Technical Report

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Traditional Chinese medicine — Priority list of single herbal medicines for developing standards

Médecine traditionnelle chinoise — Liste prioritaire de médicaments à base de plantes isolées pour l'élaboration de normes

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Contents

Page

Foreword ... **iv**
Introduction ... **vi**
1 Scope ... **1**
2 Normative references ... **1**
3 Terms and definitions ... **1**
4 Document structure ... **1**
5 Principles ... **1**
6 Evaluation indexes ... **2**
6.1 International trade ... 2
6.2 Single herbal medicines recorded in pharmacopoeias ... 6
6.3 Safety concerns ... 46
6.4 The use frequency of single herbal medicines in formula recorded in Pharmacopoeias and national formula ... 54
6.5 Single herbal medicine standards published or under development ... 71
6.6 Endangered species ... 73
7 Data processing ... **74**
7.1 The weight coefficient of evaluation indexes distribution ... 74
7.2 The range of priority rank distribution ... 74
7.3 Data statistics ... 75
8 Single herbal medicines in order of priority ... **75**
Annex A (informative) **Priority list of single herbal medicines ranked from 151 to 375** ... **83**
Bibliography ... **94**

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Foreword

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

This second edition cancels and replaces the first edition (ISO/TR 23975:2019) which has been technically revised.

The main changes are as follows:

— in 5.1, the international trading value of herbal medicines was replaced by the international trade volume as a high priority principle;

— in 5.4, a new principle of high priority was added;

— in 6.1, the data of international trade volume for single herbal medicines was updated; and Table 1 was sorted by international trade volume;

— in 6.2, the data of single herbal medicines recorded in pharmacopoeias was updated; and Table 2 was sorted by occurrence count;

— in 6.4, the data of the use frequency for single herbal medicines in formula recorded in Pharmacopoeias and national formula was added; and Table 4 was sorted by occurrence count;

— in 6.5, the data of international standard for single herbal medicines that have been published or are under development was updated, and listed in Table 5;

— in 6.6, single herbal medicines that are listed as endangered species in CITES were updated;

— in 7.1, the weight coefficient of criteria for developing single herb standards based on recent expert consultation was updated, and listed in Table 7;

— in 7.2, the range of priority rank for developing single herb standards based on recent expert consultation was updated, and listed in Table 8;

— in Clause 8, Table 9 was updated;

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— in Annex A, Table A.1 was updated.

In addition to text written in the official ISO languages (English, French, Russian), this document gives text in Chinese. This text is published under the responsibility of the Member Body for China (SAC) and is given for information only. Only the text given in the official languages can be considered as ISO text.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

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Introduction

Being a significant part of traditional medicine systems and general health services, traditional Chinese medicine is estimated to be used in over 180 countries and regions around the world. This is reflected by the statistics cited from the WHO report that there are 4 billion people in the world using herbal medicines, accounting for 80 % of the total world population. Asia, North America and Europe are regarded as the major markets for herbal medicines. Moreover, incomplete Chinese customs statistics show that the import and export of herbal medicine products in China was worth over 1,61 billion USD in 2023. Therefore, it is very important to develop globally harmonized standards in order to ensure the safety of consumers. In particular, those herbal medicines which have been reported to cause adverse drug reactions (ADR) are drawing much attention from national health administrations.

There are a great number of single herbs on the market; for instance, 618 kinds of herbs have been included in the *Pharmacopoeia of the People's Republic of China*. Currently, organizations, regions and countries including ISO, WHO, the European Union, China, Japan, Korea, the USA, the UK and Thailand are making valuable contributions by developing standards for single herbs. This document presents a list of single herbal medicines in order of priority for the purposes of developing standards on single herbs in a scientific and orderly manner. This document can be used as a reference by any organization wishing to develop standards on single herbal medicines.

The following factors have been considered in setting the priorities:

— the trade volume of each single herbal medicine in the global market;

— whether the herbal medicine is recorded by the *Pharmacopoeia of the People's Republic of China*, the *European Pharmacopoeia*, the *Japanese Pharmacopoeia*, the *Japanese standards for non-Pharmacopoeial crude drugs*, the *Korean Pharmacopoeia*, the *Korean Herbal Pharmacopoeia*, the *Thai Herbal Pharmacopoeia, Hong Kong Chinese Materia Medica Standards* or the *United States Pharmacopoeia*;

— whether there are potential risks from its use;

— whether the herbal medicine is used in formula by the *Pharmacopoeia of the People's Republic of China*, the *Japanese Pharmacopoeia*, the *Korean Pharmacopoeia*, or other national formula;

— whether the herbal medicine is listed in the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES);

— opinions from experts.

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Traditional Chinese medicine — Priority list of single herbal medicines for developing standards

1 Scope

This document provides a reference of single herbal medicines in order of their priority in the development of international standards.

This document also provides a reference of the principles and the methodology for the priority evaluation of single herbal medicines.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

No terms and definitions are listed in this document.

ISO and IEC maintain terminology 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/

4 Document structure

4.1 The principles for determing the priority of single herbal medicines are established in Clause 5.

4.2 Single herbal medicines and the data of evaluation indexes are listed in Clause 6.

4.3 The methods of data statistics, including the weight coefficient of evaluation indexes and the range of priority rank, are determined in Clause 7.

4.4 The priority list of single herbal medicines is established in Clause 8 based on the evaluation indexes data in Clause 6 and the statistical methods in Clause 7. The non-priority list of single herbal medicines is provided in Annex A.

5 Principles

5.1 Herbal medicines which have a large international trade volume are listed as high priority in Table 1.

5.2 Common herbal medicines recorded in the *Pharmacopoeia of the People's Republic of China*, the *European Pharmacopoeia*, the *Japanese Pharmacopoeia*, the *Japanese standards for non-Pharmacopoeial crude drugs*, the *Korean Pharmacopoeia*, the *Korean Herbal Pharmacopoeia*, the *Thai Herbal Pharmacopoeia, Hong Kong Chinese Materia Medica Standards*, and the *United States Pharmacopoeia* are listed as high priority in Table 2.

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