ICS 35.240.60
CCS L 67

NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

GB/T 26840-2025

Replacing GB/T 26840-2011

Electronic commerce - Core metadata for medicine

电子商务 药品核心元数据

Issued on: August 29, 2025 **Implemented on: March 1, 2026**

Issued by: State Administration for Market Regulation;
Standardization Administration of the PRC

Table of Contents

Preface III
1 Scope 1
2 Normative References 1
3 Terms and Definitions 1
4 Abbreviations 2
5 Metadata Attributes 2
5.1 Overview 2
5.2 Chinese Name 2
5.3 English Name 2
5.4 Mark 2
5.5 Definition 2
5.6 Data Types 2
5.7 Value Range 3
5.8 Constraints/Conditions 3
5.9 Maximum number of occurrences 3
6 Metadata Description Methods 3
6.1 UML Diagram Description 3
6.2 Dictionary Description 5
7 Principles and Methods of Metadata Extension 16
7.1 Metadata Extension Types and Principles 16
7.2 Metadata Extension Methods 16
References 20

Foreword

This document complies with the provisions of GB/T 1.1-2020 "Standardization Work Guidelines Part 1: Structure and Drafting Rules of Standardization Documents". Drafting.

This document replaces GB/T 26840-2011 "Core Metadata for Pharmaceuticals in E-commerce". Compared with GB/T 26840-2011, except for the following.

Aside from structural adjustments and editorial changes, the main technical changes are as follows.

a) The definition of the term "pharmaceutical" has been changed (see 3.1, 2011 edition);

b) The content of the "UML Diagram Description" has been changed (see 6.1, Chapter 7 of the 2011 edition);

c) Modified the metadata elements "Drug Identifier", "Generic Name", "Trade Name", "English Name", "Pinyin", and "Approval Number".

"OTC Category", "Specifications", "Ingredients", "Properties", "Indications", "Dosage and Administration", "Adverse Reactions", "Contraindications", "Precautions", "Storage" "Expiration Date", "Implementation Standard", "Production Date", "Production Batch Number", "Expiration Date", "Manufacturer Name", "Manufacturer License Number" The names and definitions of "legal representative (person in charge)" and "business license number" are as follows (see 6.2, Chapter 8 of the 2011 edition);

d) Modified metadata elements "Pharmaceutical Product Registration Certificate Number", "Dosage Form", "Production Address", and "Internet Drug Information Service Qualification Certificate Number".

e) Change "State Food and Drug Administration" to "relevant regulatory authorities" (see 6.2, Chapter 8 of the 2011 edition);

f) A metadata entity "Listing License Holder Information" has been added (see 6.2);

g) Added metadata elements "traceability code", "website address", and "unified social credit code" (see 6.2);

h) The names, definitions, and value ranges of the metadata elements "Approval Number" and "Import Registration Certificate Number" have been changed (see 6.2, pp. 8 in the 2011 edition). chapter);

i) The metadata elements "Organization Code", "GMP Certificate Number", and "GSP Certificate Number" have been removed (see Chapter 8 of the 2011 edition);

j) The "Drug Core Metadata XML Schema" has been removed (see Appendix A of the 2011 edition);

k) The "Example of Drug Core Metadata" has been removed (see Appendix B of the 2011 edition).

Please note that some content in this document may involve patents. The issuing organization of this document assumes no responsibility for identifying patents.

This document was proposed and is under the jurisdiction of the National Electronic Business Standardization Technical Committee (SAC/TC83).

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The release history of this document and the document it replaces is as follows.

- First published in 2011 as GB/T 26840-2011;

- This is the first revision.

1 Scope

This document specifies the attributes, description methods, and extension principles and methods for core metadata of pharmaceuticals in e-commerce transactions.

This document applies to the description, coding, database creation, and publication of basic drug information in e-commerce transactions.

2 Normative references

GB/T 7408.1

GB/T 12406

GB/T 17295

GB/T 24662-2009

GB 32100

IEC 19501

ISO 24156

3 Terms and Definitions

The terms and definitions defined in GB/T 24662-2009, as well as the following terms and definitions, apply to this document.

3.1 medicine

Used for the prevention, treatment, and diagnosis of human diseases, and for the purposeful regulation of human physiological functions, with specified indications or therapeutic functions, usage, and... Dosage of the substance.

Note 1.Medicines include traditional Chinese medicine, chemical drugs, and biological products.

Note 2.The drugs mentioned in this document do not include Chinese medicinal herbs, prepared slices of Chinese medicinal herbs, and chemical raw materials.

[Source. Article 2 of the Drug Administration Law of the People's Republic of China, with modifications]

3.2

The basic set of metadata items describing drug data.