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

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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.

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

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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~~ 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 ~~were~~ 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 ~~were~~ was updated, and listed in Table 8;
- in Clause 8, Table 9 was updated;
- in Annex A, Table A.1 was updated.

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.

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;

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- 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~~structure

~~4.1 Firstly, the~~ The principles for determining the priority of single herbal medicines ~~in the order of their priority~~ are established in Clause 5.

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

~~4.3 Thirdly, the~~ 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 ~~Finally, the~~ 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. ~~At the same time, the~~ The non-priority list of single herbal medicines is ~~also obtained~~ 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.

5.3 Herbal medicines that have safety concerns, such as those widely reported to cause adverse drug reactions (ADR), are listed as high priority in Table 3.

5.4 Herbal medicines which have a high frequency of use in formula recorded in the *Pharmacopoeia of the People's Republic of China*, the *Japanese Pharmacopoeia*, the *Korean Pharmacopoeia*, and other national formula are listed as high priority in Table 4.

5.5 Single herbal medicines for which there are existing ISO standards are listed as high priority in Table 5.

5.6 Herbal medicines which are included in CITES are listed for reference in Table 6.

6 Evaluation indexes

6.1 International trade

Table 1 provides information on the 100 single herbal medicines which had the largest international trade volume in China and Japan from 2017 to 2021 (sorted by international trade volume).

Table 1 — The top 100 single herbal medicines which had the largest international trade volume in China and Japan from 2017 to 2021

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No.	Rank	Herbal name	Pharmaceutical name	Chinese name	Chinese pinyin	English name	International trade volume (kg)
1	1	<i>Dimorcarpus longan</i> arill	longan arillus	龙眼肉	Longyanrou	longan aril	524 270 778
2	2	<i>Glycyrrhiza uralensis</i> root and rhizome/ <i>Glycyrrhiza inflata</i> root and rhizome/ <i>Glycyrrhiza glabra</i> root and rhizome	glycyrrhizae radix et rhizoma	甘草	Gancao	licorice root	78 028 000
3	3	<i>Ziziphus jujuba</i> fruit	jujubae fructus	大枣	Dazao	Chinese date	77 762 954
4	4	<i>Lycium barbarum</i> fruit	lycii fructus	枸杞子	Gouqizi	barbary wolfberry fruit	61 256 785
5	5	<i>Curcuma longa</i> rhizome	curcumae longae rhizoma	姜黄	Jianghuang	turmeric	39 770 586
6	6	<i>Poria cocos</i> sclerotium	poria	茯苓	Fuling	Indian bread	32 821 447
7	7	<i>Rehmannia glutinosa</i> root	rehmanniae radix	地黄	Dihuang	rehmannia root	24 405 600
8	8	<i>Astragalus membranaceus</i> var. <i>mongholicus</i> root/ <i>Astragalus membranaceus</i> root	astragali radix	黄芪	Huangqi	milkvetch root	24 056 566
9	9	<i>Paeonia lactiflora</i> root	paeoniae radix alba	白芍	Baishao	white peony root	23 660 308
10	10	<i>Angelica sinensis</i> root	angelicae sinensis radix	当归	Danggui	Chinese angelica	22 763 112
11	11	<i>Nelumbo nucifera</i> seed	nelumbinis semen	莲子	Lianzi	lotus seed	22 429 217
12	12	<i>Prunus armeniaca</i> var. <i>ansu</i> seed/ <i>Prunus sibirica</i> seed/ <i>Prunus mandshurica</i> seed/ <i>Prunus armeniaca</i> seed	armeniacaе semen amarum	苦杏仁	Kuxingren	bitter apricot seed	21 272 374
13	13	<i>Ligusticum chuani</i> rhizome	chuanxiong rhizoma	川芎	Chuanxiong	Szechwan lovage rhizome	17 669 422
14	14	<i>Atractylodes macrocephala</i> rhizome	atractylodis macrocephalae rhizoma	白朮	Baizhu	largehead atractylodes rhizome	16 158 735

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No.	Rank	Herbal name	Pharmaceutical name	Chinese name	Chinese pinyin	English name	International trade volume (kg)
15	15	<i>Chrysanthemum morifolium</i> capitulum/ <i>Chrysanthemum indicum</i> capitulum	chrysanthemi flos/chrysanthemi indici flos	菊花/野菊花	Juhua/Yejuhua	chrysanthemum flower/wild chrysanthemum flower	14 155 600
16	16	<i>Pinellia ternata</i> tuber	pinelliae rhizoma	半夏	Banxia	pinellia tuber	13 743 242
17	17	<i>Scutellaria baicalensis</i> root	scutellariae radix	黄芩	Huangqin	baical skullcap root	11 334 012
18	18	processed <i>Rehmannia glutinosa</i> root	rehmanniae radix praeparata	熟地黄	Shudihuang	prepared rehmannia root	11 087 029
19	19	<i>Rheum palmatum</i> root and rhizome/ <i>Rheum tanguticum</i> root and rhizome/ <i>Rheum officinale</i> root and rhizome	rhei radix et rhizoma	大黄	Dahuang	rhubarb	10 829 944
20	20	<i>Codonopsis pilosula</i> root/ <i>Codonopsis pilosula</i> var. <i>modesta</i> root/ <i>Codonopsis tangshen</i> root	codonopsis radix	党参	Dangshen	tangshen	10 768 612
21	21	<i>Paeonia lactiflora</i> root/ <i>Paeonia veitchii</i> root	paeoniae radix rubra	赤芍	Chishao	red peony root	10 308 069
22	22	<i>Glehnia littoralis</i> root	glehniae radix	北沙参	Beishashen	coastal glehnia root	9 467 180
23	23	<i>Panax ginseng</i> root and rhizome	ginseng radix et rhizoma	人参	Renshen	ginseng	9 272 878
24	24	<i>Panax quinquefolium</i> root	panacis quinquefolii radix	西洋参	Xiyangshen	American ginseng	9 062 388
25	25	<i>Eucommia ulmoides</i> bark	eucommiae cortex	杜仲	Duzhong	eucommia bark	7 918 769

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No.	Rank	Herbal name	Pharmaceutical name	Chinese name	Chinese pinyin	English name	International trade volume (kg)
26	26	<i>Atractylodes lancea</i> rhizome/ <i>Atractylodes chinensis</i> rhizome	atractylodis rhizoma	苍朮	Cangzhu	atractylodes rhizome	7 141 995
27	27	<i>Ephedra sinica</i> stem/ <i>Ephedra intermedia</i> stem/ <i>Ephedra equisetina</i> stem	ephedrae herba	麻黄	Mahuang	ephedra	6 757 413
28	28	<i>Cinnamomum cassia</i> bark	cinnamomi cortex	肉桂	Rougui	cassia bark	6 383 391
29	29	<i>Sinomenium acutum</i> stem/ <i>Sinomenium acutum</i> var. <i>cinereum</i> stem	sinomenii caulis	青风藤	Qingfengteng	orientvine stem	6 373 600
30	30	<i>Boswellia carterii</i> resin/ <i>Boswellia bhawdajiana</i> resin	olibanum	乳香	Ruxiang	olibanum	5 788 700
31	31,5	<i>Commiphora molmol</i> resin/ <i>Commiphora myrrha</i> resin	myrrha	没药	Moyao	myrrh	5 788 305
32	31,5	<i>Daemonorops draco</i> fruit resin	draconis sanguis	血竭	Xuejie	dragon's blood	5 788 305
33	33	<i>Bupleurum chinense</i> root/ <i>Bupleurum scorzoniferifolium</i> root	bupleuri radix	柴胡	Chaihu	Chinese thorowax root	5 548 577
34	34	<i>Pueraria lobata</i> root	puerariae lobatae radix	葛根	Gegen	kudzuvine root	5 049 986
35	35	<i>Alisma orientale</i> tuber	alismatis rhizoma	泽泻	Zexie	oriental waterplantain rhizome	5 033 389
36	36	<i>Zanthoxylum nitidum</i> root	zanthoxyli radix	两面针	Liangmianzhen	shinyleaf pricklyash root	4 407 279

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No.	Rank	Herbal name	Pharmaceutical name	Chinese name	Chinese pinyin	English name	International trade volume (kg)
37	37	<i>Paeonia suffruticosa</i> root bark	moutan cortex	牡丹皮	Mudanpi	tree peony bark	4 162 616
38	38	<i>Citrus reticulata</i> pericarp	citri reticulatae pericarpium	陈皮	Chenpi	dried tangerine peel	4 099 357
39	39	<i>Ophiopogon japonicus</i> root tuber/ <i>Liriope muscari</i> root/ <i>Liriope spicata</i> var. <i>prolifera</i> root	ophiopogonis radix/liriope radix	麦冬/山麦冬	Maidong/Shanmaidong	dwarf lilyturf tuber/liriope root tuber	3 827 440
40	40	<i>Platycodon grandiflorum</i> root	platycodonis radix	桔梗	Jiegeng	platycodon root	3 618 978
41	41	<i>Gardenia jasminoides</i> fruit	gardeniae fructus	栀子	Zhizi	cape jasmine fruit	3 500 354
42	42	<i>Magnolia officinalis</i> bark/ <i>Magnolia officinalis</i> var. <i>biloba</i> bark	magnoliae officinalis cortex	厚朴	Houpo	official magnolia bark	3 442 692
43	43	<i>Polyporus umbellatus sclerotium</i>	polyporus	猪苓	Zhuling	chuling	3 347 709
44	44	<i>Phellodendron amurense</i> bark/ <i>Phellodendron chinensis</i> bark	phellodendri chinensis cortex/phellodendri amurenensis cortex	黄柏/关黄柏	Huangbo/Guanhuangbo	Chinese cork-tree/amur cork-tree	3 297 263
45	45	<i>Saposhnikovia divaricata</i> root	saposhnikoviae radix	防风	Fangfeng	divaricate saposhnikovia root	3 137 656
46	46	<i>Cornus officinalis</i> sarcocarp	corni fructus	山茱萸	Shanzhuyu	asiatic cornelian cherry fruit	3 097 242
47	47	<i>Perilla frutescens</i> leaf	perillae folium	紫苏叶	Zisuye	perilla leaf	3 072 478
48	48	<i>Asarum heterotropoides</i> var. <i>mandshuricum</i> root and rhizome/ <i>Asarum sieboldii</i> var.	asari radix et rhizoma	细辛	Xixin	Manchurian wildginger root	3 030 735