Guiding Principles for the Development of Appropriate Pharmaceutical Packaging Specifications

China – NMPA National Medical Products Administration, CDE Center of Drug Evaluation

Main information

Scope of Application:

Design and selection of packaging specifications for drugs during development and registration

Effective Date:

May 21st, 2026

Related Provisions:

- Implementation Plan for Conserving Drug Resources and Curbing Drug Waste
- Provisions for the Administration of Drug Instructions and Labels
- Administrative Measures for Post-Marketing Changes of Drugs (Trial)

Key Topics

Framework

- The Guiding Principles are issued by the CDE to further **strengthen the management of excessive drug packaging** and encourage drug registration applicants to develop drugs with appropriate packaging specifications during the R&D and registration phase.

What's new

- **Three key dimensions: functional needs** (based on disease characteristics, dosage, and treatment course), **convenience for healthcare professionals and patients**, and **economic needs** (simplicity, waste reduction, environmental protection). **Non-binding guidance**.

- **Acute vs. Chronic Diseases**: For acute diseases with shorter treatment courses, packaging should be designed to match the treatment duration to avoid waste. For chronic diseases requiring long-term treatment, larger packaging sizes aligned with clinical treatment needs are encouraged to reduce unnecessary refill visits and packaging waste.

- **Outpatient vs. Inpatient Settings**: For patient self-use drugs (e.g., outpatient medications), packaging design should reduce unnecessary visits. For drugs used only in healthcare institutions (e.g., inpatient medications), development of appropriate large packaging sizes is encouraged to minimize the time healthcare workers spend unpacking individual units.

Sensitive Factors

- Readability Requirements for **Critical Information**: The document specifies that critical information such as **production date and expiry date** must be printed clearly and legibly with distinct markings.

- Necessity to coordinate with post-marketing change provisions for those packaging already approved.

Drivers

- **Post-Marketing Change Compliance:** For already-marketed drugs needing packaging specification changes, the existing post-marketing change management pathway applies. Companies should evaluate whether the proposed change falls under a minor, moderate, or major change category and follow the corresponding regulatory submission requirements.
- **Waste Reduction and Cost Optimization:** The emphasis on economic needs and waste reduction aligns with broader sustainability trends. Companies that design packaging to minimize waste and environmental impact may benefit from enhanced patient satisfaction and potentially reduced material costs.