharmaceutical Product, drug approval certificate, publicly available approval information issued by the foreign regulatory authority, documentation permitting post-marketing changes, or publicly available information on permitted changes issued by the foreign regulatory authority). If the product for which import filing is being applied falls under post-marketing approval-type changes (excluding changes related to the marketing authorization holder, registered address of the holder, manufacturing company, manufacturing site, or drug specifications), and the commercial-scale batches were produced prior to approval, and the foreign drug regulatory authority is unable to issue documentation permitting the change or there is no publicly available information on permitted changes, submission of this documentation is not required at the time of import filing. However, a written explanation must be provided.

2- A drug inspection report or documentation certifying compliance with drug Good Manufacturing Practice (GMP) issued by China, the country (or region) of production, or the country (or region) of registration/market authorization (including application for registration/marketing), such as a Certificate of Pharmaceutical Product or a drug GMP certification. Applicants shall provide at least the most recently issued documentation. If the production date of the batch intended for import is earlier than the date of the provided documentation, additional documentation covering the intended batch must also be submitted.

If the product for which import filing is being applied falls under post-marketing approval-type changes and consists of commercial-scale batches produced prior to approval, and according to China’s registration management requirements, submission of a drug inspection report or GMP compliance documentation is not required at the time of the supplemental application for the post-marketing change, then submission of such documentation is not required for the import filing. However, a written explanation must be provided.

3- Release documents (such as Certificate of Analysis, Certificate of Conformance/Compliance, Batch Certificate, etc.).

With respect to the documents mentioned in items 1 and 2 above—namely, the “documentation certifying that the drug is authorized for marketing” and the “documentation certifying compliance with drug GMP”—the following requirements apply:

If the documents are consistent with those submitted during the drug registration application in China (including supplemental applications or filings) or conform to the format recommended by the World Health Organization, they may be stamped with the domestic responsible party's official seal and do not require notarization or authentication.

If the documents are not consistent with those submitted during the drug registration application in China (including supplemental applications or filings), and the format does not conform to the WHO-recommended format, notarization and authentication are required.

For documents issued by a contracting state of the "Convention on the Abolition of the Requirement of Legalization for Foreign Public Documents," the relevant procedures shall be handled in accordance with the National Medical Products Administration Drug Evaluation Center's Notice on Matters Related to Documentation for Drugs Produced Abroad.

Inspection Items

The port-level drug regulatory authority accepting applications for drug import filing shall verify that the applicant has submitted complete materials and shall focus on the following inspection items:

1-Based on China's drug approval certificate, drug package insert and labeling, publicly available information from the drug regulatory authorities, and the materials submitted by the applicant, verify the accuracy of the basic information provided in the application letter.

2-Except in cases where submission of a drug inspection report or GMP compliance documentation is exempted, verify that the commercial-scale batches produced prior to approval for which import filing is requested: correspond to the batches listed in the drug inspection report, and any subsequent batches produced thereafter, or have production dates not earlier than the inspection start date indicated in the GMP compliance documentation. If the GMP compliance documentation does not specify the inspection date, verify that the production date of the batch is not earlier than the issuance date of the GMP compliance documentation.

3-For cases where the domestic responsible party declares that the "documentation certifying that the drug is authorized for marketing" and the "documentation certifying compliance with drug GMP" conform to the format recommended by the World Health Organization, the inspection shall verify that the documentation contains relevant statements indicating that "this certificate conforms to the format recommended by the World Health Organization" or equivalent wording.

4-Verify that the issuance date of the release document is not earlier than the issuance date of China's drug approval certificate. If the release documentation consists of multiple documents, at least one of the documents must have an issuance date not earlier than the issuance date of China's drug approval certificate.

In addition to the inspection items listed above, the port-level drug regulatory authority may conduct random verification of the materials submitted by the applicant and the declarations made by the domestic responsible party.