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

Médecine traditionnelle chinoise — Exigences d'étiquetage des produits destinés à un usage oral ou topique

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Foreword

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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 https://www.iso.org/obp

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

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

3.6
active ingredient
therapeutically-active herb or other natural material in a *finished manufactured product* (3.4) that is responsible for its physiological or pharmacological action

Note 1 to entry: In the case of "liquorice (*Glycyrrhiza uralensis*) root extract" or "Ephedra Decoction" extract, the chemical compound in the herb such as "glycyrrhizin" or "ephedrine" is not an active ingredient as defined in this document.

3.7
extract
substance obtained by using suitable solvent(s) for raw material(s)

Note 1 to entry: It includes concentrated, dried, viscous or fluid substance.

3.8
excipient
ingredient of the *finished manufactured product* (3.4) other than the *active ingredient* (3.6)

3.9
batch
specific quantity of a product that is uniform, is intended to meet specifications for identity, purity, strength and composition, and is produced to a single manufactured record during the same cycle of manufacturer from which it is possible to trace that batch through all stages of manufacture and distribution

3.10
lot
batch (3.9), or a specific identified portion of a batch, that is uniform and is intended to meet specifications for identity, purity, strength and composition; or, in the case of a product produced by continuous process, a specific identified amount produced in a specified unit of time or quantity in a manner that is uniform and that is intended to meet specifications for identity, purity, strength and composition

3.11
batch number prefix
prefix that precedes the *batch* (3.9) number and has the following characteristics:

a) clearly indicates that the information following the prefix is the batch number;

b) is in the following form: "BATCH NUMBER", "BATCH NO.", "BATCH", "B", "(B)", "B/N", or words or symbols to this effect, including a mixture of lower and upper case letters

3.12
lot number prefix
prefix that precedes the *lot* (3.10) number and has the following characteristics:

a) clearly indicates that the information following the prefix is the lot number;

b) is in the following form: "LOT NUMBER", "LOT NO.", or "LOT", or words or symbols to this effect, including a mixture of lower and upper case letters

4 Labelling information

4.1 General

On the outer package of products, the essential information given in 4.2 and 4.3 shall be stated. This information shall be visible and legible to the consumer without opening the package. Optional information is given in 4.4.

4.2 Labelling elements for both packaged herbs and finished manufactured products

4.2.1 Product name

This is the brand name of the product.

4.2.2 Category of the product in the marketed country or region

This is the category of the product as defined by the country or region in which the product will be sold. For example, pharmaceutical agent, supplement (dietary/food/health supplement, etc.) or food. The category shall not be that of the exported/manufactured country or region.

4.2.3 Net weight/quantity

This is the net quantity of the product, which shall be expressed using litres, centilitres, millilitres, kilograms or grams, as appropriate:

a) in units of mass or volume in the case of liquid products;

b) in units of mass in the case of other products.

4.2.4 Contact information

This is the name, address (not a post office box address) and telephone number of the distributor and/or importer, which facilitate inquiries about the product information and reports of adverse events. Where there has been a change in the distributor's and/or importer's name or contact details in the previous 12 months, the name and contact details of the previous distributor and/or importer shall be provided.

4.2.5 Name of raw materials

this is the Latin name (scientific name) and its part of use, e.g. root of *Glycyrrhiza uralensis* Fisher. Common herbal names such as liquorice or Glycyrrhizae Radix may be written with the Latin name, i.e. liquorice (*Glycyrrhiza uralensis*) root. The author name in the Latin name such as "Fisher" may be omitted.

4.2.6 Warning statements, if any

These are any applicable warning statements, e.g. for children, pregnant women or patients.

4.2.7 Expiry date

The expiry date shall be legible without opening the package and shall be written based on a stability test or estimation having scientific rationale. The manufacturer/distributor is responsible for performing the stability test and for the expiry date.

4.2.8 Storage method

This gives any special storage conditions before opening the package.

4.2.9 Batch/lot number

The batch/lot prefix can be added to the batch/lot number.

4.2.10 Miscellaneous

This is any other applicable information.

NOTE National regulations can apply.

4.3 Additional labelling elements for finished manufactured products only

4.3.1 Common elements for all product classifications

— Name of the excipient, which shall be written separately from the active ingredients.

— Administration method.

4.3.2 Elements depending on each product classification

4.3.2.1 Simultaneous extract of multiple herbs

For this type of product:

— the formula name as the active ingredient and its amount as an extract;

— the constituent raw material names and the individual amount for the formula;

— the extraction method including the solvent name.

4.3.2.2 Single herb extract

For this type of product:

— the extract name as the active ingredient and its amount;

— the raw material name and the weight used for the extract;

— the extraction method including the solvent name.

In this category, the combination of single herb extract is included.

4.3.2.3 Non-extract product

For this type of product, the herbal name as the active ingredient and its amount.

In this category, the combination of herbs is included.

4.4 Informative elements

4.4.1 Traditional Chinese medicine code

If there are codes for the product or raw materials (herbs) they can be stated.

4.4.2 Daily dosage

The daily dosage or daily dosage range can be stated.

4.4.3 Manufacturer

The name and address of the manufacturer can be stated.

4.4.4 Indication/functionality

If it is permitted to claim any indications or functionalities of the product in the country in which the product will be sold, the indications or functionalities can be stated.

4.4.5 Information on certification acquired by manufacturer

If the product is manufactured under a certified quality control system, for example GMP, HACCP or an International Standard, such systems can be stated along with the certification organization, subject to any importing country requirements (certification country).

4.4.6 Notice and messages

Important product notices or messages for consumers can be stated, subject to any importing country requirements (certification country).

4.4.7 Country of origin

Country of origin (country of production) of the products can be stated, e.g. China (if necessary the local name can be included, e.g. Beijing, China).

Products for which the production involved more than one country shall be deemed to originate in the country where the product was substantially transformed.

5 Labelling format

5.1 Language

Labelling shall be in the official language of the country in which the products will be sold.

5.2 Font size and colour

The font size and colour of the labelling shall be easily legible when viewed using normal vision, corrected if necessary, taking into account the specific size and conditions of use of the labelling.

5.3 Location

Labelling shall be located on the outside cover of the packaging where the information can be read without opening the package.