Uppsala Monitoring Centre

– Building a global safety culture

2020

# What's New in WHODrug

March 1, 2020

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Uppsala Monitoring Centre (UMC) is constantly developing the WHODrug portfolio, to meet the needs of users and to ensure regulatory compliance. This document outlines the most important recent developments, with a short explanation of why they have been made and how they will affect WHODrug users. It also covers some of the revisions to the content of WHODrug.

The scope of WHODrug increases continually, and the March 1, 2020 release includes more than 506,000 unique product names, and more than three million medical products, from 150 countries.

Descriptions of the core concepts of WHODrug, such as Drug Code and ATC classification, can be found in the WHODrug User guide, available on the UMC website.

## WHODrug Global

To best facilitate the use of WHODrug Global the licence not only includes the entire dictionary of drugs (now available in both English and in Chinese), but also WHODrug Insight, WHODrug Change Analysis Tool (CAT), WHODrug Change Request, and WHODrug Standardised Drug Groupings (SDGs).

## Final release of WHODrug Enhanced

WHODrug Enhanced is currently being phased out in favour of the standardised and more comprehensive WHODrug Global dictionary, required by both the U.S. FDA and the Japanese PMDA. In September 2020 the final WHODrug Enhanced version will be released, and from March 2021 the only dictionary available from UMC will be WHODrug Global.

For questions or support in moving from WHODrug Enhanced to WHODrug Global, please view our WHODrug Global Transition plan on the UMC website for more practical information on how to proceed, or contact WHODrug@who-umc.org.

## WHODrug Global Chinese

UMC released the first foreign language version of WHODrug Global on September 1 2019. WHODrug Global Chinese includes drug information available in Chinese from credible references, and features the full ATC hierarchy in Chinese. This version is seamlessly compatible with the original English WHODrug Global. Each record in WHODrug Global Chinese has an equivalent English record in WHODrug Global sharing the same Drug Code.

WHODrug Global Chinese provides standardized and quality-assured information for coding directly in Chinese. It enables international collaboration with instant translations of English and Chinese drug information.

Using the two language versions of WHODrug Global combined will simplify the regulatory submission process both inside and outside China.

Since 1 September 2019, subscribers can access WHODrug Global Chinese by implementing the dictionary files in coding applications or via our online browsing tool, WHODrug Insight. The Chinese version adopts the same dictionary file structure and is delivered as a separate but complete file package as part of the WHODrug Global subscription. A detailed guide is available to support implementation. WHODrug Global Chinese is continually updated and its new releases follows the same annual schedule, on March 1 and September 1.

Since the Chinese version of WHODrug Global has been made available to users, the UMC web has also been enriched with general information about the dictionary in Chinese language.

## WHODrug Koda

WHODrug Koda is an automated coding engine custom-built by UMC and launched in March 2019. The service is specifically designed for increasing the efficiency, consistency and quality of drug coding, with the end goal of safer use of medicines.

WHODrug Koda is retrained and optimised by UMC for each new version of WHODrug Global. For the March 2020 release, both the drug name coding and ATC selection provided by WHODrug Koda has been improved, based on user request.

All WHODrug users can evaluate the performance of WHODrug Koda by using a trial version of the WHODrug Koda web application. Please refer to the UMC website or contact UMC for more information.

### Key features of WHODrug Koda

- Combines the latest technologies (such as machine learning and automated algorithms), best practice agreed by industry, and UMC's accumulated insights on drug coding.
- Enables automated coding of drug names, including non-unique names.
- Provides automated ATC selections according to the latest regulatory recommendations.
- Trained and updated by the UMC.
- Integrable in existing coding tools or similar via an Application Programming Interface (API) service.
- Available as a web application, easily accessible via the UMC website.
- Available as an add-on to an existing WHODrug Global subscription.


## New active substances

In order to meet the demands of WHODrug users and to keep WHODrug current and comprehensive, it is continually updated with new active substances, for example by monitoring International Nonproprietary Names (INNs) lists of new drugs.

The active substances are generally added with a globally recognised non-proprietary name and herbal substances with their accepted scientific name. As for all records available in WHODrug, each new active substance has been assigned at least one ATC code.

## New Umbrella records

Umbrella records represent defined groups of drugs rather than specific drug names. Umbrella records are used for coding imprecise verbatim, when coding to specific drug names is not possible.

Based on requests from WHODrug users, ten new Umbrella records have been included in WHODrug during the last year.

***Table 1.*** *Umbrella records included in WHODrug during 2019.*

| Drug Code | Umbrella record | ATC |
|---|---|---|
| 90152601001 | Testosterone boosters | A14, G03B |
| 90152701001 | BET inhibitors | L01XX, L04AX |
| 90152801001 | CD40 ligand inhibitors | L04AA |
| 90152901001 | Gamma-secretase inhibitors | N06DX, L01XX |
| 90153001001 | Proteasome inhibitors | L01XX |
| 90153101001 | IDH mutant inhibitors | L01XX |
| 90153201001 | Protein arginine methyltransferase 5 (PRMT5) inhibitors | L01XX |
| 90153301001 | GI Cocktail | A02A |
| 90153401001 | SHP2 inhibitors | L01XE |
| 90153501001 | Immune checkpoint inhibitors | L01XC, L01XE, L01XX |

Additional alterations have been made to a group of Umbrella records for consistency.

- **Anesthetics, local**: Several Umbrella records with similar names, spelling and ATC codes, but with the same intrinsic meaning (*Anaesthetics, local; Local anesthetics; Other local anesthetics; Anaesthetics for topical use; Anesthetics for topical use)* has been merged into one Umbrella record, *Anesthetics, local,* with several ATC codes.
- **Anesthetics, general**: *Other general anesthetics* has been deleted and replaced with *Anesthetics, general* to increase consistency.
- **Anesthetics**: The Umbrella record *Anaesthetics* has been deleted and replaced with *Anesthetics* to harmonise with the spelling of ATC code texts from the WHO Collaborating Centre for Drug Statistics Methodology.
- **Chemotherapeutics**: *Chemotherapeutics* and *Other chemotherapeutics* has been deleted and replaced with *Antineoplastic agents* since chemotherapy usually refers to cancer treatment and not the historical meaning of "any use of chemicals to treat any disease".
- **Sodium**: The Umbrella record *Sodium* has been removed since the name exists as an active substance in WHODrug.

# ATC assignments

### Annual ATC revision

Every year the ATC assignments in WHODrug are revised to ensure compliance with the ATC guidelines from the WHO Collaborating Centre for Drug Statistics Methodology. Alterations, deletions, and additions of ATC codes and texts in their guidelines will affect the ATC classification of trade names and substances in WHODrug Global. For all ATC changes, please go to: www.whocc.no/. The major changes in WHODrug for the ATC revision of 2020 are described below.

### New ATC codes

100 new 5th level ATC codes were added to new substances/substance combinations. Two new 4th level ATC codes were implemented, B06AX Other hematological agents and N02CD Calcitonin gene-related peptide (CGRP) antagonists.

### ATC code name change

Seven 5th level ATC codes have been updated to a more specific name/less specific name. One 4th level ATC code, B06AB, changed name from Other hem products to Heme products.

### Additional ATC assignments

During 2019 more than 50 substances and related medicinal products have been updated with additional ATC codes to reflect new indications of use. (E.g. amitriptyline is assigned N02BG in order to reflect the pain related indications of use.)

# New WHODrug Standardised Drug Groupings (SDGs)

The SDGs are unbiased search strategies for creating groups of medicines of interest, maintained and continuously reviewed by UMC to ensure consistency with WHODrug, the ATC classification, and user requirements.

As of the March 1, 2020 release of WHODrug, there are 49 main SDGs, and 478 drug groupings in total. The major changes are listed below:

- A new SDG, Drugs for pulmonary arterial hypertension (PAH), was developed, containing subgroups mainly based on mechanism of action.
- A new SDG, World Health Organization Model List of Essential Medicines was developed, containing all substances listed in the WHO Model list of Essential Medicines.

# New developments in WHODrug Insight

### WHODrug Standardised Drug Groupings (SDGs)

The SDGs are updated with new substances for every release of WHODrug. The inclusion of a substance in a specific SDG is always based on information from reliable references.

Upon request from WHODrug SDG users, these references are now displayed in WHODrug Insight for review purposes.

### WHODrug Global Chinese

During the year, WHODrug Insight has been updated to fully support the display of the new Chinese language version of WHODrug Global. It is now possible to search for drug information in both English and Chinese and to view drug names in both languages side by side, enabling efficient drug coding and review.

### Advanced search help

In Insight it is crucial that the user finds the correct drug name, even if the searched drug name is misspelled or if there are similar drug names in WHODrug. In addition, the searches need to be fast and efficient.

To support this, UMC have introduced a "did you mean" function in Insight, for when the searched drug name is misspelled, or if there are similar drug names in WHODrug.

In addition, Insight offers immediate search support in the product name search field. The "type ahead" function has been improved to always present fast and relevant suggestions.

# Change Request

Would you like to include a new or missing medicinal product in WHODrug? Or do you have suggestions for modifications of an existing record? The WHODrug Change Request is a service that offers an easy way of submitting your suggestions to UMC. The Change Request application can be utilised by users with a valid personal UMC username.

From the release of the first WHODrug Global Chinese, the WHODrug Change Request service also supports requests for Chinese drug names.

## Dictionary files

To enable installation of WHODrug Global, the dictionary files are provided in a file package available in the customer download area to the appointed delivery contact within user organisations. From September 2019, the WHODrug Global files are provided in two file formats, Fixed Width format (.txt), and CSV format (.csv) to facilitate the loading of information depending on various system setups.

For the C3 format, it is now possible to track deleted and replaced MPIDs in a new file, called MP Cumulative Changes.

## WHODrug article

Last but not least, UMC is delighted to announce the publication of the article **WHODrug; a global, validated and updated dictionary for medicinal information** in the journal *Therapeutic Innovation & Regulatory Science*.

This article is the result of a need for a description about the history, content and capabilities of the global medicinal dictionary WHODrug and how to use it in clinical trials and post marketing safety. We believe that this article will fulfil its purpose as an important source of information about WHODrug for stakeholders within the pharmaceutical industry and academia, as well as for regulators.

## Questions?

For any questions, please do not hesitate to contact UMC at whodrug@who-umc.org.

## INSPIRE. ENGAGE. TRANSFORM.

Uppsala Monitoring Centre advances the science of pharmacovigilance and inspires patient safety initiatives all over the world. As an independent, non-profit foundation, we engage stakeholders who share our vision and collaborate to build a global patient safety culture. As a leader in the research and development of new scientific methods, we explore the benefits and risks of medicines to help minimise harm to patients, and offer products and services used by health authorities and life-science companies worldwide. Our unique expertise makes us an organisation with the capacity to transform patient safety from an ambition into a reality. For almost 40 years, we have provided scientific leadership and operational support to the WHO Programme for International Drug Monitoring, expanding the global pharmacovigilance network to reach more than 95% of the world's population (www.who-umc.org).

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