Uppsala Monitoring Centre

– Building a global safety culture

2019

What's New in WHODrug

March 1, 2019

Contents

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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, 2019 release includes more than 480,000 unique product names, and more than three million medical products, from 149 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

The WHODrug Global package has been released since March 1, 2017. The aim of WHODrug Global is to standardise and streamline the release of the WHODrug family of products. By combining all WHODrug dictionaries types into one, and by releasing it twice a year, in March and September, UMC aims to facilitate the use of WHODrug data.

All WHODrug subscriptions have now been converted to WHODrug Global subscriptions, and with this the withdrawal of WHODrug Enhanced draws closer: it will continue to be produced in parallel with WHODrug Global until September 2020, when it will be discontinued.

For new studies starting after 15th March 2019, the use of WHODrug Global is required by the U.S. FDA. For ongoing studies that are regularly upversioned and are planned to end before 2020, the sponsor and CRO should decide together whether to upgrade to WHODrug Global or not. Ongoing studies that are regularly upversioned and are planned to end after 2020, should be upgraded to WHODrug Global when convenient. It is acceptable for studies that are not upgraded to stay on the initial version, but we recommend ensuring that it complies with regulatory expectations.

If your organisation has not yet moved from WHODrug Enhanced or WHODrug Enhanced and WHODrug Herbal, please view our WHODrug Global transition plan on the UMC website for more practical information on how to proceed.

Final release of the B2/C formats

In September 2018 the files of the B2/C formats of WHODrug were released for the last time. From the March 1, 2019 release, the dictionary is only being provided in the new B3/C3 formats. To learn more about implementing the WHODrug B3/C3 formats, regulatory expectations of using the new formats, and more, please visit the dedicated WHODrug B3/C3 formats section of the UMC website.

For organisations moving from the B2 to the B3 format, UMC recommends the use of the WHODrug Change Analysis Tool (CAT), featuring complete upversioning support functionalities. For example, a text file containing all Drug Code modifications between selected versions of the WHODrug B2 and B3 formats can be generated.

Currently, 26 software systems are fully compatible with WHODrug B3/C3 formats within the WHODrug Software Certification Programme.

New substances

Every release of WHODrug is updated with new active substances; for example, the new International Nonproprietary Names (INNs) are monitored and included in WHODrug. As for all records available in WHODrug, each new active substance has been assigned at least one ATC code.

During 2018 several requests concerning cancer vaccines were received. UMC decided to name them along the lines of the names of conventional vaccines in WHODrug, starting with disease or cancer type, followed by the word 'vaccine', e.g. Melanoma vaccine and Lung cancer vaccine.

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, one new Umbrella record have been included and one Umbrella record changed in WHODrug during 2018.

New Drug Code	New Umbrella Record	New ATC	Previous Drug Code	Previous Umbrella Record	Previous ATC
90150001001	MEDICAL DEVICES, WITHOUT SUBSTANCES	V07A	90150001001	MEDICAL DEVICES	V03A V07A
90152501001	CRYOTHERAPEUTIC AGENTS	C01EB, D11AX, L01XX, M02AX, N01B	NA	NA	NA

Table 1. *Umbrella records changed (Medical devices, without substances) and included (Cryotherapeutic agents) in WHODrug during 2018.*

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 WHODrug products and substances. For all ATC changes, please go to: www.whocc.no/. The major changes in WHODrug for the ATC revision of 2019 are described below.

ATC code change C09C/C09D (including lower levels)

The 3rd level ATC codes C09C and C09D changed their names to: Angiotensin II receptor blockers (ARBs), plain, and Angiotensin II receptor blockers (ARBs), combinations. They were previously named Angiotensin II antagonists, plain, and Angiotensin II antagonists, combinations. This resulted in no changes since the meaning is still the same.

New ATC codes

80 new 5th level ATC codes were added to new substances/substance combinations.

ATC code change

Dimethyl fumarate was previously assigned N07XX09. This code was deleted and replaced with L04AX07.

Updates to the UMC assigned ATC codes

During 2018 several substances and related medicinal products have been updated with additional ATC codes to reflect new indications of use. (E.g. Paroxetine is additionally assigned G02CX in order to reflect the indication of use: "Treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause".)

New and revised WHODrug Standardised Drug Groupings (SDGs)

The SDGs are unbiased search strategies for creating lists of medicines of interest, maintained and continuously updated by UMC. They are available, free of charge, to all WHODrug Global subscribers. General SDG information and specific information on inclusion/exclusion criteria for individual SDGs can be found in the SDG User Guide provided in the SDG download package and in the WHODrug User Area. We continuously review the content of the SDGs to ensure they are consistent with WHODrug, the ATC classification and user requirements.

As of the March 1, 2019 release of WHODrug, there are 47 main SDGs, and 471 drug groupings in total. The major changes are listed below:

- A new SDG, Anticonvulsants, was developed, containing subgroups mainly based on chemical structure.
- Several new subgroups were added in SDG Cancer therapies subgroup, Targeted anticancer therapy.
- The subgroup Endocrine antineoplastic therapy was moved from the SDG Immunomodulators to the SDG Cancer therapies.
- The SDG Diuretics, and its subgroups, were made more granular.

The March 1, 2019 release of the WHODrug SDGs will only be available in the B3 format. The SDGs will be updated alongside the WHODrug release plan.

New developments in WHODrug Insight

ATC hierarchy

In WHODrug Insight, the ATC hierarchy can now be accessed by clicking on the ATC information in the drug search view.

Medicinal Product ID (MpID)

WHODrug Insight supports MpID information in a new view function. It is an additional feature in the search result and makes it possible to view the C3 format information as well as product specific ATC codes.

Unique Ingredient Identifier (UNII) names and UNII codes

It is now possible to view the UNII name connected to the corresponding UNII code in the UNII code column displayed in the drug search result.

New developments in WHODrug Change Analysis Tool (CAT)

New and improved interface

During the second quarter of 2018, WHODrug CAT got a new and modern interface, which enables quick and easy navigation within the application.

Upversioning between two different dictionary types

It is now possible to compare two different dictionary types in WHODrug CAT to assess the impact of transitions, for example, comparing WHODrug Enhanced with WHODrug Global, or WHODrug Enhanced including Herbals with WHODrug Global.

Updates to the WHODrug Cross Reference ATC 5

WHODrug Cross Reference ATC 5 offers mapping between WHODrug Drug Codes and ATC 5th level codes.

From 2019 the Cross Reference ATC 5 will be updated twice per year (March and September).

Standardised release timeline for Cross Reference Tool Japan

WHODrug CRT Japan is a two-way conversion tool between the Iyakuhinmei Data File (IDF) and WHODrug, linking the IDs in the IDF dictionary to WHODrug Drug Codes.

The biannual release of WHODrug Global (March and September) has enabled the releases of CRT Japan to be standardized and consistent with the latest information from WHODrug and IDF.

The March release of CRT Japan includes data from the March release of WHODrug and the October release of IDF. The September release of CRT Japan will include data from the September release of WHODrug and the April release of IDF.

CRT Japan version	WHODrug version	IDF version
CRT Japan March 1, 2019	WHODrug March 1, 2019	IDF October release 2018
CRT Japan September 1, 2019	WHODrug September 1, 2019	IDF April release 2019

Licence Validation Service

In March 2018 UMC released a new web-based service for automated verification of the WHODrug licenses of collaborating partners. The service provides instant responses to requests to confirm a partner's license status. The service also supports the submission of multiple requests in a batch and offer export of request results.

The validation service is accessed on our website where more information about the service may be found.

Online WHODrug training

The Introduction to WHODrug online course is maintained and developed by UMC, and all WHODrug users are welcome to sign up for it on the WHODrug User Area.

The Introduction to WHODrug course provides knowledge about WHODrug content and structure. Participants are introduced to core concepts that are necessary to record data using WHODrug such as the B3 and C3 formats, the Drug Code, ATC assignments in WHODrug as well as the best practices concerning coding concomitant medications.

The course is regularly updated to reflect the latest WHODrug developments, and therefore a new module is now available for WHODrug Koda. This provides basic information on the automated coding service custom-built

by UMC; it will be further developed concomitantly with the first official release of WHODrug Koda in early 2019.

Upon completion of the relevant modules, it is possible to print a course certificate.

New password for WHODrug applications

UMC is continually working to strengthen the security of accessing the UMC applications and website. A new login system for all applications was recently implemented, requiring all WHODrug users to set new passwords for their UMC accounts. If you have not already reset your password, you will be required to do so next time you try to access any of the WHODrug applications.

WHODrug Vendor program

UMC has long been working with software developers to ensure seamless compatibility for end users of WHODrug. Incorporating feedback, UMC is now proudly introducing a more inclusive and supportive programme for software developers.

The new WHODrug Vendor Programme supports developers to create software systems which are fully compatible with WHODrug, throughout the entire life cycle of their software. Both developers for pharmaco-vigilance platforms, support or hosting services for enrolled software systems can join, as well as the EDC, CTMS system and coding tool developers for clinical trial data. Vendors will be provided with a complete suite of material, training, support and unbiased validations, all aiming to facilitate a quick, easy and correct implementation of WHODrug Global within software systems. For those interested, please visit the dedicated WHODrug Vendor Programme page of the UMC website.

WHODrug Koda

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

The ever-expanding number of drugs available on the global market will increase the need for automated services for drug coding. WHODrug Koda is a unique coding engine based on AI, coding know-how and algorithms. In addition to being able to code a drug, WHODrug Koda also selects the most appropriate ATC code. The coding engine is available as a flexible API and a user-friendly web application.

During 2018 WHODrug Koda has been available in a trial version. UMC continues to develop and refine the functions and coding logic in WHODrug Koda up to the official launch in March 2019.

Key features of WHODrug Koda

- Combines the latest technologies (such as Artificial Intelligence 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 expectations.
- 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 from spring 2019.

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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