Guiding Principles for the Development of Appropriate Pharmaceutical Packaging Specifications[1]

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To further strengthen the administration of excessive pharmaceutical packaging and to prevent over-packaging, applicants for drug registration are encouraged to develop pharmaceutical products with appropriate packaging specifications during drug research, development, and registration. These Guiding Principles are formulated for this purpose.

I. General Considerations for Appropriate Pharmaceutical Packaging Specifications

The selection of pharmaceutical packaging generally needs to comply with the drug's indications or therapeutic functions, its physicochemical properties and stability, the characteristics of its dosage form, and the intended use scenarios. Packaging must meet the requirements for storage, transportation, use, and safety, and must therefore determine the packaging materials, containers, and packaging specifications that directly contact the drug, so as to ensure the stability of product quality and the safety of patient medication.

Appropriate packaging specifications should typically meet the functional, practical, and economic needs of clinical medication. They should be reasonably designed based on the approved indications or therapeutic functions, dosage and administration, treatment duration, and use scenarios.

Applicants for drug registration are encouraged to select appropriate packaging specifications during the product development and design stage, taking these factors into account. For marketed products requiring changes to packaging specifications, applications may be submitted in accordance with the Administrative Measures for Post-Marketing Changes of Drugs (Trial) and the relevant technical guidelines.

II. General Considerations for the Design of Appropriate Pharmaceutical Packaging Specifications

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

1 Packaging specifications shall meet functional requirements

1.1 Design based on the acute or chronic nature of the disease

It is recommended that appropriate packaging specifications be determined based on whether the disease is acute or chronic and the required treatment duration. For acute diseases with short treatment courses, packaging specifications should match the patient's treatment duration, meeting medication needs while avoiding drug waste. For chronic diseases requiring long-term treatment, and considering the varying clinical needs of patients, larger packaging specifications that align with the expected treatment duration are recommended to reduce packaging waste.

For example: (1) An oral medication for post-herpetic neuralgia is supplied in a 500-ml bottle, which provides more than one month of treatment. This aligns with the typical duration of post-herpetic neuralgia pain, which may last one month or longer, and facilitates patient use. (2) For medicines requiring daily administration and long-term continuous oral treatment, packaging may be designed to contain at least a two-week supply per box, and for patients requiring long-term stable therapy, at least a one-month supply per box may be considered.

1.2 Design based on dosage, administration, and treatment duration

It is recommended that appropriate packaging specifications be determined in accordance with the approved dosage and administration and the expected treatment duration.

The design of packaging specifications must take into account factors such as the number of daily administrations, the dose or quantity required per administration, the need for dose adjustments, the dosage form, and the volume of the product, so as to ensure a scientifically sound and reasonable design.

2 Packaging specifications shall meet the needs of convenient use by healthcare providers and patients

2.1 For medicines intended for patient self-administration (such as outpatient medications), the design should fully consider whether the disease is acute or chronic and should aim to reduce unnecessary medical visits or pharmacy purchases, meeting patient needs and facilitating use.

2.2 For medicines intended solely for use within medical institutions, applicants are encouraged to develop appropriately larger packaging specifications based on clinical needs and to simplify, as much as possible, the packaging of the smallest clinical administration unit, reducing the need for healthcare personnel to open multiple packages and avoiding unnecessary time consumption.

2.3 Key information such as the manufacturing date and expiry date should be printed clearly, legibly, and in a prominent manner to ensure proper and safe use. When printing is used, background colors may be applied to create strong contrast and improve readability. Enhancing

the accessibility of packaging information and designing packaging that is safe and easy to open are encouraged.

3 Packaging specifications shall meet economic requirements

On the basis of meeting functional requirements and the needs of convenient use for healthcare providers and patients, packaging specifications must also take economic considerations into account. Packaging should be made as simple and practical as possible, reducing the volume, weight, and number of layers of packaging materials, and minimizing unnecessary packaging that does not contribute to drug protection, so as to facilitate patient use, avoid waste, and reduce environmental pollution.

III. References

[1] Standing Committee of the National People's Congress. Drug Administration Law of the People's Republic of China. August 2019.

[2] State Administration for Market Regulation. Drug Registration Regulation. March 2020.

[3] National Medical Products Administration. Provisions for the Administration of Drug Instructions and Labels. March 2006.

[4] National Medical Products Administration. Notice on Strengthening the Administration of Drug Specifications and Packaging Specifications. July 2004.

[5] National Health Commission and State Administration for Market Regulation. Implementation Plan for Conserving Drug Resources and Curbing Drug Waste. December 2023.