Implementation Opinions of the National Medical Products Administration on Promoting the Integration of Artificial Intelligence into Drug Regulation[1]

Authority: **NMPA**

Document number: No. 6

Promulgation Date: March 11, 2026

To the Drug Regulatory Administrations of all provinces, autonomous regions, municipalities directly under the Central Government, and the Xinjiang Production and Construction Corps; and to all departments and directly affiliated institutions of the Administration:

Since the implementation of the Action Plan for Smart Drug Regulation, drug regulatory authorities at all levels have actively explored the use of information technologies to enhance regulatory capacity, and have preliminarily established a nationally integrated smart drug regulatory system. At present, the rapid development and iterative advancement of new-generation information technologies, including artificial intelligence, provide new means and inject new momentum into smart regulation.

In order to implement the Opinions of the State Council on Deeply Advancing the Artificial Intelligence and Initiative, and the 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, to seize major strategic opportunities arising from the development of artificial intelligence, to promote the in-depth integration of artificial intelligence with drug regulation, and to accelerate the modernization of drug regulation, the following opinions are hereby put forward.

I. General Requirements

Guided by Xi Jinping Thought on Socialism with Chinese Characteristics for a New Era, full implementation shall be made of the guiding principles of the 20th National Congress of the Communist Party of China and all plenary sessions of the 20th Central Committee of the Communist Party of China. The important instructions and directives of General Secretary Xi Jinping on drug regulation shall be thoroughly implemented.

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

Adherence shall be made to informatization-led modernization of drug regulation, with a focus on problem orientation and systems thinking, and overall coordination of development and security. Full play shall be given to the role of the central hub of the smart regulatory platform, system-wide coordination and open sharing shall be strengthened, and data elements shall be leveraged as a key driving force, with scenario-based applications serving as the primary traction.

Innovative application of artificial intelligence in whole-life-cycle drug regulation shall be further advanced. Through automation, precision, coordination, and intelligence, the level of "one-stop online services, integrated online governance, and coordinated online operations" shall be enhanced. A high-level, nationally integrated smart drug regulatory system shall be established, thereby providing robust digital and intelligent support for the comprehensive deepening of drug regulatory reform.

By 2030, a preliminary integrated innovation system for the convergence of drug regulation and artificial intelligence shall be basically established, and a fundamental operational and management mechanism for "Artificial Intelligence + Drug Regulation" shall be formed. The computing power support infrastructure shall be more intensive, integrated, and efficient. High-quality datasets, vertical domain large models, and intelligent agents meeting the needs of regulatory intelligence shall be developed. Artificial intelligence shall be effectively applied in areas including review and approval, supervision and inspection, testing and monitoring, and government services. The efficiency of human–machine collaboration shall be significantly enhanced, and the digital and intelligent regulatory capacity across the entire lifecycle shall be substantially elevated.

By 2035, a new pattern of smart governance for drug safety shall be fundamentally established, characterized by data- and intelligence-driven operations, agile responsiveness, self-reliance and controllability, and ecosystem-wide coordination.

II. Focusing on Key Smart Regulation Scenarios to Ensure Effective Implementation of Digital and Intelligent Empowerment in Regulatory Reform

a. Establishment of a human–machine collaborative intelligent review and approval system. Standardized and structured electronic submission of application materials shall be promoted, and the knowledge base for review and approval shall be improved. Accelerated development and application of large models and intelligent agents for the review and approval of drugs, medical devices, and cosmetics ("two products and one device") shall be carried out, thereby effectively enabling intelligent classification of products, task allocation, document review, knowledge retrieval, issue identification, report generation, and issuance and delivery of certificates. The efficiency and quality of review and approval shall be significantly enhanced. With a focus on high-frequency operational scenarios of local regulatory authorities in review

and approval work, and under the principle of guidance from the National Medical Products Administration with coordinated division of responsibilities among provincial drug regulatory authorities, a pilot-to-scale approach shall be adopted to accelerate the implementation of intelligent applications in key scenarios, including Class II medical device review, post-marketing drug change filing, general cosmetic filing, and production and operation licensing approval. The transformation and sharing of outcomes shall be strengthened, and low-level redundant construction shall be avoided.

The system for artificial intelligence–assisted review and approval work shall be further improved. Adhering to the baseline requirement of ensuring product safety and effectiveness, and focusing on enhancing the efficiency and quality of review and approval, a sound human–machine collaborative mechanism characterized by "digital and intelligent empowerment, human re-examination, and full-process traceability" shall be established and refined. Efforts shall be accelerated to develop an intelligent review and approval system that is efficient, secure, and controllable.

b. Enhancing whole-chain intelligent regulatory capabilities. In the research and development stage, standardized governance of clinical trial data shall be continuously advanced. Supporting technical specifications, including technical guidelines for electronic clinical trial records and guidelines for computerized system validation, shall be studied and formulated, and the technical guideline system shall be further improved. Regulatory efficiency shall be enhanced through the use of large-scale clinical trial datasets.

In the manufacturing stage, the digital and intelligent regulatory mechanisms for high-risk products such as vaccines, blood products, and special medicinal products shall be continuously improved. A regulatory model combining on-site inspection with off-site supervision shall be refined. Intelligent risk-monitoring agents shall be developed and deployed, and dynamic monitoring of quality and safety risks in the production process shall be conducted based on real-time analytical results derived from enterprise data on production process monitoring videos, images, and IoT sensing information.

In the distribution and use stage, the digital and intelligent upgrading of the drug traceability system shall be promoted. Enterprises shall be further urged to fulfill their primary responsibilities for traceability, and platform enterprises shall be encouraged to enhance their technical support capabilities and service levels. Accelerated efforts shall be made to implement full-product coding for all marketed products, thereby enabling end-to-end traceability across production, distribution, and use.

Relying on the traceability coordination platform, accelerated efforts shall be made to establish a filing system for full-category traceability coding rules, and a multi-code correlation and mapping database shall be developed linking drug traceability codes, commodity barcodes,

and medical insurance codes. Full-process information-based traceability supervision of key product categories shall be strengthened, and trigger-based traceability supervision shall be further advanced. Technical guidelines for the typical application of the Unique Device Identification (UDI) system across manufacturing, distribution, and use shall be formulated for medical devices, and active exploration shall be undertaken to expand the application of UDI in whole-chain regulatory oversight.

c. Advancing the digital and intelligent upgrade of the risk supervision system. Efforts shall be undertaken to advance the digital and intelligent transformation of the risk supervision framework by enabling the multi-source aggregation of risk signals, as well as their intelligent analysis, tiered allocation, and end-to-end traceable tracking. Data-driven supervisory approaches shall be strengthened, and the risk consultation and response mechanism—encompassing monitoring and early warning, deliberation and assessment, directive issuance and implementation, and subsequent tracking and retrospective evaluation—shall be further refined.

Capabilities for risk perception, intelligent early warning, and coordinated response shall be enhanced with respect to key products, key enterprises, and critical links, so as to comprehensively improve the effectiveness of risk supervision. The in-depth implementation of "smart pharmaceutical inspection" initiatives shall be promoted, with a view to establishing an integrated and digitalized inspection system, improving inspection efficiency and accuracy, and enhancing the identification of risk signals. Exploration of the application of robotic technologies in inspection activities is encouraged.

The monitoring and evaluation system for "two products and one device" shall be upgraded and refined, promoting the digitalization and intelligentization of processes such as reporting, review and evaluation, intelligent analysis, risk early warning, and cross-level coordination, thereby improving the overall level of intelligent monitoring and evaluation. An intelligent system for the analysis and early warning of complaints and reports shall be established.

Coordinated efforts shall be made to upgrade the systems for monitoring safety risks in online sales and for public opinion monitoring relating to "two products and one device," improve operational mechanisms, and achieve comprehensive real-time monitoring, accurate assessment, scientifically grounded early warning, and effective handling.

The intelligent analysis of traceability data shall be strengthened, and models for risk screening and early warning based on traceability shall be developed, so as to enhance intelligent monitoring of circulation risks.

Efforts shall be intensified to integrate, govern, and analyze big data for full lifecycle supervision, focusing on high-risk products and key scenarios, developing intelligent risk supervision models in areas such as quality and safety, distribution anomalies, and online sales monitoring. The

development of intelligent agents for risk monitoring and assessment shall also be promoted, along with the creation of dynamic risk profiles for key products, enterprises, and critical links.

d. Advancing the intelligent and standardized development of inspection and enforcement. efforts shall be undertaken to advance the intelligent and standardized development of inspection and enforcement activities. The implementation of "smart inspection" initiatives shall be deepened through the integration and upgrading of inspection systems, and by establishing a centralized and intelligent comprehensive management platform for smart inspections.

Risk assessments shall be conducted on the basis of big data derived from product dossiers and credit records relating to "two products and one device." Inspection targets, frequency, and plans shall be determined in a scientific and proportionate manner according to risk classification, with a view to reducing duplicative inspections and enabling targeted, risk-based inspections.

Provincial-level medical products regulatory authorities are encouraged to establish unified systems for supervision, inspection, and enforcement case management, and to strengthen digital and intelligent support for supervisory inspections and enforcement activities conducted by municipal and county-level personnel in relation to "two products and one device."

The deeper application of artificial intelligence shall be promoted to support real-time access to information on regulated entities, real-time recording of supervisory processes, intelligent identification of risk indicators, and the automated generation of documentation and reports. Efforts shall be accelerated to standardize inspection and enforcement workflows, thereby enhancing the efficiency and consistency of on-site inspection and enforcement activities.

The development of mobile inspection and enforcement tools shall be strengthened, including the implementation of "scan-to-enter enterprise" mechanisms, enabling supervision and inspection to be conducted through mobile, on-the-go digital platforms.

e. Enhancing the effectiveness of coordinated supervision. Efforts shall be made to enhance the capacity for coordinated supervision across regions, administrative levels, and departments through the application of digital and intelligent technologies, with a focus on addressing prominent issues such as inadequately developed coordination mechanisms, inefficient workflow circulation, lack of information sharing, and difficulties in achieving closed-loop case handling.

Relying on the smart regulatory platform, a highly efficient, intelligent, and multi-stakeholder national integrated system for business coordination shall be developed. A list-based management mechanism for coordinated matters shall be established and improved, and standardized rules for workflow coordination and interface specifications shall be developed.

Focusing on key areas and critical links, including clinical trials, registration inspections, cross-provincial commissioned manufacturing, and supervision of centrally procured selected products, efforts shall be made to promote intelligent allocation, end-to-end traceability, and

closed-loop management of coordinated supervisory activities across administrative levels and regions.

Information sharing and operational coordination among regulatory departments shall be strengthened to promote integrated development and governance across the "three medical sectors". This shall provide robust support for joint inspections, case investigation and handling, criminal–administrative coordination, and clue-based enforcement, thereby improving overall coordination and supervisory effectiveness.

f. Enhancing the level of intelligent government services. Efforts shall be made to implement the requirement of continuously advancing the reform of "efficient completion of a single matter" on a routine basis, and to strengthen inter-departmental coordination and service integration. The development of "artificial intelligence + government services" shall be accelerated. A comprehensive policy and service knowledge base shall be established and improved by integrating data on laws and regulations, service guidelines, frequently asked questions, online consultations, user feedback, and historical processing records.

Policy requirements, policy tagging, and service delivery conditions shall be further refined, and algorithmic models shall be optimized. On this basis, enterprises and the public shall be provided with intelligent services including automated question answering, guided service navigation, intelligent pre-filling of forms, and assisted handling of procedures, thereby advancing the intelligent, precise, and user-friendly development of government services.

g. Promoting the coordinated digital and intelligent development of regulation and industry. In alignment with the requirements for intelligent supervision, industries shall be encouraged and guided to accelerate digital and intelligent transformation and upgrading, and to enhance the level of digitalization and intelligence across the entire lifecycle, including pharmaceutical research and development, manufacturing, quality inspection, and post-market surveillance and evaluation.

Efforts shall be accelerated to study and formulate guiding principles for the standardized application of artificial intelligence in the pharmaceutical industry, so as to adapt to the evolving needs arising from the application of new technologies.

The full-process digitalization and intelligentization of production and inspection activities for high-risk product categories such as blood products and traditional Chinese medicine injections shall be promoted. Supporting regulatory requirements shall be studied and developed, with gradual extension to other product categories, thereby guiding the industry to enhance its end-to-end quality control capabilities in accordance with applicable standards.

III. Grasp New Trends in Artificial Intelligence Development and Strengthen Foundational Support for "AI + Drug Regulation"

a. Advancing the construction of high-quality data sets for drug regulation. Adhere to the principle of "scenario-driven development with priority given to urgent needs," and, with reference to core business scenarios across the full life cycle of drug regulation as well as the practical requirements of artificial intelligence applications, advance the construction of high-quality data sets for drug regulation in a phased and step-by-step manner.

Further improve the nationally integrated drug regulatory data resource system, using national- and provincial-level data centers as hubs. On the basis of foundational resources such as product master files, enterprise credit dossiers, legal and regulatory databases, and repositories of typical cases, establish and refine a data aggregation and governance framework to enhance data accuracy, consistency, and usability, thereby providing fundamental support for the development of high-quality data sets.

Focusing on the training, fine-tuning, and implementation of vertical large-scale models for drug regulation, define data format, quality, and content requirements according to specific application scenarios. Formulate scientifically standardized data collection protocols and annotation guidelines. Carry out multi-source data fusion governance, specialized annotation, and knowledge extraction, and construct both general-purpose and domain-specific knowledge bases for drug regulation. In doing so, establish a high-quality data set system that is stratified, categorized, dynamically updated, and traceable throughout its full life cycle.

Subject to strict safeguards for security and privacy, the knowledge bases and high-quality data sets shall be orderly and lawfully utilized in scenarios such as model training, knowledge reasoning, and decision-support assistance, ensuring compliant and efficient application.

b. Strengthening the supporting system for artificial intelligence applications. Adhere to a business-oriented approach and comprehensively advance the training, deployment, and application of large-scale models in the field of drug regulation.

Relying on existing intelligent regulatory infrastructure, establish a platform for large-model application and algorithm management, formulate guidelines for model application and relevant security standards, and promote the co-construction and shared use of common technical components. Enhance capabilities in model and algorithm management, and facilitate technological interoperability, resource sharing, and ecosystem coordination.

Promote the deep integration of artificial intelligence with existing business information systems, and accelerate the large-scale implementation of AI-assisted regulatory scenarios. Centered on the full life cycle of drug regulation, establish a multi-agent collaborative mechanism, improve system integration and business coordination frameworks, and advance the intelligent upgrading of drug regulatory capabilities.

c. Strengthening the construction of computing infrastructure. The National Medical Products Administration shall make overall plans for a multi-tier collaborative system of intelligent computing resources. Regulatory authorities at both the national and provincial levels shall, in accordance with actual needs, advance the provision of intelligent computing resources. A standardized and scalable intelligent computing infrastructure shall be developed to meet the requirements of intelligent applications across different network domains, including the public internet, government extranet, and government intranet. Efforts shall be made to enhance cross-domain coordination and disaster recovery capabilities, and to gradually establish a deployment framework characterized by "joint construction, joint governance, and shared utilization." This will strengthen computing support capacity and provide continuous and stable assurance for the intelligent transformation of regulatory systems.

d. Strengthening the security protection system. Strictly implement the responsibility system for security, upgrade the cybersecurity protection framework, and improve mechanisms for cybersecurity situational awareness, information sharing, joint analysis and assessment, threat early warning, and traceability. Leverage artificial intelligence technologies to enhance proactive cybersecurity defense capabilities, and establish an intelligent and coordinated protection system.

Establish and improve a comprehensive data security management system, clearly define lists of core and important data, and refine the technical framework for data security protection. Strengthen risk monitoring and evaluation for artificial intelligence, formulate requirements for algorithm transparency and standards for model validation, and enhance security capabilities across model algorithms, data resources, infrastructure, and application systems.

Reinforce risk assessment, monitoring, and response mechanisms for AI applications, prevent classified and sensitive information from being input into non-classified models, and promote the compliant, transparent, and trustworthy use of artificial intelligence.

e. Improving the construction and operational management mechanism. Adhere to the auxiliary positioning of artificial intelligence within the field of pharmaceutical regulation, clearly defining the functional boundaries and responsible entities of large models and various intelligent auxiliary applications, and preventing practices such as deployment without prior review, fragmented development, and redundant construction. Establish a dedicated mechanism responsible for the governance of artificial intelligence applications in pharmaceutical regulation, coordinating model development access, security review, and scenario-based compliance review, and formulating a management framework for "Artificial Intelligence + Pharmaceutical Regulation" that delineates duties and operational standards.

Improve the filing and registration system for models and algorithms by formulating fundamental principles and technical specifications, and conduct effectiveness and reliability verification and evaluation of models and their auxiliary applications. Strengthen the management of data resources, including training data, fine-tuning data, and knowledge bases, ensuring lawful sourcing, accurate content, compliant use, and full-process traceability. Explore the authorized operation of public data in pharmaceutical regulation, establish dedicated public data zones, and promote domain-specific and scenario-based authorization to enhance the development and utilization of pharmaceutical regulatory public data.

IV. Organization and Implementation

Pharmaceutical regulatory authorities at all levels shall fully recognize the new development trends of artificial intelligence and regard it as an important lever for supporting the comprehensive deepening of pharmaceutical regulatory reform, as well as a strong foundation for enhancing regulatory capacity. Relevant planning arrangements shall be coordinated and properly aligned, investment shall be increased, and the application of artificial intelligence in frontline regulatory work shall be actively promoted. Efforts shall be made to promote development through application and to integrate development with application, so as to ensure the effective implementation and practical impact of artificial intelligence in regulatory practice.

Authorities shall strengthen demonstration and leading initiatives, focusing on key difficulties and bottlenecks in regulatory operations, and deepen innovative applications of intelligent regulation to effectively empower business innovation. Regulatory scientific research support for “Artificial Intelligence + Pharmaceutical Regulation” shall be reinforced, promoting the implementation and transformation of major scientific and technological projects.Training efforts shall be intensified to enhance the digital thinking, digital skills, and digital literacy of the regulatory workforce.

National Medical Products Administration

March 11, 2026