Implementation Opinions on Promoting the Integration of Artificial Intelligence into Drug Regulation

China – NMPA National Medical Products Administration

Main information

Scope of Application:

Encourage a new Regulatory Innovation System covering research and development, manufacturing, distribution, use, inspection, monitoring, and law enforcement

Effective Date:

March 11th, 2026

Related Provisions:

- Action Plan for Smart Drug Regulation
- Opinions of the State Council on Deeply Advancing the Artificial Intelligence and Initiative
- Opinions of the General Office of the State Council on Comprehensively Deepening the Reform of Drug and Medical Device Regulation to Promote the High-Quality Development of the Pharmaceutical Industry

Pharm.east.

Key Topics

Framework

- **Two-phase roadmap: by 2030,** an integrated AI and regulatory innovation system shall be initially established, with effective AI application in review, inspection, monitoring, and government services. **By 2035**, a "digitally and intelligently driven, intelligent and agile, autonomous and controllable, and coordinated across the ecosystem" smart governance pattern shall be largely established.

- Full lifecycle regulation of the "**two products and one device**" (drugs, cosmetics, and medical devices).

What's new

- **Human-Machine Collaborative Review System**: The Opinions mandate the establishment of a "human-machine collaboration mechanism" featuring "digital and intelligent enablement, manual verification, and end-to-end audit trails". AI assists with product classification, task allocation, document review, knowledge retrieval, issue identification, report generation, and certificate preparation, but human review remains mandatory.

- **Remote and Continuous Inspection Authorization**: The Opinions authorize a regulatory model that combines on-site inspection with off-site regulation using AI-powered video analysis and IoT (Internet of Things) sensing data. For high-risk products (vaccines, blood products, special drugs), AI agents shall dynamically monitor manufacturing process quality and safety risks in real time.

Sensitive Factors

- **AI as "Assistive" Only – No Fully Automated Decisions**: The Opinions explicitly maintain AI's "assistive role", requiring clear definition of functional boundaries and responsible entities. Practices such as deployment without prior review and duplicative development are expressly prohibited.

- **Mandatory Filing for Models and Algorithms**: A filing management system for models and algorithms shall be established, requiring validation and assessment of model effectiveness and reliability. **Algorithm transparency requirements and model validation specifications**.

Drivers

- **Industry Digital Transformation Guidance**: The Opinions explicitly encourage and guide the pharmaceutical industry to accelerate digital and intelligent transformation across R&D, manufacturing, quality testing, and post-marketing monitoring.
- **Traceability System Upgrades:** Companies are required to fulfill primary responsibilities for drug traceability, accelerate code assignment for all currently produced product varieties, and achieve whole-process traceability from production through distribution to use.