Announcement of the National Medical Products Administration on Further Strengthening Digital Drug Traceability Management[1]

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In accordance with the Drug Administration Law of the People's Republic of China and the Regulations for the Implementation of the Drug Administration Law of the People's Republic of China, the National Medical Products Administration has advanced digital drug traceability in a steady and orderly manner, established and improved the digital drug traceability framework, and formulated and issued traceability standards and specifications. The basic infrastructure has largely been established, the system of technical standards has been continuously improved, and a framework for joint development and sharing has taken shape under government guidance, with enterprises taking the lead and multiple stakeholders participating.

To ensure that drug marketing authorisation holders (hereinafter referred to as "holders"), domestic responsible persons designated by overseas drug marketing authorisation holders (hereinafter referred to as "domestic responsible persons"), manufacturers, distributors and entities using drugs further improve digital drug traceability management, fulfil their statutory obligations and continuously enhance the effectiveness of digital drug traceability, thereby safeguarding public medication safety, the following matters concerning further improvements to digital traceability management across all drug products and the entire supply chain are hereby announced:

I. Continuously Strengthening Digital Drug Traceability Management

In accordance with the Drug Administration Law of the People's Republic of China and its Implementing Regulations, the responsibilities of holders, domestic responsible persons, manufacturers, distributors, entities using drugs, traceability system operators and other relevant parties shall be fully implemented. Codes shall be assigned to all drug products subject to coding requirements, and codes shall be scanned throughout the supply chain wherever scanning is required.

1. Strengthening the management of traceability code filing. Holders and domestic responsible persons shall, in accordance with the Guidelines for the Development of Drug Information Traceability Systems, access the National Drug Traceability Collaborative Service Platform through the NMPA government services portal and file information relating to drug identification codes in a timely, accurate and complete manner. They shall establish links between drug identification codes, commodity barcodes, national drug identification codes, medical insurance codes and

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other relevant codes. Traceability code issuing bodies and traceability system operators shall register with the National Drug Traceability Collaborative Service Platform to ensure the uniqueness of traceability codes.

2. Standardising code assignment during manufacturing. Holders, domestic responsible persons and manufacturers shall discharge their primary responsibility for drug traceability. Following the principles of "one item, one code" and "tracking the physical item together with its code", they shall, before products are placed on the market, complete the assignment and activation of traceability codes for all products currently manufactured (excluding active pharmaceutical ingredients, medical oxygen and preparations made by medical institutions; traceability requirements for prepared slices of Chinese crude drugs shall be formulated separately; the same exclusions apply below), link traceability codes across all levels of sales packaging, and upload traceability information promptly and accurately. They shall ensure that codes are assigned in a standardised manner to sales packaging units at every level and that the links between those codes are accurate, so that products can be traced and verified.

Holders, domestic responsible persons and manufacturers shall retain receipt information in the traceability system when finished products enter storage. When products are dispatched for sale, they shall provide the relevant traceability information through the system to downstream enterprises or entities using drugs, enabling those recipients to verify the information and provide feedback. They shall promptly address traceability code anomalies reported by downstream parties and ensure that traceability information is authentic and reliable.

3. Strengthening scanning requirements in distribution and use. Digital drug traceability management is an integral part of the quality management systems of drug distributors. Drug distributors and entities using drugs shall cooperate with holders, domestic responsible persons and manufacturers in developing traceability systems and shall upload the corresponding traceability information to those systems. When accepting drugs into storage, drug wholesalers shall obtain the relevant traceability information from upstream enterprises through the traceability system, verify traceability codes, make scanning and verification a mandatory part of receipt and acceptance procedures, and provide receipt information to upstream enterprises. When conducting dispatch verification for drugs sold, they shall provide the relevant traceability information through the system to downstream enterprises or medical institutions.

Drug retailers and entities using drugs shall verify traceability codes with upstream enterprises when accepting drugs into storage and provide receipt information to those enterprises. When selling drugs, they shall retain detailed sales records and promptly upload sales information through the traceability system at the time of sale. Sales receipts shall display traceability code information or provide another convenient means for consumers to access the relevant drug information themselves. Where the traceability system generates an anomaly alert, receipt into storage and sales shall cease immediately, and the anomaly shall be investigated and addressed. The findings and corresponding measures shall be reviewed and signed off by the person

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responsible for quality before those measures are implemented. Relevant records shall be retained in accordance with the requirements governing quality management in drug distribution.

Drug distributors and entities using drugs shall refuse receipt where, during receipt and acceptance procedures, traceability information indicates that the drugs have already been sold by a drug retailer or an entity using drugs.

4. Continuously improving traceability system operation and service capabilities. Traceability system operators shall maintain a public-interest orientation, continuously improve the development and operation of their systems, meet digital drug traceability management requirements, and ensure the security of traceability data. As required by drug regulatory authorities, they shall provide traceability information relating to holders, domestic responsible persons, manufacturers, distributors and entities using drugs in a timely and accurate manner, and actively cooperate in regulatory inspections, case investigations and the management of drug quality risks.

Traceability system operators shall provide drug recall support services to holders and domestic responsible persons to facilitate rapid recalls. They shall cooperate with holders and domestic responsible persons in improving system functions and provide the necessary access rights to enable them to monitor drug movements. They shall provide drug wholesalers, retailers and entities using drugs with real-time traceability anomaly alerts during receipt and acceptance procedures, including alerts for drugs already sold to terminal outlets and for abnormal traceability code status.

Traceability system operators shall, in accordance with the Data Security Law of the People's Republic of China and other applicable laws and regulations, establish and improve data security management systems, discharge their data security responsibilities and safeguard drug traceability data. They shall improve rules governing data security and use. Data contained in drug traceability information that may involve personal privacy, trade secrets or other confidential matters shall be kept confidential in accordance with the law and shall not be disclosed or unlawfully provided to others.

II. Comprehensively Enhancing Digitalisation

1. Holders, domestic responsible persons, manufacturers, distributors, entities using drugs and traceability system operators shall effectively discharge their drug traceability responsibilities, strictly comply with applicable drug administration laws, regulations and technical standards, and establish and improve digital drug traceability management systems. Traceability data shall be collected, stored and uploaded in strict accordance with the relevant standards and specifications to ensure that the data are timely, accurate and complete. Tampering with or falsifying traceability data is strictly prohibited. The relevant parties shall submit to regulatory inspections by drug regulatory authorities, immediately investigate and promptly rectify traceability anomalies notified by those authorities, and continuously improve traceability throughout the drug supply chain.

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2. Holders and domestic responsible persons shall proactively establish and continuously improve drug traceability systems. They shall use those systems to collect traceability information covering all drug products and the entire supply chain and obtain timely information on traceability throughout the distribution process. Manufacturers, distributors and entities using drugs shall cooperate with holders and domestic responsible persons in establishing traceability arrangements, provide traceability information, and proactively upload it to the relevant systems.

III. Comprehensively Strengthening Supervision and Administration

Provincial drug regulatory authorities shall further align their understanding, strengthen organisational leadership, establish and improve working mechanisms, maintain coordination between healthcare services, medical insurance and pharmaceuticals, eliminate potential risks, promote orderly distribution practices, and adopt coordinated measures to advance the development of digital drug traceability systems.

Drug regulatory authorities at all levels shall ensure that relevant enterprises and entities within their jurisdictions assign and activate codes for all products subject to coding requirements and scan and upload information throughout the supply chain wherever required. Implementation of traceability requirements by enterprises shall be included in routine inspections. Failure to comply with statutory provisions or traceability requirements shall be dealt with strictly in accordance with the Drug Administration Law of the People's Republic of China, the Measures for the Supervision and Administration of Drug Quality in Distribution and Use, Good Supply Practice for Pharmaceutical Products and other applicable laws and regulations. Regulatory authorities shall make full use of drug traceability data to improve the quality and effectiveness of supervision and enhance their capacity to identify and address drug safety risks. They shall strengthen policy communication and organise awareness-raising and training activities to improve understanding among relevant enterprises and entities of the importance of drug traceability systems, ensuring continued improvement in traceability across all drug products and the entire supply chain.

National Medical Products Administration

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