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Traditional Chinese medicine — Coding rules for Chinese medicines in supply chain management

Médecine traditionnelle chinoise — Règles de codage des médecines chinoises dans la gestion de la chaîne logistique

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 249, *Traditional Chinese medicine*.

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Introduction

The popularity of medicinal products derived from natural materials, particularly herbal materials, is increasing rapidly. For example, the international market for medicines used in traditional Chinese medicine (TCM) was valued at USD 16 billion and is increasing at a rate of 10 % to 20 % per year.

Most goods traded internationally use bar coding to monitor the movement and use of the products. For example, even pencils and erasers have bar codes which permit their individual identification. However, this does not currently apply to medicines used in TCM. While at least 70 countries now have administrative systems in place to regulate TCM, the lack of bar coding is a barrier to the increasing trade and to ensuring the identity and quality of ingredients and products for the well-being of communities.

This document introduces a bar coding for TCM which is consistent with existing standards. It also provides a basis for similar coding systems for the products of related traditional health systems.

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Traditional Chinese medicine — Coding rules for Chinese medicines in supply chain management

1 Scope

This document specifies coding rules for Chinese medicines to assist in supply chain management. The coding provides information such as the trade item, producing area, unit, grade, production date, batch number, quantity of medicines, and logistic unit. This includes Chinese Materia Medica and decoction pieces, but excludes granule forms of individual medicinals for prescriptions (GFIMP) and Chinese patent medicines (CPM).

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO/IEC 15416, *Information technology — Automatic identification and data capture techniques — Bar code print quality test specification — Linear symbols*

ISO/IEC 15418, *Information technology — Automatic identification and data capture techniques — GS1 Application Identifiers and ASC MH10 Data Identifiers and maintenance*

ISO/IEC 15420, *Information technology — Automatic identification and data capture techniques — EAN/UPC bar code symbology specification*

ISO/IEC 15438, *Information technology — Automatic identification and data capture techniques — PDF417 bar code symbology specification*

ISO/IEC 16022, *Information technology — Automatic identification and data capture techniques — Data Matrix bar code symbology specification*

ISO/IEC 18000-6, *Information technology — Radio frequency identification for item management — Part 6: Parameters for air interface communications at 860 MHz to 960 MHz General*

ISO/IEC 18004, *Information technology — Automatic identification and data capture techniques — QR Code bar code symbology specification*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at http://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3.1
Chinese medicine
substance or combination of substances used under the guidance of traditional Chinese medicine (TCM) theory for medical care and the prevention and treatment of disease

Note 1 to entry: This includes Chinese Materia Medica, decoction pieces, granule forms of individual medicinals for prescriptions (GFIMP), and Chinese patent medicines (CPM).

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[SOURCE: ISO 18668-1:2016, 3.1]

3.2
supply chain
linked set of resources and processes that begins with the sourcing of raw material and extends through the delivery of products or services to the end user across the modes of transport

Note 1 to entry: The supply chain may include vendors, manufacturing facilities, logistics providers, internal distribution centres, distributors, wholesalers and other entities that lead to the end user.

[SOURCE: ISO 28000:2007, 3.9]

3.3
supply chain management
management primarily concerned with the efficient integration of suppliers, factories, warehouses and stores so that the merchandise is produced and distributed in the right quantities, to the right locations and at the right time, and so as to minimize total system cost subject to satisfying service level requirements

3.4
global location number
GLN
GS1 identification key used to identify physical locations or parties

Note 1 to entry: The key comprises a GS1 Company Prefix, Location Reference, and Check Digit.

[SOURCE: GS1 General Specifications, modified]

3.5
application identifier
AI
numeric prefixes describing the meaning, structure, and function of the GS1 element strings so they can be correctly processed in users' application programs.

[SOURCE: GS1 General Specifications, modified]

3.6
serial shipping container code
SSCC
GS1 identification key used to identify logistics units

Note 1 to entry: The key comprises an Extension Digit, the GS1 Company Prefix, Serial Reference, and Check Digit.

[SOURCE: GS1 General Specifications, modified]

4 Coding principles

4.1 Uniqueness

Each kind of Chinese medicines corresponds to a unique code.

4.2 Compatibility

The coding rules are consistent with relevant existing International Standards.

4.3 Stability

The code for each Chinese medicine remains unchanged once assigned, as long as the basic characteristic of the medicinal does not change. Even if some Chinese medicines are discontinued for production and use, their codes should still be kept.

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