Announcement on Further Strengthening Digital Drug Traceability Management

China – NMPA National Medical Products Administration

Main information

Scope of Application:

Drug marketing authorisation holders, overseas holders' designated domestic responsible persons, manufacturers, distributors, entities using drugs and traceability-system operators.

Effective Date:

September 1st, 2026

Related Provisions:

- Drug Administration Law
- Guidelines for the Development of Drug Information Traceability Systems
- Good Supply Practice for Pharmaceutical Products

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Key Topics

Framework

- The Announcement covers **all in-production formulations** except for three categories: **active pharmaceutical ingredients (APIs), medical oxygen, and medical institution preparations**. Traditional Chinese medicine decoction pieces are subject to separate provisions
- The drug traceability system has moved beyond building platforms and running pilots. Official data shows the system already covers 100% of drug manufacturers, approximately 80% of wholesale and logistics enterprises, and over 530,000 retail pharmacies (about 79% penetration). The Announcement is designed to **close the "execution gaps" in distribution and terminal sales**

What's new

- **Receipt Must Display Traceability Code:** Sales receipts issued by retail pharmacies and user units must **display the traceability code** or provide a convenient query method for consumers
- **Signed Verification for Abnormalities:** When the traceability system issues an abnormality warning, the enterprise must **immediately stop warehousing and sales**. The verification and handling must be reviewed and **signed by the quality responsible person**, creating a documented, personal accountability trail
- **Mandatory Rejection of "Diverted Drugs":** A critical new enforcement provision requires that if a drug's traceability information shows it has **already been sold at a retail pharmacy or user unit**, the receiving enterprise must **refuse to accept it** during warehousing inspection.

Sensitive Factors

- **Personal Accountability via Signature:** The requirement that the quality responsible person **sign off** on abnormality verification means that individual managers can be held personally accountable for failures to properly handle traceability alerts
- **Coordination with NHSA Medical Insurance "Code-Based Settlement":** fail to scan codes implies NMPA penalties and **medical insurance settlement issues**. NMPA and NHSA are enforcing traceability from two sides

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Drivers

- **Quality Responsible Person Workflow Integration:** The signed verification requirement means enterprises must **embed the quality responsible person into the traceability exception-handling workflow**
- **Interaction with the Pharmaceutical Representative Measures:** the traceability Announcement (controlling the **drug**) and the Pharmaceutical Representative Measures (No. 42 of 2026, controlling the **person**) together eliminate "phantom sales"—volume that exists on paper but never reached a patient. Diverted drugs and channel stuffing are technically blocked, leaving only **real prescriptions and real patient use** as valid volume

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