Welcome to the WHO Drug Dictionary

This document is a guide to the general features of the WHO Drug Dictionary. You will get 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.

Some basic facts about the WHO Drug Dictionary:

– Essential information on drugs from all major markets
– Easy reference to both single- and multiple-ingredient drugs
– A Medicinal Products dictionary compatible with other major software
– Record numbers for linking and grouping information
– Anatomical Therapeutic Chemical classification (ATC) used throughout

On December 31, 2002, the WHO Drug Dictionary contained:

45 457	proprietary drug names, of which
29 078	single-ingredient drugs
16 379	multiple-ingredient drugs
9 395	chemical substances.

The WHO Drug Dictionary is unique. It is an international classification of drugs providing proprietary drug names used in different countries, together with all active ingredients and the chemical substances with unique reference numbers.

The hierarchical record number system allows for easy, flexible information retrieval. Drugs are classified according to the Anatomical-Therapeutic-Chemical classification (ATC) 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.
New drug names are routinely classified and added, but at a small cost it is possible to have drugs entered on request within 3 working days. Drugs are not deleted from the dictionary, although the products may no longer be on the market.

Drug information has been entered into this database since 1968, as part of the WHO Programme for International Drug Monitoring. The database now covers drugs from over 70 member countries of the Programme and some countries no longer existing (e.g. German Democratic Republic). Drugs recorded are those which have occurred in Adverse Reaction reports, but as all drugs taken by patients are included (whether they are suspected of having caused the reaction or not), the database covers most drugs used in countries in the Programme. The data is taken from official data from drug regulators, national drug compendia or other trustworthy sources. An increasing number of companies and regulators submit files with product data when products are launched on the market, which means that the entries get into the dictionary faster.

The WHO Drug Dictionary is currently being enhanced to accommodate commonly used herbal and traditional medicines. This is a formidable undertaking in view of the vast quantity of combinations available and the difficulties involved in having them appropriately classified. The UMC has in the past years done extensive work in the area of herbal nomenclature and classification, so the framework for managing these entries has already been created.

In order to make our service optimal, we welcome user comments and suggestions.

What You Get

Deliverables

The WHO Drug 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".

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 a 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 – drugdictionary@who-umc.org.

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".

Additional Services

New entries to the WHO Drug Dictionary are mainly taken from adverse reaction reports sent from member countries to *the* Uppsala Monitoring Centre.
We also have a service called 'New Drug Request' where it is possible for customers to come in with proposals for new entries to the WHO Drug Dictionary. This service has two options - regular updates and expedited updates.
To enter a drug in the dictionary you need to provide us with some basic facts about the requested drug – see the form at the end of this document. 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.

If you choose the regular service you will get the drug coded in the next quarterly release of the dictionary unless you have provided the information too close before the production of the dictionary. After you have made a request you will get a reply telling you when you can expect the entry to be added to the dictionary. If a request can't be added because of incorrect information, lack of adequate sources or if it is already coded, you will be informed.

If you chose the expedited service the UMC will enter the request within three days and the data will be sent to you. The data will also appear in the next quarterly release of the dictionary. For the expedited service we will charge you an hourly fee.

User Group

As a WHO Drug Dictionary user you will be invited to the 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 the UMC services.

The UMC has a WHO Drug Dictionary Support service that you will have access to as a subscriber. There is also an e-mail based discussion group where all users are welcome to ask questions, discuss specific issues and suggest new features. It is also a channel through which the UMC can communicate news like new documents, clarifications and coming User Group Meetings.

Introduction to the WHO Drug Dictionary

The WHO Drug Dictionary is a computer register containing information on all drugs mentioned on adverse reaction reports submitted by countries participating in the WHO International Drug Monitoring Programme from 1968 onwards. This makes the WHO Drug Dictionary a unique source of drug names from all major pharmaceutical markets - of both single and multiple ingredient drugs.

A new format of the WHO Drug Dictionary has been available from 2002. During a transition period both the old formats will be produced. The new format is known as the C Format and the old formats are known as A and B. Any new customer should implement the C Format.

Sources of substances and drug names

Sources of **non-proprietary names** are: the INN (International Non-proprietary Names, WHO) publications of nationally approved agencies (e.g. USAN) and well-known reference books, such as the Martindale - The Complete Drug Reference and the Merck Index.
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**.

Record number system

Drug Code and Medicinal Product ID

The **Medicinal Product ID** is the unique identification number in the C Format. The Medicinal Product ID is just a numeric name of a product, and has no intrinsic meaning. The ID identifies a Medicinal Product which is the product as it is marketed in a specific country. A Medicinal Product ID identifies a unique combination of the following data fields:

- Medicinal Product Name
- Name Specifier
- Market Authorisation Holder
- Country
- Strength (amount and unit of active ingredient/s)
- Dosage form (Available as Pharmaceutical Form in the Pharmaceutical Product table)

As an example a product called X, which is available both in a regular form and in a sustained release form. Sustained release would be the Name Specifier. Both products are available in capsules and in tablets. Capsules and tablets are available in 500 mg and 750 mg. All products are available in several countries. Each of these individual products would be assigned an individual Medicinal Product ID.

The **Drug Code** has an intrinsic meaning, it identifies a substance (or a combination of substances), a salt or an ester of the substance and the name of a product. This coding system was introduced when the WHO Drug Dictionary was a dictionary of drug names. In the C format a name can be repeated, but the Drug Code system will be retained and the same logic will be applied.

A Drug Code consists of a **Drug Record Number** (DRECNO) and two **sequence numbers** (Sequence 1 and Sequence 2).

A Drecno identifies a generic identification level. In most cases the generic identification level is the one active ingredient, but it can also identify a unique combination of active ingredients.

Sequence number 1 identifies the salt or the ester of the active ingredient in single ingredient Drecnos. The number '01' identifies the base substance, without any salt or ester, and values above '01' will identify salts and esters. Drecnos which identify more than one active ingredient will have only one Sequence 1 with value '01'.

Sequence 2 identifies thePreferred Name or Trade Names. The entry with Sequence 2 value '001' identifies the name of the generic Drecno level the Preferred Name. In single ingredient Drecnos this will be the INN name, in multi-ingredient Drecnos it will be the trade name of the first product with the given combination that was entered into the Dictionary.

The identification levels are useful for querying and analysis of aggregated data. The Drecno can be used to identify all products with the same active ingredient(s), the Drecno + Sequence 1 to identify different salts/esters and the Drecno + Sequence 1 + Sequence 2 to identify a trade name.
The **same Drug Name and the same Ingredients** get the same Drug Code. Note that Name Specifier is not included in the Drug Name, ie Alvedon and Alvedon Forte has the same Drug Code. If the same trade names are used by different MAHolders for the same ingredients they will have the same Drug Code, but they all have unique Medicinal Product IDs.

Example showing the coding system of the WHO Drug Dictionary:

Single ingredient drugs:

MP ID	Drug	Name+Name Specifier	DRECNO	SEQ1	SEQ2
	1	Ampicillin	000005	01	001
	2	Ampicillin sodium	000005	02	001
	3	Acilin for injection	000005	02	002
	4	Becillin for injection	000005	02	003
	5	Becillin tablet	000005	02	*003*
	6	Becillin	000005	02	*003*
	7	Ampicillin trihydrate	000005	03	001
	8	Cecillin	000005	03	002

Multiple ingredient drugs:

MP ID	Drug name	DRECNO	SEQ1	SEQ2
9	Ampiclox	001903	01	001
	Ampicillin			
	Cloxacillin			
10	Sinteclox	001903	01	002

Deleted entries

In rare cases an entry in the dictionary will be deleted; if an entry has been included with incorrect substance(s) or salt/esters –and if it also appears in the dictionary with the correct composition. In these cases a list will be produced with the old, now deleted Medicinal Product ID and the new.

Definitions - Main Files

Medicinal Product

*A **Medicinal Product** is a product intended to be administered to human beings or animals for treating or preventing disease, with the view to making a medical diagnosis or to restore, correct or modify physiological functions.* [Definition from the European Economic Community - Directive 65/65 EEC - modified]

This is the main file in which most information about the product is recorded. A Medicinal Product entry represents one product as it is marketed in a specific country. The Medicinal Product file contains the unique identifier and the Trade Name. It also contains information about the company responsible for the product internationally and the company that markets the product in this given country, the Market Authorisation Holder. The concept Name Specifier is often used as a synonym to Strength, but it can also be used for text strings like "Forte" or "Sustained Release".
The type of product is also recorded, a majority of the entries are regular Medicinal Products, but an increasing number of Herbal Remedies and Vaccines are recorded.

Pharmaceutical Product

The WHO Drug Dictionary format allows for the use of a two-level structure of the product information. Some Medicinal Products contain more than one dosage form or more than one type of the same dosage form. For example: a suppository packaged together with a cream; oral contraceptives with three different types of tablets. The two level structure makes it possible to record both the Medicinal Product – the Product Name, Market Authorization Holder etc, and the Pharmaceutical Products with their individual ingredients.

Therapeutic Group

Each Medicinal Product can be coded to one or several Therapeutic Groups. The Therapeutic grouping uses the Anatomical Therapeutic Chemical classification (ATC).
For more information about the ATC see the section "Therapeutic Group".

Ingredient

Each Pharmaceutical Product contains one or several Ingredients. In this file there is a link to the Substance database and the amount of each ingredient can be recorded here.

Definitions – Data Fields

Medicinal Product

Medicinalprod_Id /Drug record number /Sequence number 1 /Sequence number 2

For a description of the coding system please see section "Record Number System".

Generic

A Yes or No value. A Yes signifies that the drug entry is a generic level – a Preferred Name or a synonym to a Preferred name. E.g. Paracetamol and Acetaminophen are both flagged as generic.

Drug name

Preferred Name

Drugs containing the same active ingredient(s) are found by reference to **Preferred name** of the drug. In the case of single ingredient drugs, the INN (International Non-proprietary Name) in English is the Preferred name, but where no INN exists another non-proprietary name is used. For multiple ingredient drugs, the first reported Drug Name of a given ingredient combination is chosen as the Preferred name. Any subsequently reported drug having the same combination of ingredients is sorted under the Preferred name. For any chemical substance that is an ingredient in a multiple ingredient drug, reference is given to all Preferred names where this substance is a constituent.
A Preferred Name is the text in the Drug Name field where the Sequence 2 equals "001".
For more information about the coding system, see the document "Codes and IDs"

Medicinal Product Name

A name used in the identification of a Medicinal Product. It can be a made up name, a proprietary name or a non-proprietary name. We enter product names as much like the original name as possible within our principles of coding, eg replacing special characters like ö, ü and ä with oe, u and ae. We try to follow the registered trade marks as much as possible.
'Medicinal Product Name' is a synonym to 'trade name'.
A Medicinal Product Name is the text in the Drug Name field where the Sequence 2 is higher than "001".

Name Specifier

The Name Specifier is an additional element added to the Medicinal Product Name in order to distinguish Medicinal Products with the same Medicinal Product Name.
These Name Specifiers can be based on any possible property of a Medicinal Product, e.g. "Sustained Release", a reference to dosage form or strength or even be a proprietary combination of letters and/or numbers.
As a rule, pharmaceutical forms are not included in the Medicinal Product Name. However, in some cases entered in the old system this has been necessary in order to avoid ambiguity, for example where different pharmaceutical forms contain different salts of a substance. In the new system we have Pharmaceutical Form as a separate field.
The concept and the term Name Specified is also taken from the Directive 65/65 EEC.

Country

The country in which the product is marketed.

Company /MA Holder

The recorded Company and Market Authorization Holder of a drug is the one given in the source where the drug name was found. The Marketing Authorisation Holder is in possession of the licence or marketing authorisation for a Medicinal Product within a given Country. The Company, or Main Company is the owner of the product world-wide. The Company is frequently also the holder of the Market Authorisation of the Medicinal Product.

Source code /Source country /Source year

These fields identifies the source from where the information about the drug entry has been taken. It is a National Drug Compendium or other reliable sources. The country of the source and the year of the source are also recorded.

Product type

A Product Type can be a regular Medicinal Product, a Herbal Remedy, a Vaccine etc.

Product group

The Product Group is a way to group products that are owned by the same company, contains the same substance(s) but is marketed under different names in different countries.
Note that this feature is NOT introduced yet. The file is prepared for the feature and it will be introduced when the User Community prioritises it.

Create date /Date changed

The date when the drug was first entered and the date of the latest change.

Pharmaceutical Product

The new format allows for the use of a two level structure of the product information. Some Medicinal Products contain more than one form, or more than one type of the same form. For example: a suppository is packaged together with a cream; oral contraceptives often contain three different types of tablets. The two level structure makes it possible to record both the Medicinal Product – the product name, Market Authorization Holder etc, and the Pharmaceutical Products with their individual ingredients.
It is however possible to connect the ingredients directly to the Medicinal Product because Medicinal Product ID is included in the Ingredient file.

Pharmaceutical Form

The pharmaceutical form is the form in which a Pharmaceutical Product is presented in a Medicinal Product. It is a synonym to galenic form.
EXAMPLE: tablet, capsule, syrup, suspension, cream.

Number of ingredients

The number of ingredients of this Pharmaceutical Product.

Create date

The date when the Pharmaceutical Product entry was created.

Therapeutic Group

ATC-code /Official ATC code

For coding of the therapeutic use of drugs, Anatomical Therapeutic Chemical classification (ATC) is used. Each drug is assigned at least one ATC-code. Official ATC-codes and instructions for coding are issued by the WHO Collaborating Centre for Drug Statistics Methodology, Oslo Norway.
Drug entries in the WHO Drug Dictionary that have not been assigned official ATC-codes by the Oslo Centre, have received provisional codes by *the* Uppsala Monitoring Centre staff. In some instances drugs have been assigned provisional codes in addition to the official ATC-codes, to meet the needs for classifications in the WHO Programme. In the C Format official ATC-codes are marked by an 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 *.
Each Medicinal Product is coded with the ATC code of its most common use, sometimes more than one is needed but we try to limit the numbers of ATC codes as much as possible. This allows for a more flexible analysis and comparison of the drugs using the ATC classification. By using the ATC code assigned on the Preferred Name level a broader range of indications is covered, whereas using the ATC codes assigned on the product level limits the selection to the individual products for which a particular ATC reflects the product's main use.

For an example, see table below.

Type	Name	ATC code	Use	Form
Preferred Name	Atropine Sulfate	A03BA, S01FA		
Trade name	Atropine NM Pharma	A03BA	Antispasmodic	Injection substance
Trade name	Atropine Novartis	S01FA	Mydriatic and Cycloplegic	Eye drops

For general information about the ATC classification, see the document "The ATC Classification".

Create date

The date when the Therapeutic Group entry was created.

Ingredient

Substance_Id

The Ingredient file contains a link to the Substance file in which the name of the Substance can be found.
Only active substances are included (no excipients, colouring agents, filling agents etc.) The distinction between auxiliary ingredients (help substances) and active ingredients are not always clear, and the legislation varies between countries. Therefore auxiliary substances may be coded as active ingredients.
Substances are entered according to the source of information used. Substance names are always given in English.

Quantity /Unit /Strength

The amount/quantity of a substance is entered together with the unit (mg, ml etc).
The Strength is the amount and unit of the active ingredient(s).

Create date

The date when the Ingredient entry was created.

the UPPSALA MONITORING CENTRE

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PROPOSED NEW ENTRY TO THE WHO DRUG DICTIONARY

.Reporter_____

.Company_____

Address

._____   _____

._____   _____

.Country _____

Fax No. _____

.

Please mark the desired alternative below:

Regular Updates	**Expedited Updates**
- **Update in regular quarterly input**	- **Immediate update**
- **No separate info on new entry**	- **Info sent by fax or mail**
- **No charge**	- **Charge 1000 SEK/hour, min. 500 SEK**
[ ] check if required	**[ ]** check if required

DRUG NAME			
Name Specifier			
COMPANY			
MaHolder			
SOURCE OF DRUG			
NAME (REFERENCE			
BOOK ETC.)			
ACTIVE INGREDIENTS			
Form			
Amount			
Unit			
THERAPEUTIC USE			
(ATC-CODE IF			
AVAILABLE)			

Drug names and active ingredients must be identifiable in international reference sources. If available, INN should be used for substances.