附件 1

# NMPAB

# 国家药品监管信息化标准

NMPAB/T XXXX.X—201X

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Text of the
**China National Drug Regulatory Information Standard**
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Attachment 1

# NMPAB

## National Drug Regulatory Information Standard

NMPAB/T XXXX.X—201X

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## Guidelines for the Construction of Drug Information Traceability System

Drug traceability information system construction guidelines

201X-XX-XX Release 201X-XX-XX Implementation

Issued by the State Drug Administration

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# Foreword

This standard is drafted in accordance with the rules given in GB/T 1.1-2009.

This standard was proposed by XXXX.

This standard is under the jurisdiction of XXXX.

This standard was drafted by:

The main drafters of this standard:

# Guidelines for the Construction of Drug Information and Traceability System

## 1 Scope

This standard stipulates the basic requirements for the construction of various systems in the drug information traceability system and the basic requirements for the participants of the drug information traceability system.

This standard is applicable to traceability participants such as drug listing license holders (including pharmaceutical manufacturing enterprises holding drug approval number), drug management enterprises, drug users and drug regulatory authorities to jointly establish a drug information traceability system.

## 2 Terms and definitions

### 2.1 drug information traceability system

It is a traceability system related to the quality and safety of drugs, such as drug-licensing license holders (including drug manufacturers that hold drug approval documents), drug-operated enterprises, users, drug regulatory authorities, and consumers. The organic whole of tracking and traceability of information on all aspects of drug production, distribution, and use.

### 2.2 Drug traceability collaborative service platform

It is an information service platform for realizing the interconnection and intercommunication of drug information systems. It can provide access address analysis of different drug traceability systems, filing and management of drug traceability code coding rules, and services such as drug and enterprise basic data distribution.

### 2.3 Drug traceability code

A code that consists of a series of numbers, letters, and symbols that uniquely identifies a drug sales package unit.

## 3 Basic requirements for system construction of drug information traceability system

The basic composition of the drug information traceability system (shown in Figure 1) includes the drug traceability system, the drug traceability collaborative service platform (hereinafter referred to as the collaborative platform) and the drug traceability supervision system.

The above various types of systems (platforms) construction requirements are as follows:

1) The drug traceability system is divided into two categories: the enterprise self-built traceability system and the drug traceability system provided by the third-party organization. All of them should include the functions of collecting, storing and sharing the traceability information of the drug during production, circulation and use.

2) The collaborative platform shall include an enterprise collaboration module and a supervisory collaboration module to provide collaborative services for the enterprise traceability system and the supervisory traceability system respectively; for the

repetition of the drug traceability code, the collaborative platform shall include the filing service of the traceability code encoding rules.

3) The provincial traceability supervision system should include enterprise traceability data acquisition, data statistics, data analysis, intelligent early warning, recall management, information release, and the function of exchanging data with the national traceability supervision system.

4) The national-level traceability supervision system should include functions such as traceability data acquisition, data statistics, data analysis, intelligent early warning, recall management, and big data application.

5) The data exchange between the drug traceability system, the collaborative platform, the provincial traceability supervision system, and the national traceability supervision system shall comply with the data exchange technical standards formulated by the State Drug Administration.

6) System construction security requirements:
    a. User security access - should provide the user's identity registration, verification and unified management functions; should provide user authentication, rights management and access control functions.

    b. Data security transmission—The acquisition interface shall provide an access verification mechanism to ensure the validity of data added to the platform or system; privacy protection and tamper-proof functions during data transmission shall be provided.

    c. Data security storage - should provide confidentiality, integrity protection and validity verification methods for data storage, prevent data leakage, prevent unauthorized users from illegally obtaining data, and prevent users from illegally modifying valid data that has been verified in the platform. Or delete; data backup and disaster recovery mechanism should be established to back up data regularly.

    d. System security management - should provide log and security event management and analysis functions, statistics of security events, and can quickly query the system and statistical analysis system logs and events according to different conditions.

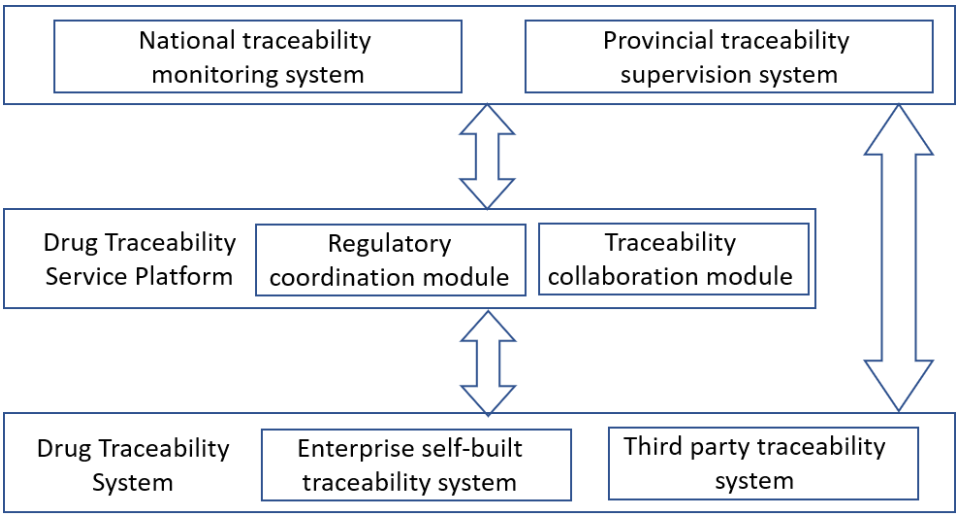


Figure 1 Basic composition of drug information traceability system

## 4 Basic requirements for participants in the drug information traceability system

The main participants of the drug information traceability system include: drug listing license holders, drug business enterprises, drug use units, regulatory authorities and social participants. All participants shall actively participate in the construction and maintenance of the drug information and traceability system in accordance with the corresponding standards and requirements.

1) Drug listed license holders, pharmaceutical companies, and drug users:
    a. The drug marketing permit holder shall assign a unique drug traceability code to the sales packaging unit at all levels of the drug production. The drug traceability code shall comply with the requirements of the Drug Traceability Code Coding Requirements.

    b. The drug marketing permit holder shall record the relevant activities in accordance with the requirements of the quality management regulations; the records shall be true, accurate, complete, tamper-proof and traceable; when selling drugs, relevant traceability information shall be provided to downstream enterprises or medical institutions. In order to verify feedback from downstream companies or medical institutions.

    c. The drug marketing permit holder may self-built the drug traceability system, or may use the traceability system provided by the third-party technical organization; it shall be able to obtain the information on the whole process of circulation and use of the produced drugs in a timely and accurate manner, and shall follow the supervision It is required to provide relevant data to the regulatory authorities; the drug traceability system should be used to provide

the public with traceability information for the drug, and the content of the inquiry should be in line with the Basic Data Set for Drug Traceability Public Query Information.

d. Pharmaceutical enterprises and drug users should obtain relevant traceability information from upstream enterprises when purchasing drugs, and should check the above information at the time of drug acceptance; when selling drugs, the sales record details should be kept and should be updated in time. The status indicator of the drug; the drug traceability system should be constructed in conjunction with the drug marketing license holder, and the relevant traceability information should be uploaded to the corresponding drug traceability system.

e. Drug listing license holders, drug trading enterprises and drug users should record the drug traceability data in a timely, true, accurate and complete manner and keep relevant documents. The traceable data fields should be consistent with the “Drug Master Dataset for Drug Listing Licensors”. , "Drug management enterprise traceability basic data set" and "drug use unit drug traceability basic data set" provisions. The drug traceability information record and the voucher storage period shall not be less than five years after the drug expires, and the records of the vaccine and specially managed drugs shall be kept in accordance with relevant regulations.

2) Drug regulatory authorities:

a. The national drug regulatory department shall establish a collaborative platform to provide access address analysis of different drug traceability systems, filing and management of drug traceability code coding rules, and services such as drug and enterprise basic data distribution to provide support for drug traceability system interconnection.

b. The national drug regulatory authority shall establish a national-level retrospective monitoring system to collect and trace relevant data and conduct a summary analysis.

c. The provincial-level drug regulatory department shall establish a provincial-level traceability supervision system, and collect traceability information of drug-licensing license holders, drug-operated enterprises and drug-using units in their administrative areas on-demand for each drug traceability system. Statistics and summary of the implementation of construction requirements, and give full play to the role of retroactive information in the supervision of risk prevention and control, emergency response.

3) Social participants:
   Information technology companies, industry associations, etc. can provide professional services for drug traceability as a third party. Relevant coding organizations (including third-party coding organizations, third-party traceability systems, enterprise self-built traceability systems, etc.) should ensure that the traceability codes of the drugs issued are unique and cannot be repeated and cannot be reused.

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