WHO monographs on

medicinal plants commonly used in the Newly Independent States (NIS)





WHO
monographs on
medicinal plants
commonly used
in the Newly
Independent States
(NISE 书章



Selected WHO publications of related interest

Information on medicinal plants:

WHO monographs on selected medicinal plants, Volume 4 (ISBN 978 92 4 154705 5), 2009

WHO monographs on selected medicinal plants, Volume 3 (ISBN 978 92 4 154702 4), 2007

WHO monographs on selected medicinal plants, Volume 2 (ISBN 92 4 154537 2), 2002

WHO monographs on selected medicinal plants, Volume 1 (ISBN 92 4 154517 8), 1999

Quality assurance and control of herbal medicines:

WHO Guidelines on good agricultural and collection practices (GACP) for medicinal plants (ISBN 92 4 154627 1), 2003

WHO good agricultural and collection practices (GACP) monograph on Artemisia annua L. (ISBN 978 92 4 159443 1), 2006

Quality control methods for medicinal plant materials (ISBN 92 4 154510 0), 1998

Basic tests for drugs: pharmaceutical substances, medicinal plant materials and dosage forms (ISBN 92 4 154513 5), 1998

WHO guidelines for assessing quality of herbal medicines with reference to contaminants and residues (ISBN 978 92 4 159444 8), 2007

WHO guidelines for good manufacturing practices (GMP) for herbal medicines (ISBN 978 92 4 154716 1), 2007

Regulation, evaluation and safety monitoring of herbal medicines:

Summary report of the global survey on national policy on traditional medicine and complementary/alternative medicine and regulation of herbal medicines (ISBN 92 4 1593237), 2005

WHO guidelines on safety monitoring and pharmacovigilance of herbal medicines (ISBN 92 4 159221 4), 2004

General Guidelines for Methodologies on Research and Evaluation of Traditional Medicine (WHO/EDM/TRM/2000.1), 2000

Consumer information:

WHO guidelines on development of consumer information on proper use of traditional medicine and complementary/alternative medicine
(ISBN 92 4 159170 6), 2004

Further information on WHO technical documents in the field of traditional medicine including those listed above, can be found at the address below:

http://apps.who.int/medicinedocs/en/cl/CL10/

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Introduction

Background

The results from the recent WHO/TRM Global Survey on National Policy on Traditional and Complementary/Alternative Medicine and on Regulation of Herbal Medicines in 2003 show that the European herbal medicines market is growing steadily. For example, between 1999 and 2001, herbal medicines sales increased by 22% in the Czech Republic, doubled in Turkmenistan, and increased by 170% in Bulgaria.

Currently, the European market is considered to be the world's largest single commercial market for medicinal plants and herbal medicines. European countries are not just importers, but also producers of a large variety of medicinal plants and herbal medicines. European consumers, for example, in France, Germany, Italy, Sweden, Switzerland and the UK often use herbal medicines to complement treatment with conventional medicines.

In the Newly Independent States (NIS) and Countries of Central and Eastern Europe (CCEE), consumers likewise often favour herbal products, but for a different reason. Difficult economic conditions often limit access to the rather expensive conventional medicines that are available, with the result that they seek out less expensive alternative medicines such as herbal products.

Many European Union countries already have well-established national policies and programmes for regulating and monitoring herbal medicines. Many NIS and CCEE Member States are now similarly striving to develop and implement national policies and programmes to regulate herbal medicines.

Difficulties and needs in the field of herbal medicines in NIS countries

In some NIS and CCEE countries a number of medicinal plants are grown and not only consumed domestically, but also exported to other countries. Indeed, exporting medicinal plants is a principal source of income for some NIS and CCEE countries. Many NIS and CCEE governments are therefore keen to ensure quality control of medicinal plants and me-

dicinal plant materials, so as to maintain and increase the credibility of their products on the international market. However, they often lack technical expertise, skills and knowledge in this area, as well as resources for conducting research and establishing national standards and quality assurance measures for medicinal plants and herbal medicines.

According to the information collected during WHO's recent global survey on traditional medicine:

- nine NIS countries would like WHO to facilitate information sharing between Member States on regulatory issues;
- ten NIS countries would like WHO to provide general guidance on research and evaluation of traditional medicine;
- additional requests included requests for support for national capacity building in establishing national regulation of herbal medicines, and provision via databases of information on herbal medicines.

Some NIS and CCEE countries have developed their own national monographs on herbal medicines, either within national pharmacopoeias or national formularies. These countries include Armenia, Kyrgyzstan, Romania, Slovakia and Uzbekistan. However, since most NIS lack research data and funds, they have been unable to develop their own national monographs.

At the WHO regulatory training workshop for Europe in September 2003, many of the NIS participating national drug regulatory authorities requested assistance from WHO in developing monographs on medicinal plants commonly used in the NIS.

The objectives of development of the monographs for NIS countries

Since 1999, WHO has published four volumes of the WHO monographs on selected medicinal plants, that include 116 monographs. All of these volumes are now available on the WHO web site (http://www.who.int/medicines).

Despite the increasing use of herbal medicines, there is still a significant lack of research data in this field, so that the WHO monographs are playing an increasingly important role. For example, in the recent WHO global survey on national policy and regulation of herbal medicines, of the 34 countries reporting that they do not have their own national monographs and use other monographs, 13 use the WHO monographs as an authoritative reference. Moreover, the format of the WHO monographs continues to be commonly used for developing national monographs. In the same survey, of the 46 countries that have already developed national

monographs on herbal medicines, several countries reported having used the WHO format as a basis.

In order to meet demands of NIS countries to regulate herbal medicines and to ensure safety, efficacy and quality of herbal medicines, WHO has provided technical guidance and worked with the national health authorities of interested NIS and CCEE to develop monographs on commonly-used medicinal plants in the NIS.

The NIS monographs include comprehensive scientific information on the safety, efficacy and quality of medicinal plants. The format of the NIS monographs is the same as of the WHO monographs on medicinal plants. Each monograph follows a standard format, with information presented in two parts, followed by a reference list. The first part presents pharmacopoeial summaries for quality assurance, while the second part includes sections on medicinal uses, pharmacology, safety issues and dosage forms.

Through the participation in the development of the monographs, the objectives are to:

- assist national authorities and experts in NIS and CCEE countries to learn how to develop official monographs on medicinal plants;
- facilitate the national regulatory authorities to build their national capacity in establishing national quality specifications and standards for herbal medicines, national formularies on herbal medicines, as well as quality assurance and control measures for herbal medicines in NIS and CCEE countries;
- promote research on herbal medicines and networking of researchers on herbal medicines within and outside the NIS and CCEE;
- establish a network among the NIS and CCEE to facilitate sharing of information and experience in regulation, research and use of herbal medicines.

Process of the development of the monographs for NIS countries

Firstly WHO worked with the national health authorities and experts of NIS and CCEE countries to establish a working group on development of the monographs. Then they developed a list of monographs on commonly-used medicinal plants in the NIS. The list was finalized by a Working group meeting. It was agreed that there would be a total of 30 to 35 monographs, which would be developed through two mechanisms:

· development of new monographs;

 adoption of existing relevant monographs from the four volumes of WHO monographs on selected medicinal plants and translation into Russian.

Then WHO coordinated collection of relevant research information – not only with the national health authorities and experts of NIS and CCEE countries, but also together with WHO Collaborating Centres for traditional medicine and other research institutions and nongovernmental organizations (NGOs). The experts from NIS and CCEE countries drafted the new monographs, based on the standard format, simultaneously in English and Russian. The draft monographs have been widely circulated to 256 experts and national regulatory authorities in 99 countries, as well as NGOs, for their comments and opinions.

Then, draft new monographs were reviewed and finalized by a WHO Consultation. The participants included the national health authorities and experts of NIS and CCEE countries, as well as experts from WHO Collaborating Centres for traditional medicine and other research institutions and NGOs. Following extensive discussion, 13 of 14 new monographs were approved by the WHO Consultation.

In order to ensure the quality of the monographs, the final version has been reviewed by the experts from the WHO Collaborating Centre for Traditional Medicine at the University of Illinois at Chicago, IL, USA.

Use of the monographs

The monographs may serve as an authoritative source of information for national drug regulatory authorities, since they have been fully involved in the development of the monographs. However, it should also be emphasized that the descriptions included in the section on medicinal uses should not be taken as implying WHO's official endorsement or approval and also not intended to replace any national monographs or national pharmacopoeia of medicinal plants. They merely represent the systematic collection of scientific information available at the time of preparation, for the purpose of information exchange.

Dr Xiaorui Zhang Coordinator Traditional Medicine Department of Essential Medicines and Pharmaceutical Policies (EMP) World Health Organization Geneva, Switzerland

General technical notices

These WHO monographs are not pharmacopoeial monographs. Their purpose is to provide scientific information on the safety, efficacy and quality control/quality assurance of widely used medicinal plants, in order to facilitate their appropriate use in WHO's Member States; to provide models to assist WHO's Member States in developing their own monographs or formularies for these and other herbal medicines; and to facilitate information exchange among WHO's Member States.

The format used for this volume essentially follows that of volumes 2, 3 and 4 of WHO monographs on selected medicinal plants.

The Definition provides the Latin binomial name, the most important criterion in quality assurance. Latin binomial synonyms and vernacular names, listed in Synonyms and Selected vernacular names respectively, are names used in commerce or by local consumers. The monographs place outdated botanical nomenclature in the synonyms category, based on the International Code of Botanical Nomenclature. The vernacular names comprise an alphabetical list of selected names from individual countries worldwide, in particular from areas where the medicinal plant is in common use. They refer to the medicinal plant itself not the medicinal plant part, which is identical to the monograph name. The lists are not complete, but reflect the names of the concerned medicinal plant appearing in the official monographs and reference books consulted and those in the Natural Products Alert (NAPRALERT) database (a database of literature from around the world on ethnomedical, biological and chemical information on medicinal plants, fungi and marine organisms, located at the WHO Collaborating Centre for Traditional Medicine at the University of Illinois at Chicago, Chicago, IL, USA). While every effort has been made to delete names referring to the medicinal plant part, the relevant section of each monograph may still include these.

Geographical distribution is not normally found in official compendia, but is included here to provide additional quality assurance information. The detailed botanical description under Description is intended for qual-

ity assurance at the stages of production and collection; the description of the crude drug material under *Plant material of interest* is for the same purpose at the manufacturing and commerce stages.

General identity tests, Purity tests and Chemical assays are all normal compendial components included under those headings in these monographs. Where purity tests do not specify accepted limits, those limits should be set in accordance with national requirements by the appropriate authorities of Member States.

Each medicinal plant and the specific plant part used as crude drug material contain active or major chemical constituents with a characteristic profile that can be used for chemical quality control and quality assurance. These constituents are described in the *Major chemical constituents*.

Descriptions included in *Medicinal uses* should not be taken as implying WHO's official endorsement or approval for such uses. They merely represent the systematic collection of scientific information available at the time of preparation, for information exchange.

The first category, *Uses supported by clinical data*, includes medical indications that are well established in some countries and have been validated by clinical studies documented in the scientific literature. Clinical trials may be controlled, randomized, double-blind studies, open trials, cohort studies or well documented observations on therapeutic applications.

The second category, *Uses described in pharmacopoeias and well established documents*, includes medicinal uses that are well established in many countries and are included in official pharmacopoeias or governmental monographs. Uses having a pharmacologically plausible basis are also included, as well as information resulting from clinical studies that clearly need to be repeated because of conflicting results.

The third category, *Uses described in traditional medicine*, refers to indications described in unofficial pharmacopoeias and other literature, and to traditional uses. Their appropriateness could not be assessed, because sufficient data to support the claims could not be found in the literature. Traditional uses that address severe pathologies, such as cancer, AIDS, hepatitis, etc., as they relate to these modern biomedical terms, should only be included under the third heading if pharmacological data or robust ethnopharmacological/ethnobotanical reports are available to support the claims.

The Experimental pharmacology section includes only the results of investigations that prove or disprove the cited medicinal uses. Brief details of the best-performed studies have been included in this section. Other published experimental data that are not associated with the medicinal uses have not been included, to avoid confusion.

The details included in the *References* have been checked against the original sources wherever possible. For references in languages other than English, except for those in Chinese and Japanese, the title is given in the original language, except in cases where an English summary is available.

Bulbus Allii Sativi*

Definition

Bulbus Allii Sativi consists of the fresh or dried bulbs of *Allium sativum* L. (Liliaceae) (1, 2).

Synonyms

Porvium sativum Rehb. (1, 3).

Selected vernacular names

It is most commonly known as "garlic". Ail, ail commun, ajo, akashneem, allium, alubosa elewe, ayo-ishi, ayu, banlasun, camphor of the poor, dai tóan, dasuan, dawang, dra thiam, foom, Gartenlauch, hom khaao, hom kía, hom thiam, hua thiam, kesumphin, kitunguu-sumu, Knoblauch, kra thiam, krathiam cheen, krathiam khaao, l'ail, lahsun, lai, lashun, lasan, lasun, lasuna, Lauch, lay, layi, lehsun, lesun, lobha, majo, naharu, nectar of the gods, ninniku, pa-se-waa, poor man's treacle, rason, rasonam, rasun, rustic treacles, seer, skordo, sluôn, stinking rose, sudulunu, ta-suam, ta-suan, tafanuwa, tellagada, tellagaddalu, thiam, toi thum, tum, umbi bawang putih, vallaippundu, velluli, vellulli (1–13).

Description

A perennial, erect bulbous herb, 30–60 cm tall, strong smelling when crushed. The underground portion consists of a compound bulb with numerous fibrous rootlets; the bulb gives rise above ground to a number of narrow, keeled, grasslike leaves. The leaf blade is linear, flat, solid, 1.0–2.5 cm wide, 30–60 cm long, and has an acute apex. Leaf sheaths form a pseudostem. Inflorescences are umbellate; scape smooth, round, solid, and coiled at first, subtended by membraneous, long-beaked spathe, splitting on one side and remaining attached to umbel. Small bulbils are produced in inflorescences; flowers are variable in number and sometimes absent, seldom open and may wither in bud. Flowers are on slender

^{*} Adopted from the volume 1 of WHO monographs on selected medicinal plants.

pedicels; consisting of perianth of 6 segments, about 4–6 mm long, pinkish; stamens 6, anthers exserted; ovary superior, 3-locular. Fruit is a small loculicidal capsule. Seeds are seldom if ever produced (8, 9).

Plant material of interest: fresh or dried bulbs

General appearance

Bulbus Allii Sativi consists of several outer layers of thin sheathing protective leaves which surround an inner sheath. The latter enclose the swollen storage leaves called "cloves". Typically, the bulb possesses a dozen sterile sheathing leaves within which are 6–8 cloves bearing buds making a total of 10–20 cloves and 20–40 well-developed but short and embedded roots. The cloves are asymmetric in shape, except for those near the centre (1).

Organoleptic properties

Odour strong, characteristic alliaceous (1, 6, 8); taste very persistently pungent and acrid (1, 6, 8).

Microscopic characteristics

The bulbs show a number of concentric bulblets; each is 5–10 mm in diameter and consists of an outer scale, an epidermis enclosing a mesophyll free from chlorophyll, a ground tissue and a layer of lower epidermal cells. Dry scales consist of 2 or 3 layers of rectangular cells having end walls with a broadly angular slant. These cells contain many rhomboid crystals of calcium oxalate. The upper epidermal cells next to the dry scale layer consist of a single layer of rectangular to cubical cells next to which are several layers of large parenchymatous cells. Among these cells are interspaced many vascular bundles, each of which consists of xylem and phloem arranged alternately. Lower epidermis consists of cubical cells which are much smaller than the upper epidermal cells. The same arrangement of tissues is met within different bulblets, 2 or 3 of which are arranged concentrically (1, 6).

Powdered plant material

Pale buff to greyish or purplish white, with characteristic aromatic alliaceous odour and taste. It is characterized by the presence of sclereids of the epidermis of protective leaves, thin epidermis of storage cells, latex tubes, swollen parenchyma cells with granular contents, and lignified narrow spiral and annular vessels (1).

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