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## Traditional Chinese medicine — Labelling requirements of products intended for oral or topical use

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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 <a href="www.iso.org/directives">www.iso.org/directives</a>).

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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 ./TC 249, URL: www.iso.org/iso/foreword.html.

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

# Traditional Chinese medicine — Labelling requirements of products intended for oral or topical use

### 1 Scope

This document specifies general requirements for the labelling of products intended for oral or topical use in and as traditional Chinese medicine (TCM).

It is applicable to all finished manufactured products including packaged herbs used in and as TCM. This document includes the essential and informative elements for labelling of products to assist in the choice and safe use of these products by consumers and practitioners.

NOTE A list of TCM labelling requirements of the WHO and various regions and countries is given in Annex A.

#### 2 Normative references

There are no normative references in this document.

#### 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 <a href="https://www.iso.org/obp">https://www.iso.org/obp</a>
- IEC Electropedia: available at <a href="http://www.electropedia.org/">http://www.electropedia.org/</a>

#### 3.1

#### label

tag, brand, mark, pictorial or other descriptive matter, written, printed, stencilled, marked, embossed or impressed on, or attached to the packaging or container of a *finished manufactured product* (3.4)

#### 3.2

#### labelling

words, particulars, trademarks, brand name, pictorial matter or symbol relating to a product and placed on any packaging, document, notice or *label* (3.1) accompanying or referring to a *finished manufactured* product (3.4)

#### 3.3

#### packaged herb

herbs pre-packaged and delivered to consumers or practitioners with *labelling* (3.2) that can be used for traditional Chinese medicine with simple processing such as decoction or ingestion as tea, etc.

#### 3.4

#### finished manufactured product

finished product used by consumers or practitioners for oral and topical use in and as traditional Chinese medicine without further processing

Note 1 to entry: Packaged herb is also included in this term.

#### 3.5

#### expiry date

<finished manufactured product> date (month and year) after which the product should not be used