



Uppsala  
Monitoring  
Centre

– Building a global safety culture

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# WHODrug Global

Transition plan  
version 1.2

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## Background and rationale

With the increasing focus and recommendations 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 into one dictionary named *WHODrug Global* and by releasing the dictionary twice a year, in March and September, we aim to facilitate the use of WHODrug data.

## What is included in WHODrug Global

WHODrug Global includes all the information from the old dictionary types, which means 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 – WHODrug Insight, WHODrug Change Analysis Tool (CAT), WHODrug Change Request and the WHODrug Standardised Drug Groupings (SDGs) – they are also included in the license for WHODrug Global.

## The difference between the WHODrug Global dictionary and the old WHODrug Dictionary types

### ***WHODrug Global vs WHODrug Enhanced***

Since the 1<sup>st</sup> March, 2017 release, *WHODrug Global* has included all information from *WHODrug Enhanced* and also herbal remedies.

### ***WHODrug Global vs WHODrug Enhanced and WHODrug Herbal***

Since the release on 1<sup>st</sup> March, 2017, *WHODrug Global* is essentially a renamed combination of *WHODrug Enhanced* and *WHODrug Herbal*. *WHODrug Global* has exactly the same content as the corresponding release (March and September) of *WHODrug Enhanced* and *WHODrug Herbal*.

### **Chinese drug names (with Latin characters)**

Since the release on 1<sup>st</sup> March, 2017, Chinese drug names in Latin characters have been made available in *WHODrug Enhanced* as well as *WHODrug Enhanced* and *WHODrug Herbal*. This is a step toward the introduction of *WHODrug Global*, and facilitates upgrading from *WHODrug Enhanced* and *WHODrug Herbal* to *WHODrug Global*. Effectively, this will allow a smooth transition from *WHODrug Enhanced* and *WHODrug Herbal* to *WHODrug Global*, as the content is now the same in both dictionaries.

## Timeline

All WHODrug users will automatically move to WHODrug Global when their license is due for renewal. This process starts in September 2017 and will end by June 2018, when all users will have been moved to WHODrug Global licenses.

### ***WHODrug Global***

As displayed in figure 1, starting from 1<sup>st</sup> March 2017 *WHODrug Global* will be released twice per year, in March and September.

### ***WHODrug Enhanced and WHODrug Herbal***

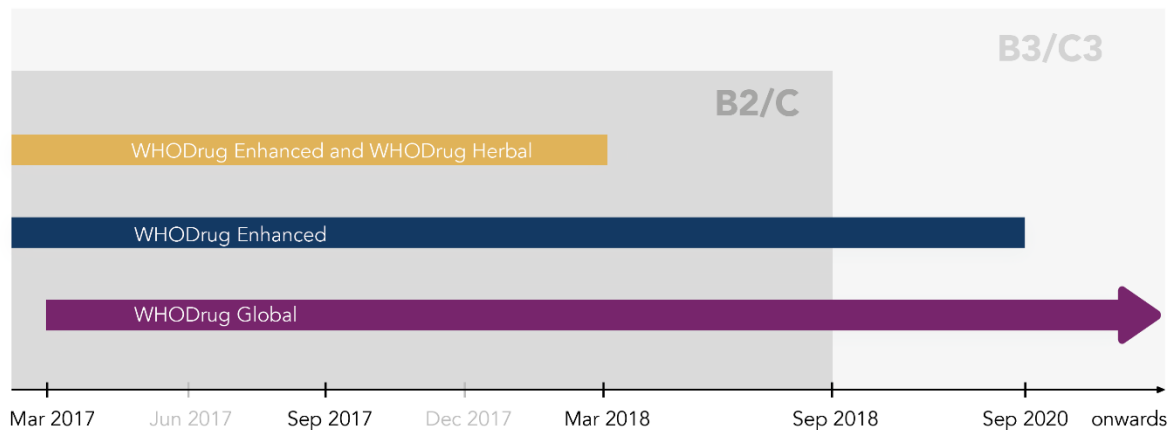
As displayed in figure 1, the combined *WHODrug Enhanced* and *WHODrug Herbal* dictionary will be available in parallel with *WHODrug Global*, with identical content, until March 2018. This is to make sure that the WHODrug agreements are handled correctly and users get access to what is stated in the agreement. *WHODrug Enhanced* and *WHODrug Herbal* will be released four times per year until its final release in March 2018.

### ***WHODrug Enhanced***

As displayed in figure 1, *WHODrug Enhanced* will be available in parallel with *WHODrug Global* until September 2020. This is to enable WHODrug users to choose the most convenient time to move to the *WHODrug Global* dictionary. *WHODrug Enhanced* is released four times per year during 2017 and twice per year starting from March 2018 until 2020.

### **Transition to the B3/C3 formats**

The introduction of WHODrug Global overlaps the introduction of the B<sub>3</sub>- and C<sub>3</sub>-formats. However, the implementation plan for the new formats remains unchanged. The old B<sub>2</sub>- and C-formats remain available until September 2018 and with the limitations communicated in the WHODrug B<sub>3</sub>/C<sub>3</sub> Implementation Guide (please refer to this document for details). All dictionary types (*WHODrug Enhanced*; *WHODrug Enhanced* and *WHODrug Herbal*; *WHODrug Global*) will be available in the formats B<sub>2</sub>/B<sub>3</sub>/C<sub>3</sub> as described in figure 1; with the exception of the C-format, which will be available only upon request.



**Figure 1. The WHODrug Dictionaries types, formats and releases timeline.** *WHODrug Enhanced and Herbal* will be released four times per year until its final release in March 2018. *WHODrug Enhanced* is released four times per year during 2017 and twice per year starting from March 2018 until 2020. *WHODrug Global* is released twice per year respectively in March and September. All dictionary types (*WHODrug Enhanced*; *WHODrug Enhanced and WHODrug Herbal*; *WHODrug Global*) will be available in the formats B2/B3/C3 as described in figure 1; with the exception of the C-format, which will be available only upon request.

### Which dictionary should I implement? UMC recommendations

For the transition to *WHODrug Global*, UMC recommends the following:

- New studies, starting after 1<sup>st</sup> March, 2017, should use *WHODrug Global* once accessed by the user. For new studies starting after 15<sup>th</sup> March, 2019, the use of *WHODrug Global* is required by 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* at your convenience.
- It is acceptable for studies that are not upgraded to stay on the same version, but we recommend ensuring that it complies with regulatory expectations.

### License validation

UMC acknowledges the need for flexibility during the transition period. Therefore, it is permissible for all users of WHODrug (including, but not limited to sponsors, service providers and software system providers) to:

- Start studies with, or upgrade studies to *WHODrug Global* even if one of the collaborating organisations has not yet moved to *WHODrug Global* and is still only licensed to use either *WHODrug Enhanced* or *WHODrug Enhanced and WHODrug Herbal*. The only requirement is that all parties involved have a valid ongoing WHODrug subscription.
- Start studies with, or upgrade studies to *WHODrug Enhanced* or *WHODrug Enhanced and WHODrug Herbal*, even if one of the collaborating organisations is only licensed to use *WHODrug Global*. The only requirement is that all parties involved have a valid ongoing WHODrug subscription.
- The License validation team at UMC will be happy to answer any questions about this.

### UMC support

We want to do our best to make the transition into the richer and more standardised dictionary as easy as possible. Please contact us for any feedback or questions at [WHODrug@who-umc.org](mailto: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](http://www.who-umc.org)).



WHO Collaborating Centre for  
International Drug Monitoring

**Uppsala Monitoring Centre (UMC)**

Box 1051, SE-751 40 Uppsala, Sweden

Tel: +46 18-65 60 60 [www.who-umc.org](http://www.who-umc.org)