# Welcome to the WHO Herbal Dictionary

This document is a guide to the general features of the WHO Herbal Dictionary. It provides you with information about the structure and content of the dictionary as well as information about some services provided by *the* Uppsala Monitoring Centre (UMC) – the WHO Drug Dictionary maintenance organisation.

Please note that the WHO Herbal Dictionary has the same structure and general principles as the WHO Drug Dictionary. This document therefore only covers features unique to the WHO Herbal Dictionary.

### Some basic facts about the WHO Herbal Dictionary

The WHO Herbal Dictionary is based on the WHO Drug Dictionary which is the world's most comprehensive dictionary of medicinal product information. It is used by pharmaceutical companies, clinical trial organisations and drug regulatory authorities for identifying drug names, their active ingredients and therapeutic use, in the course of their clinical research. It translates a drug name to useful information which is used for analysis. The dictionary is used for coding and analysing clinical research data – pre- and post-marketing.

The WHO Herbal Dictionary is populated with data from WHO Drug Dictionary as well as additions from other sources.

The products that are included in the WHO Herbal Dictionary contain only substances of natural origin. The WHO Drug Dictionary/WHO Drug Dictionary Enhanced cover the products that contain conventional substances or a combination of conventional substances and natural substances.

The hierarchical record number system allows for easy, flexible information retrieval. Drugs are classified according to the Herbal Anatomical-Therapeutic-Chemical classification (HATC) which allows for grouping of drugs in different ways for comparison purposes. The dictionary also contains cross-references to market authorization holders and reference sources.

The Herbal ATC system is an integral part of the WHO Herbal Dictionary and provides a unique scientific framework for a harmonised, global nomenclature and therapeutic classification of herbal substances and combinations of them. The HATC is based on the Anatomical-Therapeutic-Chemical classification (ATC) which is a part of the WHO Drug Dictionary.

The main benefits offered by the WHO Herbal Dictionary are:

- Consistent, quality-assured, and up-to-date information
- A hierarchical structure that allows easy and flexible data-retrieval and analysis at different levels of precision
- Chemical and therapeutic classifications using the WHO drug record number system and the Herbal ATC classification
- Computerised software-independent format for easy implementation in the user's systems

The WHO Herbal Dictionary is produced twice per year – on March 1 and September 1 each year. The March 1 version contains the new revision of the Herbal ATC classification.

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# **Content of the WHO Herbal Dictionary**

The information routinely recorded by UMC specialist staff refers to all drugs of natural origin and herbal substances, whether or not suspected of causing an ADR, mentioned in all international ADR reports submitted to the WHO Programme since its beginning in 1968, as well as products entered from other sources, such as IMS Health.

The products entered in the WHO Herbal Dictionary are those that only contain natural ingredients. Products that contain a mixture of herbal ingredients and conventional medicines appear in the WHO Drug Dictionary and WHO Drug Dictionary Enhanced.

The current version of WHO Herbal Dictionary contains only drugs with ingredients that originate from plants. Future development will also include drugs that contain ingredients such as animal parts and extracts. These types of products are common in for example Asian traditional medicine.

Herbal remedies are products of plants. They can be crude drugs which consist of dried whole plants or dried plant parts. Other plant products such as fixed and volatile oils, resins, balsams and tars are also referred to as crude drugs. A herbal remedy can also be a comparatively simple preparation of a crude drug such as an extract or a tincture. Sometimes such preparations are made from fresh plants or plant parts. Pure isolated compounds (alkaloids, glycosides, etc.) are not regarded as herbal remedies and are in most cases classified as conventional medicinal products.

The WHO Herbal Dictionary is coded with the Herbal ATC classification. The combined WHO Herbal Dictionary and WHO Drug Dictionary/WHO Drug Dictionary Enhanced are coded with both Herbal ATC and the conventional ATC used in WHO Drug Dictionary/WHO Drug Dictionary Enhanced.

# What You Get

#### **Deliverables**

The WHO Herbal Dictionary is distributed in two different ways; either in separate data files, or merged together with the WHO Drug Dictionary (or WHO Drug Dictionary Enhanced). In the latter case conventional products and herbal products are available in the same tables in order to facilitate the loading of the combined dictionary.

The file structure is the same in the WHO Herbal Dictionary and WHO Drug Dictionary. The only important difference in the data is the use of the 'Official ATC code'.

The use of the CAS number also holds some additional information – but the general principle is the same.

### The Files

The dictionary is an information service. The data can be imported into your Clinical Data or Adverse Event database system or any other system. To make the dictionary independent of all possible database systems it is delivered in basic flat files.

To get started you need to understand the relationship between the dictionary's different files and the meaning of the different fields. To understand the relationship between the files please look at the document 'Format C –File Diagram'. To understand how to identify the different fields, please look at the document 'Format C File Descriptions'.

The definitions of the different files are described in this document in the section 'Definitions – Main Files'. A description of the different fields is given in the section 'Definitions – Data Fields'.

When you have a clear idea of the content of the dictionary and how you are going to use it you need to map the data to your in-house database system. If you have commercial software you might get support from the software provider on how to do this. *The* Uppsala Monitoring Centre is collaborating with some providers, if you want to know more please contact your provider or *the* UMC – <u>drugdictionary@umc-products.com</u>.

### **Support**

As a subscriber to the WHO Herbal Dictionary you will have full access to our support services. Support will help you with questions about the data and how to interpret documents and files. You should also report any errors or inconsistency to Support so we can solve the problem. Support is staffed during European office hours. You may find it easier to communicate via e-mail-drugdictionary@umc-products.com.

# **New Drug Requests**

New entries to the WHO Herbal Dictionary are mainly taken from adverse reaction reports sent from member countries to *the* Uppsala Monitoring Centre and from IMS Health data.

We provide a service called 'New Drug Request' which makes it possible for customers to propose new entries to the dictionary.

To enter a drug in the dictionary you need to provide us with some basic facts about the requested drug. If you request a large number of entries you might prefer to enter the request in an electronic Excel format. Contact the UMC for more information.

Please notice that the entry of herbal product information is less straightforward than conventional products. Sometimes an investigation needs to be done to identify the content of the product, and sometimes new plant species need to be added. This process takes more time than with conventional products.

To request an entry please write to <u>newdrugs@umc-products.com</u>.

### **User Group**

As a WHO Herbal Dictionary user you will be invited to the WHO Drug Dictionary User Group activities. We have a number of face-to-face meetings per year where we discuss future development and issues and problems with the dictionary or UMC services.

### The User Group Portal

A portal dedicated to the WHO Drug Dictionary and WHO Herbal Dictionary users has been set up at <a href="http://usergroup.umc-products.com/">http://usergroup.umc-products.com/</a>.

The User Group Portal is designed to:

- introduce the WHO Drug Dictionary and the WHO Herbal Dictionary to new customers
- support experienced customers with the latest updates
- keep a library of articles and documents related to the User Group
- advertise forthcoming User Group Meetings
- provide a forum for discussion among subscribers

We hope you will find this a useful way to keep up-to-date with the WHO Herbal Dictionary.

# Introduction to the WHO Herbal Dictionary

### Sources of substances and drug names

The primary name source for **non-proprietary names** of herbal substances is the accepted scientific name of the plant. The naming of the plants is undertaken in collaboration with Royal Botanic Gardens, Kew, UK.

National drug lists, selected by the countries participating in the WHO International Drug Monitoring Programme, or international reference books are used as sources for **proprietary names**, ie trade names of drugs.

#### Structure of tables and fields

The WHO Herbal Dictionary is based on the same format and the same general principles as the WHO Drug Dictionary. This section describes the fields that are used - slightly differently - in the two dictionaries.

### **Herbal ATC flag**

The WHO Drug Dictionary uses the field 'Official ATC code' in the Therapeutic Group table in the C format, and the table DDA in the B formats in order to differentiate between ATC assignments that are included in the official ATC Guidelines and entries that have been given individual ATC assignment by UMC staff. In the C format official ATC codes are marked by a Y next to the ATC code and ATC codes set by *the* UMC are marked with N. In the old B format the official codes are flagged with a \*.

In the WHO Herbal Dictionary the 'Official ATC code' field has a similar meaning.

- If a product is coded with an HATC code that is included in the official HATC guide it will be marked with a H which stands for 'herbal'.
- If the HATC code is unofficial it will be marked with a U which stands for 'under assessment'. The U code means that the code is available in the HATC guideline, but for other active ingredient(s). The HATC code is under assessment and may be added in future versions of the HATC guidelines.

The official herbal ATC codes are identified by an 'h' – meaning herbal. The provisional HATC codes are identified with a 'u' – meaning under assessment.

Please note that if you use the combined WHO Herbal Dictionary/WHO Drug Dictionary you will find both the Herbal ATC and the conventional ATC in the look-up table ATC Code (in C) and INA (in B).

### **Drug Code**

The Drug Code is a hierarchical code used in WHO Drug Dictionary, WHO Drug Dictionary Enhanced and WHO Herbal Dictionary; it consists of Drug Record Number, Sequence 1 and Sequence 2.

The Drug Code is available in the table Medicinal Product in the C format and the table DD in the B formats.

For conventional medicinal products the Drug Record Number identifies the active ingredient, or unique combination of active ingredients, Sequence 1 identifies the salt or the ester of the active ingredient and Sequence 2 identifies a specific drug name.

Herbal products in WHO Herbal Dictionary, WHO Drug Dictionary and WHO Drug Dictionary Enhanced use the fields in a corresponding way. The Drug Record Number is used to identify the plant(s) instead of the ingredient(s), and Sequence 1 is used to identify plant parts or extractions instead of salts and esters.

For example, this means that Atropa belladonna is given a Drug Record number – 015687, the 'root dry extract' of Atropa belladonna is given the Drug Record Number 015687 and the Sequence 1 03. In the example below Tremoforat is the trade name of a product that contains the dry extract of the root of Atropa belladonna.

01568701001 ATROPA BELLADONNA

01568703001 ATROPA BELLADONNA ROOT DRY EXTRACT

01568703002 TREMOFORAT

#### The CAS number field

The field CAS number in the table SUN (C format) and BNA (in B format) contain the number from Chemical Abstract System. The herbal substances are coded with the Herbal Code Number – HCN.

The CAS/HCN number is the unique key in the B format. It is used to link the substance to the product.

In the C format the CAS/HCN field is mainly a reference field.

You do not have to make any modifications to your systems because of the differences between the CAS and the HCN codes. The inherent meaning of the HCN code can be useful for advanced users of the WHO Herbal Dictionary.

The HCN has the following structure:

The first two positions give you information about the type of entry:

- All substances starting with 90 96 are plants with specified genus and specie, e.g. Atropa belladonna
- All substances starting with 97 are 'NOS entries' substances coded on a very unspecific level, such as Herbal NOS, Herbal Extract NOS or as a common name such as Ginseng NOS, which can be any plant reported as ginseng. This category is kept to a minimum and is only used when no more information is available.
- All substances starting with 98-99 are coded on the botanical genus level. e.g. Echinacea spp.

Positions 3-5 identifies the plant.

Positions 6-8 identifies the plant part. The plant parts follow a standardised code list – see the appendix

If the positions are 000 there is no information about the plant part.

Positions 9-10 identifies the extraction type. The extracts follow a standardised code list – see the appendix.

If the positions are 00 there is no information about extraction type.

Example 1. The plant is Atropa belladonna, but no information is available about plant part or extraction type.

9008800000 ATROPA BELLADONNA

Example 2. The plant is Atropa belladonna, extract. No information is available about the plant part. 9008800003 ATROPA BELLADONNA EXTRACT

Example 3. The plant is Atropa belladonna, root dry extract 9008800502 ATROPA BELLADONNA ROOT DRY EXTRACT

### **Product Type**

All products in the WHO Herbal Dictionary are flagged as '002' which stands for 'Herbal Remedy'.

# Appendix.

## Standardized list of plant parts used in the Herbal Code Number (HCN)

# Standardized list of extraction types used in the Herbal Code Number (HCN)

1 LIQUID EXTRACT 2 DRY EXTRACT 3 **EXTRACT** 4 FLUID EXTRACT 5 **TINCTURE** 6 **BUTTER** 7 OIL 8 JUICE 9 **SYRUP**  $\mathsf{WAX}$ 10 11 **BALSAM MUCILAGE** 12 13 **STARCH** TAR 14 15 WATER EXTRACT **POWDER** 16 VINEGAR EXTRACT 17 18 **ESSENTIAL OIL** 19 ETHANOL EXTRACT 20 **PASTE** ACETONE EXTRACT 21 22 **OLEORESIN** 23 RESIN 24 METHANOL EXTRACT