What's New in WHODrug

March 1, 2018
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What’s New in WHODrug March 1, 2018

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 new developments, 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, 2018 release includes more than 450,000 unique product names, and more than three million medical products, from 147 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.

WHODrug Global

Background
With the increasing recommendations and requirements from authorities to use WHODrug for coding of concomitant medications, UMC has decided to standardise and streamline our products and releases. By combining all WHODrug dictionaries types into one dictionary, named WHODrug Global, and by releasing it twice a year, in March and September, we aim to facilitate the use of WHODrug data.

What is included?
WHODrug Global is essentially a combination of WHODrug Enhanced and WHODrug Herbal; it includes conventional medications, herbal remedies, and Chinese drug names in Latin characters (Pinyin). Since we also want all users to be able to access and benefit from the four tools and services that are most commonly used in coding they are also included in the license for WHODrug Global.

- WHODrug Insight
- WHODrug Change Analysis Tool (CAT)
- WHODrug Change Request, and
- WHODrug Standardised Drug Groupings (SDGs).

Transition timeline
All WHODrug subscriptions are currently being converted to WHODrug Global subscriptions when the license is due for renewal. This process started in September 2017 and will end by June 2018. All WHODrug users will then have WHODrug Global licenses.

Regulatory requirements
The U.S. Food and Drug Administration (FDA) has recently published a notice in the Federal Register, in which they state that the use of the most current B3 format version of WHODrug Global will be required in submissions for studies starting after March 15, 2019. Furthermore, the U.S. FDA Data Standards Catalog has also been updated with this information.

WHODrug Global transition plan
Please refer to our document WHODrug Global Transition plan, available at the UMC website, for detailed information on
- the difference between the WHODrug Global dictionary and the old WHODrug dictionary types
- dictionary types, formats and release timeline
- UMC recommendations for the transition to WHODrug Global, and
- licenses validation.

Figure 1. ‘WHODrug Enhanced and WHODrug Herbal’ will be released four times per year until their final release in March 2018. ‘WHODrug Enhanced’ is released four times per year during 2017 and twice per year from March 2018 until 2020. ‘WHODrug Global’ is released twice per year (in March and September). All dictionary types will be available in the B2/B3/C3 formats. The C format will only be available upon request.

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Increased granularity of biosimilars in WHODrug

A biosimilar medicine is a similar version of a reference biological substance. For the March 1, 2018 release WHODrug has been updated with a more granular structure for biosimilar substances. Within this new structure, active substances that are recognised as biosimilars by regulatory authorities, and have distinctive substance names, are available as salt variations to their respectively reference biological substances.

Figure 2. An example of the new structure for biosimilars, available in WHODrug from the March 1, 2018 release.

New umbrellas

Based on requests from WHODrug users eight new umbrella terms have been included in WHODrug during 2017.

<table>
<thead>
<tr>
<th>Drug code</th>
<th>Umbrella term</th>
<th>ATC</th>
</tr>
</thead>
<tbody>
<tr>
<td>901523 01 001</td>
<td>Immunotherapy</td>
<td>L03A, L04A</td>
</tr>
<tr>
<td>901517 01 001</td>
<td>Counterirritants</td>
<td>D11A, M02A</td>
</tr>
<tr>
<td>901522 01 001</td>
<td>Antivirals for treatment of HCV infections</td>
<td>J05AP</td>
</tr>
<tr>
<td>901518 01 001</td>
<td>Cancer vaccines</td>
<td>J07, L03AX</td>
</tr>
<tr>
<td>901519 01 001</td>
<td>Cancer vaccines, therapeutic</td>
<td>L03AX</td>
</tr>
<tr>
<td>901520 01 001</td>
<td>Cancer vaccines, preventive</td>
<td>J07</td>
</tr>
<tr>
<td>901521 01 001</td>
<td>Corticosteroids, topical</td>
<td>A01AC, A07EA, C05AA, D07A, R01AD, R03BA, S01BA, S02BA, S03BA</td>
</tr>
<tr>
<td>901524 01 001</td>
<td>Erythropoiesis-stimulating agents</td>
<td>B03XA</td>
</tr>
</tbody>
</table>

Table 2. Umbrella terms included in WHODrug during 2017.

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 the ATC guidelines will affect the ATC classification in WHODrug. The major changes in WHODrug for the ATC revision of 2018 are described below.

New ATC code J05AP

A new ATC code for treatment of HCV infections, J05AP, was introduced. As a result, a considerable number of ATC reclassifications have been made WHODrug.

New guideline text for NSAIDs in combination with paracetamol

In the guideline text it was clarified that NSAIDs in combination with paracetamol are classified in N02BE. This resulted in several changes.

ATC code change R03AL

The ATC code R03AL changed its name to ‘Adrenergics in combinations with anticholinergics incl. triple combinations with corticosteroids’ (it was previously named ‘Adrenergics in combinations with anticholinergics’).
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 Global subscribers. General SDG information 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.

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, 2018 release of WHODrug, there are 46 main SDGs, and more than 450 drug groupings in total. The major changes are listed below:

- A new SDG, Cancer therapies, was developed, covering several subgroups based on both chemical properties and mechanistic pathways. The Antineoplastic subgroup in the SDG Immunomodulators was consequently discontinued.
- A new SDG, Anti-infectives, was developed to include anti-infective drugs regardless of routes of administration. The SDG Systemic anti-infectives was therefore discontinued.
- The SDG Vaccines was revised and new subgroups were added to reflect the increased granularity of vaccines in WHODrug.
- The SDG Antihypertensives subgroup Calcium channel blocker is now divided into two subgroups.

The March 1, 2018 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.

New developments in WHODrug Insight

WHODrug B3/C3 format

Both WHODrug Insight and WHODrug CAT offer complete WHODrug B3/C3 format compatibility. WHODrug Insight supports the option to choose B3 format from 2017 and onwards, complete B3 compatibility applies for Drug Search as well as SDG, CDG functionalities and ATC tree.

Upcoming data available

Where drug dictionary type is selected in WHODrug Insight there is now a possibility to select ‘WHODrug Upcoming Data’. In doing so the user accesses all WHODrug records before the actual WHODrug dictionary release. The upcoming data reflects how the dictionary would look like if it was released today.

New and improved SDG search functionalities

The SDG tab in WHODrug Insight has been improved and now includes a substance search function. The search result displays all SDG assignments for the active substance.

Medicinal Product ID (MpID) available

From March 1, WHODrug Insight will be able to support Mpid information in a new view function. This is an additional feature in the WHODrug Insight search result, which makes it possible to view all C format information as well as product specific ATC codes.

Figure 3. Example of how the C format specific information is visualised in WHODrug Insight.
**WHODrug Change Request**

A WHODrug change request can relate to the inclusion of a new medicinal product in WHODrug or a modification of an existing record. From October 2017, WHODrug users are encouraged to make use of the newly launched web-based service, the WHODrug Change Request, for submitting WHODrug change requests.

The WHODrug Change Request service allows the user to:
- keep track of submitted requests
- search for previous submitted requests, and
- submit multiple requests in a batch.

The WHODrug Change Request service is best used in tandem with the upcoming data in WHODrug Insight. The upcoming data is updated daily and reflects how the dictionary would look like if it was released today.

If you are missing a drug in WHODrug, start by thoroughly searching WHODrug upcoming data in WHODrug Insight. Submit a change request if you cannot find the drug.

If UMC accepts the request, links provided in the WHODrug Change Request service will direct you to WHODrug upcoming data in WHODrug Insight, where you will be able to find drug details for the recently approved WHODrug record.

It normally takes three business days to process a change request, unless it is complex and requires further investigation, in which case UMC will communicate the expected time required for handling. Newly approved drug names are included in the earliest possible release of WHODrug and drug details can be viewed instantly in WHODrug Insight’s upcoming data.

Watch our WHODrug Change Request video to learn more about the service at this link: [https://www.who-umc.org/whodrug/training/videocasts/](https://www.who-umc.org/whodrug/training/videocasts/)

**WHODrug CAT**

**WHODrug Global**

WHODrug Global is now selectable in WHODrug CAT.

**WHODrug B3/C3 format**

WHODrug CAT can not only provide you with the full B3 impact analysis between two WHODrug versions, but also give you the option to see how the upgrade of version affects your data. Do this by uploading your own synonym list, and the result is an output file with the specific B3 changes affecting the uploaded drug names.

**WHODrug Best Practices**

**Version 6.0**

During March, a new version of the WHODrug Best Practices will be released. This will include a new chapter that describes when and how to use Umbrella and NOS records. This new chapter explains the difference between Umbrella and NOS records, and aims to guide the user when coding to an imprecise verbatim.

**Questions?**

If you have any questions on WHODrug please do not hesitate to contact us at whodrug@who-umc.org!

*Figure 4.* Using the new WHODrug Change Request service facilitates submitting, and keeping track of, WHODrug change requests.
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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-sciences 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).