# Technical guidance for use of WHODrug Global in XMLs uploaded in VigiFlow eReporting for Industry for E2B(R3) compliance

VERSION 2.0

# Content

# Changes from previous versions

| Version | Summary of changes |
|---|---|
| **December 2023** | General updates: Images, support email change, updated version format.<br>• Introduction: Updated images and support email.<br>• WHODrug Global – format considerations: Changes in text and insert a link to WHODrug Best Practices.<br>• Submitting reports using E2B(R3) XMLs and use of OIDs: Updated images.<br>• Receiving reports in VigiFlow: Updated images.<br>• Versions considerations: Changes in text and updated version format.<br>• Support: Updated support email. |

# Introduction

WHODrug Global developed and maintained by Uppsala Monitoring Centre (UMC) is an international reference for medicinal product information and the most actively used drug reference dictionary in the world today. WHODrug Global effectively facilitates the exchange of medicinal product information.

This 'Technical guidance for use of WHODrug Global for E2B(R3) compliance' is aimed towards National or Regional Regulatory Agencies and other policymakers in the development of national or regional recommendations and/or requirements for XML submissions of information from WHODrug Global, via VigiFlow eReporting for industry, to be compatible with the E2B(R3) standard format for sharing of Individual Case Safety Reports (ICSRs).

This document does not claim to be a comprehensive guide to all aspects of WHODrug Global or E2B(R3) submissions, but rather a brief description, highlighting key considerations. For any questions, please contact support@who-umc.org.

## Executive summary

*Recommendations for use of WHODrug Global for E2B(R3) compliance in VigiFlow eReporting*

- ✓ Use the WHODrug Global **C3 format** for drug coding.
- ✓ If possible, use the WHODrug Global **Medicinal Product Identifier (MPID)** as unique identifier for coded medicinal products.
- ✓ Use the WHODrug Global **MPID Object Identifier (OID)**, to indicate that the WHODrug Global MPID has been used.
- ✓ Use the **latest version** available of WHODrug Global when performing drug coding.

## Example

To illustrate the various considerations to be made, the example WHODrug trade name *Accogem* with the active ingredient *Gemcitabine hydrochloride* (Figure 1) will be used throughout this text:
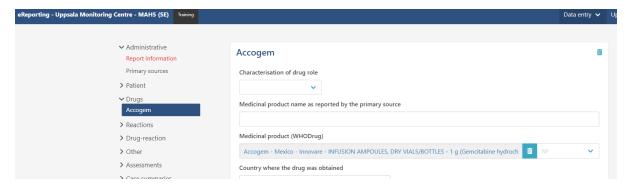
**Figure 1.** The WHODrug trade name Accogem, containing the active ingredient Gemcitabine hydrochloride, as selected within the UMC hosted platform VigiFlow eReporting for industry. The example could be similarly represented also in other reporting systems.

# WHODrug Global – format considerations

Traditionally, users of the WHODrug Global have been able to access the drug information provided in two different formats; the B3 format and the C3 format (see table 1 for an example). Both two formats contain information about the very same medicinal products, but with different levels of specificity – with the C3 format providing more detailed information.

**Table 1.** A simplified example, highlighting the difference in specificity between the B3 and C3 formats.

| WHODrug format | Trade name | Active ingredient(s) | ATC code | Country of sales | MAH | Pharmaceutical form | Pharmaceutical strength |
|---|---|---|---|---|---|---|---|
| **B3** | Accogem | Gemcitabine hydrochloride | L01BC, Pyrimidine analogues | | | | |
| **C3** | Accogem | Gemcitabine hydrochloride | L01BC, Pyrimidine analogues | Mexico | Innovare | Infusion ampoules, dry vials/bottles | 1 g |

The ICH E2B(R3) format has placeholder data elements for providing information on the medicinal product(s) in line with the upcoming implementation of ISO Identification of Medicinal Products (IDMP) standards. In WHODrug Global, the WHODrug Medicinal Product Identifier (MPID) from the C3 format can be used as a proxy until regional implementation plans have been established and formalized ISO identifiers have been developed.

Hence, **UMC recommends the use of the C3 format**, whenever possible, for the use case described within this documentation. As the WHODrug B3 format does not contain as detailed information, compared to what can be extracted from the C3 format, UMC does not recommend the submission of identifiers originating from the B3 format.

As the WHODrug C3 format enables drug coding using pre-defined information levels, the MPID representing the most appropriate information level according to the reported information is recommended, to not either under- or over-interpret the reported information. If an MPID for any reason cannot be selected, less specific information may be submitted.

For users of the manual data entry module within VigiFlow eReporting for Industry, MPIDs are automatically assigned within the back-end solution of the manual drug coding application.

For more information about the recommended best practices when coding drug information with WHODrug Global C3 format and how to achieve accurate and consistent medicinal product selection, please review the document "How to use the WHODrug C3 format for drug coding" available at https://who-umc.org/whodrug-library/coding-c3-guidelines/.

# Submitting reports using E2B(R3) XMLs and use of OIDs

To facilitate the exchange and interpretation of the data coded with WHODrug Global, please observe the following when E2B(R3) XMLs are generated:

- Make use of the WHODrug Global Medicinal Product Identifier (MPID) within the code attribute of the <code> tag.
- Use the WHODrug Global MPID Object Identifier (OID) = **2.16.840.1.113883.6.294** within the codeSystem attribute of the <code> tag.
- See Figure 2 for an example:

```
<instanceOfKind classCode="INST">
  <kindOfProduct classCode="MMAT" determinerCode="KIND">
    <!--G.k.2.1.1a: MPID Version Date / Number -->
    <!--G.k.2.1.1b: Medicinal Product Identifier (MPID)-->
    <code code="4961787" codeSystem="2.16.840.1.113883.6.294" codeSystemVersion="Sep012023" />
    <!- G.k.2.2: Medicinal Product Name as Reported by the Primary Source ->
    <name>Accogem 1g</name>
```

**Figure 2.** Example of how to make use of WHODrug Global specific identifiers within generated XMLs.

# E2B(R3) fields compatible with information from WHODrug Global

E2B(R3) fields where WHODrug Global MPID can be used include suspected, concomitant and interacting products as well as Patient drug histories, see Table 2 for more details.

**Table 2.** Guidance for how and when information from WHODrug Global can be used to populate E2B(R3) fields

| | ICH E2B(R3) field | ICH E2B(R3) and WHODrug XML configuration guidance |
|---|---|---|
| **G.k Drug(s) information**<br>**Free text field indicated to the right**<br>*And (see below)* | G.k.2.2 | Medicinal Product Name as Reported by the Primary Source |
| **WHODrug ID**<br>*Suspect /Concomitant /Interacting/*<br>*Drug not administered* | G.k.2.1.1a | WHODrug version |
| | G.k.2.1.1b<br>*Code system OID  2.16.840.1.113883.6.294* | WHODrug Medicinal Product ID (MPID) |
| **D.8.r Relevant Past Drug History**<br>*Free text field indicated to the right*<br>*And (see below)* | D.8.r.1 | Medicinal Product Name as Reported by the Primary Source |
| | D.8.r.2a | WHODrug version |
| **Patient Past drug therapy** | D.8.r.2b<br>*Code system OID  2.16.840.1.113883.6.294* | WHODrug Medicinal Product ID (MPID) |
| **D.8.r Relevant Past Drug History of Parent**<br>**Free text field indicated to the right**<br>*And (see below)* | D.10.8.r.1 | Medicinal Product Name as Reported by the Primary Source |
| | D.10.8.r.2a | WHODrug version |
| **Parent Past drug Therapy** | D.10.8.r.2b<br>*Code system OID  2.16.840.1.113883.6.294* | WHODrug Medicinal Product ID (MPID) |

# Receiving reports in VigiFlow

When reports become available in VigiFlow, WHODrug Global information is automatically retrieved and displayed, given that the correct identifiers (as mentioned above and as the example in Figure 3) have been assigned by the submitter.

If non-current WHODrug codes have been used, the VigiFlow user will be notified, and the drugs need to be processed manually.
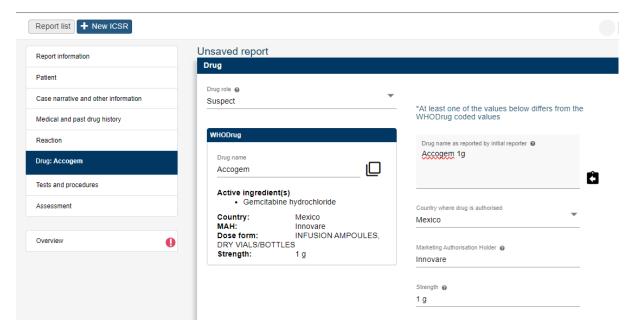
**Figure 3.** Example of how the use current WHODrug Global identifiers are flagged in VigiFlow.

## Versions considerations

To avoid the use of non-current WHODrug identifiers, industry users uploading XMLs should use the latest version available of WHODrug Global at the time of processing. WHODrug Global is released on a biannual basis – 1 March and 1 September.

To indicate the version used, the year and month for the WHODrug release in the format of 'MmmDDYYYY' (e.g. 'Sep012023') as described in the file "Version for E2B submission description" available in the WHODrug file package.

Users of VigiFlow's manual data entry module in the eReporting for Industry platform always access the latest WHODrug Global information. Therefore, they don't need to provide or submit version information.

## Support

For support related to your implementation of WHODrug Global, please contact your appointed focal person at UMC or support@who-umc.org.