CFDAB/T 0301.3—2014

附件 2

NMPAB

国家药品监管信息化标准

NMPAB/T XXXX.X—201X

Text of the

China Drug Traceability Code Coding Requirements

as translated by Google Translate

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August 24, 2018

Attachment 2

NMPAB

National Drug Regulatory Information Standard

NMPAB/T XXXX.X—201X

Drug Traceability Code Coding Requirements

General rules for drug traceability code

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:

Drug Traceability Code Coding Requirements

1 Scope

This standard specifies the terms and definitions of the drug traceability code, the coding principle, the coding object and the traceability of the drug.

This standard applies to drug marketing license holders (including drug manufacturers that hold drug approval number), drug business enterprises and drug users to select or use codes that conform to this standard for drugs sold and used in China.

2 Normative references

The following documents are indispensable for the application of this document. For dated references, only the dated version applies to this document. For undated references, the latest edition (including all amendments) applies to this document.

GB/T 7027 basic principles and methods of information classification and coding

GB/T 10113 classification and coding general terminology

3 Terms and Definitions

3.1 Drug traceability code drug traceability code

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

3.2 drug marketing license holder drug marketing authorization holder

Refers to the pharmaceutical company, research and development institution or scientific researcher who holds the document for the listing of the drug.

4 Coding Principles

4.1 Practicality

The drug traceability code must not only ensure its scientific and reasonable, but also meet the needs of drug traceability business.

4.2 Uniqueness

The drug traceability code shall be uniquely marked on the sales packaging unit at all levels of the drug according to the traceability requirements to ensure “one object, one code ”. Drug traceability codes are not repeatable and cannot be reused.

4.3 Security

The drug traceability code should ensure that it is not easily counterfeited.

4.4 expandability

The drug traceability code should be able to expand capacity according to the actual use requirements without changing the coding rules.

4.5 Conciseness

The code structure should be as simple as possible, and the code length should be as short as possible to save equipment storage space and reduce the error rate of automatic code recognition.

4.6 Universality

The drug traceability code shall be designed based on the coding rules widely used by the drug listing permit holder (including the drug manufacturer holding the drug approval number), the drug wholesale and retail enterprise, and the drug use unit, and fully consider the upstream and downstream related to it. enterprise, Technical requirements for third-party or regulatory information system docking to avoid code conflicts and repetitive investments.

5 Coding Object

The coding object is a sales packaging unit at all levels of the medicine. The holder of the drug marketing license (including the pharmaceutical manufacturer holding the drug approval number) shall be coded according to the specific coding rules that the coding object selects to meet the requirements of this standard.

6 Drug Traceability Code Requirements

The composition of the drug traceability code should meet the following requirements:

1) The drug traceability code can be composed of numbers, letters and symbols, and the code length should be no less than 10 characters;

2) The drug traceability code should be associated with the name of the drug listing license holder, the name of the drug manufacturer, the generic name of the drug, the drug approval number, the drug standard code, the dosage form, the formulation specification, the packaging specification, the date of manufacture, the batch, the expiration date and the order. Product sequence and other data;

3) The drug traceability code should include the serial number code segment of the product;

4) The drug traceability code should include a check digit to verify the correctness of the drug traceability code.