



Uppsala
Monitoring
Centre

– Building a global safety culture

2017

What's New in WHODrug

March 1, 2017

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What's New in WHODrug March 1, 2017

UMC is constantly developing the WHODrug portfolio, to meet the needs of users and to ensure regulatory compliance. This document outlines the most important new developments in WHODrug, with a short description of why they have been made and how they will affect you as a user. It also covers some of the revisions that have been made to the content of WHODrug.

The scope of WHODrug increases continuously, and the March 1, 2017 release includes almost 400,000 unique product names and 2.8 million medical products, from 141 countries.

Explanations of the core concepts of WHODrug, such as Drug Code and ATC classification, can be found in the WHODrug User Guide, available in the User Area of the UMC website.

Please do not hesitate to contact us at whodrug@who-umc.org!

New UMC website

The new UMC website, www.who-umc.org, provides information on all the activities of the Uppsala Monitoring Centre. You can find detailed information about the WHODrug portfolio, such as subscriptions, training offers and validation requests.



New WHODrug User Area

By logging in to the new User Area, you can access all WHODrug tools, the delivery platform, webinars, user group meeting information and support documentation - all by a single login. The login details used for the old website's user group portal are no longer valid, instead please use your e-mail address to create a new password on the login page. If you have problems with your access, please contact sales@who-umc.org.

New download area

To improve the service to subscribers, UMC have created a new area for downloading WHODrug files. This aims to give you a better overview of your latest dictionary releases as well as any additional requested files. For your convenience, all files belonging to the same WHODrug version, format and dictionary type will be available in one package. To access the download area, login to the User Area at the UMC website, www.who-umc.org.

New WHODrug formats

We are very excited to be able to offer the new WHODrug B₃ and C₃ formats for the first time on March 1, 2017. These improved formats provide a harmonised WHODrug structure and greatly facilitate compliance with the CDISC SDTM standard. For all B₃/C₃ information, please visit the WHODrug User Area.

WHODrug Software Certification Programme

The WHODrug Software Certification Programme enables developers to create software systems which are fully compatible with WHODrug. To obtain a certification within this programme, software suppliers are required to demonstrate that their system displays the WHODrug data at its full strength.

WHODrug Software Certification Programme for B3 and C3

UMC is introducing an updated version of the WHODrug Software Certification Programme, compatible with the B3 and C3 formats. The programme has been updated with new documentation (e.g. sample data, test cases and requirements), and will be available for enrolment during the first half of 2017.

WHODrug Software Recertification Programme

For software systems already certified for handling the B2 and/or the C format data, the WHODrug Software Recertification Programme was launched in November 2016.

For more information, please contact us at: WHODrug@who-umc.org.

New functionalities in WHODrug Insight

WHODrug Insight, the new WHODrug browsing tool, was developed to increase efficiency when coding and analysing medications in clinical trials and safety reports. An updated version was launched in 2016, taking account of changing user needs and feedback from expert users. WHODrug Insight has since continued to develop, and for the March 1 2017 release of WHODrug the following functionalities have been introduced.

New functionality: WHODrug CRT Japan

WHODrug Cross Reference Tool Japan (WHODrug CRT Japan) was created by UMC together with Ijoken, the maintenance organisation of the Iyakuhinmei Data File (IDF), and consists of a mapping between the IDF and WHODrug. WHODrug CRT Japan subscribers can now access these mappings in WHODrug Insight. To facilitate coding in Japanese, WHODrug Insight can now handle drug searches in Japanese.

New functionality: B2 and B3

From March 1st, 2017 all WHODrug Insight users will be able to use both the WHODrug B2 and B3 formats in WHODrug Insight. When coding to a specific WHODrug version, you should make sure this version and your chosen format are selected in WHODrug Insight.

Improved functionality: CDG

Results from searches made in WHODrug Insight can be exported, or saved and modified as a customised drug grouping (CDG). WHODrug Insight now has a new and improved functionality for creating CDGs. When creating a CDG there is an option to export the preferred records only, as in the SDGs, or an entire search result.

New functionality in WHODrug CAT

The WHODrug change analysis tool (CAT) facilitates the assessment of changes between two WHODrug versions. From March 1, 2017, CAT users can run a full change analysis between any WHODrug B2 version and the WHODrug B3 format. If you prefer not to use WHODrug CAT it is also possible to access all Drug Code changes from WHODrug B2 to B3 format in a txt file.

WHODrug CAT also makes it possible to update your standardised drug groupings (SDGs) to the WHODrug B3 format.

New version of the WHODrug User Guide

The WHODrug User Guide offers theoretical background information and describes the features of WHODrug. It can help you to get started if you are a new WHODrug user, but it can also be used as a reference for experienced users.

The WHODrug User Guide has been extensively revised and is now available and updated in accordance with the new features and concepts of the B₃ and C₃ formats.

The WHODrug User Guide, version 3.0, is available in the WHODrug User Area.

New version of the WHODrug Best Practices

The WHODrug Best Practices offer advice on the best ways to handle different coding scenarios.

A new chapter has been added on 'Essential Information for WHODrug Coding Review'. In many organisations a review of coded drugs forms part of several processes during a clinical trial. In some instances, the reviewer is not a coder and may not have in-depth knowledge of the different features of WHODrug. For this reason, we have added this chapter to set out some important facts, in order to achieve a more efficient review.

The WHODrug Best Practices, version 5.0, has also been updated to reflect the new characteristics of the B₃ and C₃ formats. It also is available on the WHODrug User Area.

New substances

WHODrug is continuously updated with new drug substances, ensuring the dictionary is as current as possible. During 2016, WHODrug was updated with new International Nonproprietary Names (INNs). As with all records in WHODrug, each new substance has been assigned at least one ATC code.

New increased granularity of vaccines

All vaccine substances and products in WHODrug have been reviewed, and to allow for more flexible analysis we have increased the granularity for the vaccines substances. The existing vaccine substances were unchanged and the granularity was implemented through addition of salts to the vaccine preferred bases.

Previous structure of vaccine substances

Disease/pathogen – Vaccine

New basic structure of vaccine substances

Disease/pathogen–Vaccine–Vaccine type–Vaccine specific properties*–(other properties)**

Table 1 Previous and new basic structure of vaccine substances (*if applicable)

The increased granularity generated changes to vaccine products. Information on the vaccine type and on vaccine properties have been added to vaccine products when specified in product labels. No changes have been made to vaccine products where the specific information could not be verified.

Product Name	Previous Ingredient (Drug Code)	New Ingredient (Drug Code)
VACCINO ANTIPNEUMOCATA	Pneumococcal vaccine (004966 01 033)	Pneumococcal vaccine (004966 01 033)
Cervarix	HPV Vaccine (067887 01 003)	HPV vaccine VLP rL1 2v (baculovirus) (067887 02 002)
Gardasil	HPV Vaccine (067887 01 002)	HPV vaccine VLP rL1 4v (yeast) (067887 03 002)

Table 2 Example of the new structure of vaccines

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 WHODrug products and substances.

For all ATC changes, please go to: www.whocc.no/. The major changes in WHODrug for the ATC revision of 2017 are described below.

New ATC code N02AJ

A new ATC code for opioid analgesics in combination with non-opioid analgesics, N02AJ, was introduced. As a result, a considerable amount of ATC reclassification (e.g. for products containing *paracetamol* and *codeine*) has been undertaken in WHODrug.

New ATC codes A10BJ and A10BK

Two new ATC codes for blood glucose-lowering drugs were introduced, A10BJ 'Glucagon-like peptide-1 (GLP-1) analogues' and A10BK 'Sodium-glucose co-transporter 2 (SGLT2) inhibitors'. These drugs were previously assigned the ATC code A10BX 'Other blood glucose lowering drugs, excl. insulins'.

ATC code change C07F

The 3rd level ATC code C07F changed its name to: 'C07F Beta blocking agents, other combinations' (it was previously named 'Beta blocking agents and other antihypertensives'). This resulted in changes to the corresponding 4th level ATC codes under C07F.

ATC review of multi-ingredient records

ATC codes of related multi-ingredient (i.e. salt and/or base differences) records have been reviewed and revised to ensure harmonisation of ATC classification in WHODrug, in preparation for the new B3/C3 formats.

Updates to the WHODrug Cross Reference ATC 5

WHODrug Cross Reference ATC 5 offers mapping between WHODrug Drug Codes and ATC 5th level codes. It is designed to simplify and rationalise ATC 5th level assignment when complying with regulatory demands, especially EMA requirements for article 57; xEVMPD submission.

WHODrug developments during 2016 which especially affected the Cross Reference ATC 5 are the addition of vaccine substances and the annual ATC revision.

Vaccines

The increased granularity of vaccine substances in WHODrug has optimised the ATC 5 mapping for several vaccine Drug Codes. Previously, WHODrug only included unspecific vaccine records, which often had several possible ATC 5th code levels. The new substances, with more detailed information, generally correspond to one specific ATC 5th level code.

Drug Record Number + Seq1	Substance Name	ATC 5 th level
065593 17	Meningococcal vaccine C conj	J07AH07 -meningococcus C, purified polysaccharides antigen conjugated

Table 3 Example of a vaccine and its 5th level ATC

ATC revision

Due to the annual ATC revision, Drug Codes affected by the ATC reclassifications have also had revised ATC 5th level codes. A majority of these changes are for Drug Codes with an ATC code under ATC N02-Analgesics.

New and revised SDGs

The SDGs are unbiased search strategies for creating lists of medicines of interest, maintained and continuously updated by the UMC. They are available, free of charge, to all WHODrug Insight users, and on request to all WHODrug Enhanced subscribers. More background, and specific information on inclusion/exclusion criteria for the separate SDGs can be found in the SDG User Guide provided in the SDG download package and in the WHODrug User Area.

As of the March 1, 2017 release of WHODrug, there are 45 main SDGs, and more than 320 drug groupings in total.

New SDGs

For the March 1, 2017 release of WHODrug five new SDGs have been developed:

- Antiarrhythmics
- Antiemetics and antinauseants
- Drugs acting on NMDA receptors
- Drugs interacting with UGT
- Radiopharmaceuticals

SDG changes

We continuously review the content of the SDGs to ensure they are consistent with WHODrug, the ATC classification and user requirements. The thorough review made for the March 1, 2017 release of WHODrug has resulted in major changes to some SDGs.

SDG	Change
Drugs for obstructive airway diseases	Revised and refined subgroup structure
Blood and related drugs	Revised and refined subgroup structure. Renamed.
Drugs for gastric acid related disorders	Renamed. Now includes all antacids.
Immunomodulators	Expanded, and with a new refined subgroup structure to cover the discontinued drug groupings.
Antithrombotic drugs	Revised, and now with a refined subgroup structure for Heparins.
Antineoplastics	Discontinued. The subgroups can be found in other SDGs
Biologicals	Discontinued. Most subgroups can be found in other SDGs
QT-prolongation	Discontinued.

Table 4 Example of some major SDG changes 2017

Several SDGs and subgroups have had a slight name change to harmonise the naming of SDGs.

An index of the SDGs and subgroups has been created in the SDG User Guide to help you to find the drug groupings you are interested in using.

SDGs in the B2 and B3 formats

The March 1 2017 release of the SDGs will be in the WHODrug B2 and B3 formats. This is the final SDG release in the B2 format. Existing SDGs will be updated alongside the WHODrug release plan, but only in the B3 format.

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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