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COFEPRIS
COMISIÓN FEDERAL PARA LA PROTECCIÓN CONTRA RIESGOS SANITARIOS

Executive Direction of Pharmacopeia and Pharmacovigilance

Uppsala Monitoring Centre

CEMAR

WHODRUG

Implementation plan

Version 1.1

WHODrug implementation plan

Table of contents

Version history

Date	Version	Summary of changes
March 2023	1.1	• Product update in WHODrug has been expanded in detail • Addition to Appendix 1. Technical guidance for use of WHODrug Global in XML uploaded in Vigiflow eReporting for Industry for E2B (R3) compliance. *English version* • Update to version 2.0 of Appendix 2. How to use WHODrug C3 format for drug coding *English and Spanish version*

Glossary of terms

CAS – Comisión de Autorización Sanitaria (*Sanitary Authorization Commission*)
CEFV – Centro Estatal de Farmacovigilancia (*Pharmacovigilance State Centre*)
CEMAR – Comisión de Evidencia y Manejo de Riesgos (*Commission of Evidence and Risk Management*)
CICFV – Centro Institucional Coordinador de Farmacovigilancia (*Institutional Pharmacovigilance Coordinating Centre*)
CIFV - Centro Institucional de Farmacovigilancia (*Institutional Pharmacovigilance Centre*)
CRO - *Contract Research Organization*
CNFV – Centro Nacional de Farmacovigilancia *(National Pharmacovigilance Centre*)
COFEPRIS – Comisión Federal para la Protección contra Riesgos Sanitarios (*Federal Commission for the Protection against Sanitary Risks*)
DEFFV – Dirección Ejecutiva de Farmacopea y Farmacovigilancia (*Executive Direction of Pharmacopoeia and Pharmacovigilance*)
E2B – ICH Guideline for Electronic Transmission of Individual Case Safety Reports
EA – Evento Adverso (*Adverse event)*
EMA – *European Medicines Agency*
ESAVI - Evento supuestamente atribuible a la vacunación o inmunización (*Adverse event following immunization*)
FDA – *Food and Drug Administration*
FEUM – Farmacopea de los Estados Unidos Mexicanos (*Pharmacopeia of the United Mexican States*)
ICH – *International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use*
ICSR - *Individual Case Safety Report*
IDMP – *Identification of Medicinal Products*
ISO – *International Organization for Standardization*
KIDS - Korea Institute of Drug Safety & Risk Management
LGS – Ley General de Salud (*General Health Law*)
PMDA – *Pharmaceuticals and Medical Devices Agency*
RAM - Reacción adversa a un medicamento (*Adverse Drug Reaction*)
RIS – Reglamento de Insumos para la Salud (*Health Supplies Regulations*)
SRAM - Sospecha de reacción adversa a medicamento (*Suspected adverse drug reaction*)
UFV – Unidad de Farmacovigilancia (*Pharmacovigilance Unit*)
UMC – *Uppsala Monitoring Centre*
WHO – *World Health Organization*

Background

On May 2, 2022, the National Pharmacovigilance Centre issued a press release on the Cofepris website, aimed to the pharmaceutical industry with the following objectives:

- To endorse e-Reporting Industry as the only valid tool for the notification of SRAM, RAM, AE, ESAVI or any other safety issue related to the use of medicines and vaccines by Pharmaceutical Industry.
- To endorse the use of MedDRA as the official clinical terminology for reporting, as established in the Mexican Official Standard NOM-220-SSA1-2016 and its modification.
- To inform about the upcoming implementation of WHODrug as a standard for the coding of drugs and vaccines in pharmacovigilance.

Derived from the actions established in this press release to give continuity to the implementation of the WHODrug standard, this approach was developed.

Introduction

The WHODrug Global, developed and maintained by the Uppsala Monitoring Centre (UMC), is an international reference for drug information (including vaccines) and is the most widely used drug reference dictionary in the world today. WHODrug Global facilitates the identification and exchange of drug information.

Features

- It contains nearly 4 million different medicinal product identifiers from 168 countries (September 2022). It is the international reference for pharmaceutical product information.
- WHODrug contains conventional medicines, vaccines, biological and biotechnological products, herbal products, chemotherapy regimens, traditional Chinese medicine and umbrella records (specific groups or types of medicines)
- Coding in WHODrug is based on a hierarchy that provides information on the active ingredient(s), salts and their variants and the commercial name, generating an 11-digit drug code
- In WHODrug Global, drug names are classified according to:
  - ATC (Anatomical, Therapeutic, Chemical Classification System) classification
  - ATC Herbal Classification, for herbal products
  - ATC codes created by UMC

- It is currently used in 2,500 organizations around the world, by Regulatory Authorities, Pharmaceutical Companies, Research Centers and Universities
- In Latin America and the Caribbean, 22 Regulatory Authorities have implemented the dictionary in their databases (VigiFlow and VigiLyze).
- The use of WHODrug Global is required by reference organizations such as the Regulatory Authorities of the United States (FDA), Japan (PMDA) and South Korea (KIDS).

Advantages of product identification through WHODrug

- Standardized data facilitates the identification of drug and vaccine-related problems and contributes to drug and vaccine safety analysis
- In clinical trials, it allows efficient analysis of the effect of experimental and concomitant drugs. Uniform drug coding is of great importance, but can be challenging, especially in multi-center, multi-site trials in several countries
- Safety signal detection
    - WHODrug allows the identification and aggregation of data at different reporting levels due to the dictionary data structure. This applies to both drugs reported as concomitant or interacting drugs and those reported as suspected to have caused an adverse drug reaction (ADR)
    - The WHO global adverse reaction database - VigiBase - is coded with WHODrug, which facilitates the interpretation and evaluation of safety signals
- Electronic exchange of ICSRs. The precise identification of medicinal products opens up the possibility of exchanging information between databases, facilitating feedback among the members of the pharmacovigilance system

Rationale

- High standard coding of medicinal products systematically provides identifiers to ensure traceability within the process of adverse reaction reporting, data analysis and risk communication associated with drugs and vaccines.
- WHODrug represents a worldwide recognition tool supported by the UMC and is part of the international strategy for the homologation of medicinal product identifiers by the WHO and Regulatory Agencies.
- ICH. The multidisciplinary guidelines, which are transversal and therefore do not apply only to one of the categories (Quality, Safety and Efficacy), include

the MedDRA medical terminology, the Common Technical Document (CTD), data elements and standards for drug dictionaries

- Guide M5. Data elements and standards for drug dictionaries. It recognizes the need to harmonize pharmaceutical product information to facilitate the electronic exchange of ICSRs between ICH regions, using the ICH E2B (R3) format

Cofepris has been a full member of ICH since November 17, 2021, when the Assembly approved the membership for this regulatory authority to join this international initiative, so from that date, it is committed to gradually implement the guidelines in the regulation of medicines and vaccines in the country.

Purpose

Establish the approach for the WHODrug implementation as a unique dictionary for the identification of drugs and vaccines in the pharmacovigilance processes, specifically in the notification of EA's in clinical trials as well as in the notification of SRAM, RAM, ESAVI and other safety problems related to the use of drugs.

Scope

VigiFlow users, i.e. CNFV, CEFVs, CICFVs, CIFVs and UFVs in the national health system, are acquainted with the use of WHODrug as since the start of VigiFlow operation in September 2019 it is used for the coding of medicinal products in adverse drug reaction reporting.

Marketing Authorization Holders or their legal representatives in Mexico, establishments where health research is performed, distributors and marketers must use WHODrug as a unique and valid dictionary for coding drugs and vaccines in the report of EA, RAM, SRAM, RAM, ESAVI and any other safety problem derived from the use of drugs and vaccines. This applies both to companies submitting via XML/E2B and to those using the manual data entry module in *e-Reporting Industry*.

WHODrug should be used in reporting for both pre-marketing and post-marketing products.

- Pre-marketing: Serious EAs of patients in Mexico resulting from clinical trials with at least one investigational site or center in Mexico

- Post-marketing: SRAM, RAM, EA, ESAVI and any other safety issues related to the use of the drugs and vaccines

The coding of medicines and vaccines with WHODrug will be applicable to:

- All drugs, including vaccines that have a Market Authorisation
- All recognized orphan drugs
- All drugs with Emergency Use Authorizations (EUAs)

Within the notifications of EA, SRAM, RAM, ESAVI and any other safety issues related to the use of medicines and vaccines, coding should be applied in the following sections:

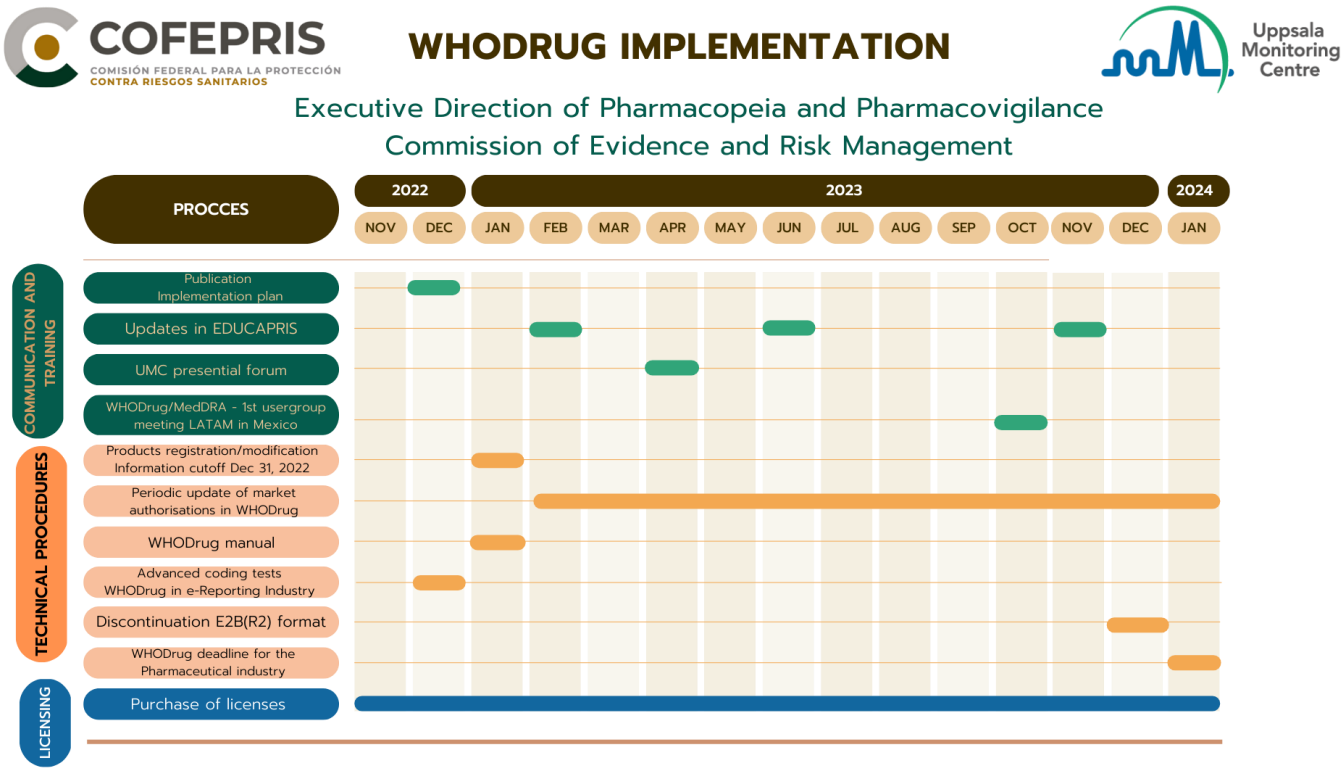
- Suspected medications
- Concomitant medications
- Interacting medications
- Previous medical treatments
- For parent-child reports, on medications given to the mother/father

Drugs administered for the treatment of RAM/SRAM/EA/ESAVI are exempt from coding in the reports and will only be described in the case narrative section of the report.

Development

The following diagram shows the chronogram of the main milestones that make up the WHODrug implementation process. The main milestones are detailed below.

Diagram 1. WHODrug implementation activity timeline



Technical processes

WHODrug implementation

- Companies with E2B databases using the e-Reporting Industry XML/E2B module should configure their XML based on the *Technical guidance for use of WHODrug Global in XMLs uploaded in VigiFlow eReporting for Industry for E2B (R3) compliance*, which can be found in Appendix 1 of this document.

  In addition to what is specified in the technical guide, it is necessary to enter information on the market authorisation number, the country of authorization and the name of Marketing Authorisation Holder for the

suspected, interacting, concomitant or non-administered drug (if available). The E2B fields that apply for this information are:

- G.k.3 Holder and Authorisation / Application Number of Drug
- G.k.3.1 Authorisation / Application Number
- G.k.3.2 Country of Authorisation / Application
- G.k.3.3 Name of Holder / Applicant

Companies can request the CNFV to review test XMLs already configured with WHODrug by sending an email to xmlvigiflow@cofepris.gob.mx . The following information will be requested:

- A first batch of 3 initial test reports with different products
- A second batch of 3 initial test reports and their follow-ups with different products

- Companies that do not have E2B databases and exclusively use the manual module of e-Reporting Industry, only need to have their respective WHODrug license to be able to code their products in the WHODrug search tool, which will have an advanced coding within the manual upload module environment.

Both companies with E2B bases and those using only the e-Reporting Industry manual module should adhere to the WHODrug Coding Best Practices set out in Appendix 2 *How to use the WHODrug C3 format for drug coding* of this document.

Registration of Medicinal Products in WHODrug

WHODrug is updated with the information on marketed drugs whose information is provided by the Regulatory Authorities of the 168 countries (September 2022) that use this dictionary. Each Authority defines the periodicity with which it sends its information to update the list of drugs and vaccines.

According to the attributions established in the LGS, RIS and Cofepris Regulations, the CAS is the area in charge of issuing, extending or revoking market authorisations related to health products, including medicines (according to the definition established in Article 224 of the LGS), herbal remedies and others.

The DEFFV will be in charge of requesting from the CAS, through the specific format established by the UMC, the market authorisations of medicines and vaccines to send this information to the UMC in order to make the corresponding update of the Mexican listing.

On November 1st, 2022, the DEFFV sent to the UMC a preview of the information on drugs marketed in Mexico, with the following data:

- 13,326 unique drug names
- 3,742 unique combinations of active ingredients
- 64,852 WHODrug MPID drug identifiers in C3 format (16,611 new identifiers after the last CAS update)

The above amounts correspond to approximately 95% of the total number of sanitary registrations in the country.

During January 2023, there will be an update of new registrations, holder/legal representative modifications, cancellations, with a cut-off date of December 31, 2022. With this update, it is estimated to have 99% of the list of medicines in Mexico within WHODrug.

Herbal Products

The inclusion of herbal medicines in pharmacovigilance systems is increasing, given the growing use of herbal products and medicines worldwide. Therefore, in terms of population exposure, it is essential to identify the risks associated with their use. Therefore, it is necessary to consider including medicines and herbal remedies marketed in Mexico to WHODrug.

The DEFFV will request to the CAS the particular identification of herbal products from the general request of medicines mentioned in the previous point. The extracted data will be sent to the UMC for evaluation in order to determine how many can be uploaded to WHODrug. The FEUM will give the UMC access to the Herbal Pharmacopeia of the United Mexican States for validation of the information in the records provided by the CAS. If necessary when the information is insufficient or not available, the FEUM will support in the validation.

In the future, it is planned to add information on the herbal medicine of the native populations of Mexico.

Market authorisations cancelled/revoked

Cancelled/revoked market authorisations will remain active in WHODrug for a certain period to be defined by Cofepris. This is in order to have available the identifiable products that are still on the market despite no longer having an active registration and an adverse drug reaction report of such product is required.

Products with this feature will have a special marking within WHODrug (old form), which will indicate to the user that the product is not currently marketed at the time of coding (even with the marking, the product will still be codable for the reason explained in the paragraph above). In the manual data entry module of eReporting industry an exclamation mark (!) will appear when trying to code a product with these characteristics.

Products out of WHODrug's scope

The WHODrug dictionary may contain information on some products described in the following paragraph, but since they are not within the scope of the project, they will be outside the coding requirements.

Products that will not be considered in the project:

- Medical devices
- Misleading products (formerly called miracle products)
- Dietary supplements

Continuous update of Market authorisations records

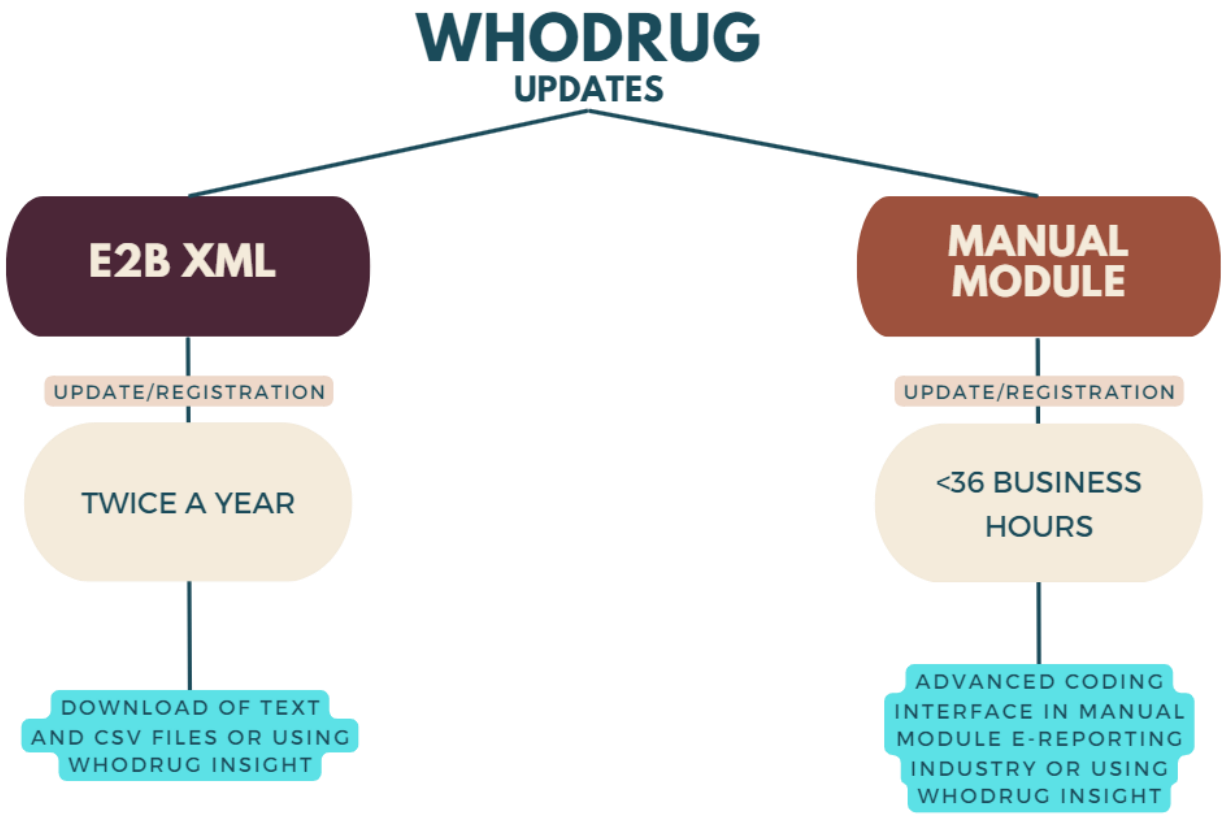
The DEFFV will request to the CAS, on a quarterly basis, updates on market authorisations of medicines in accordance with the following:

- New sanitary registrations
- Modifications of holder/legal representation (transfer of legal rights)
- Cancelled/revoked registrations

The information will be sent to the UMC so that the list of registered drugs in Mexico can be updated in WHODrug.

The time required for a WHODrug Global user to have a record available in WHODrug following an update/upgrade request for use in a report will depend on whether the company uses WHODrug in its E2B database or uses the manual module of e-Reporting Industry.

Diagram 2. Frequency of WHODrug updates



- For WHODrug subscribing organizations with E2B databases, data is updated continuously, with new releases twice a year, (March 1st and September 1st) and such updates will be available to download as text and CSV files through the WHODrug user area. However, updated information can be found within 36 business hours through the WHODrug Insight browser tool, with the information obtained from Insight you can adjust your E2B R3 database and thus have this updated information available for coding (a process that can be done internally by the company). In case of not being able to adjust your E2B database, you can always code the case manually according to the point mentioned below.

- For WHODrug subscribing organizations that use manual module in e-Reporting Industry, an update of a record will be available once the UMC has received the update request within 36 business hours.

The process to request product update or product registration in WHODrug is summarized in the following diagram.

Diagram 3. Product modification/registration request

1. Identification

As of February 2023 (once the Mexican drug listing in WHODrug is updated as of December 31, 2022), companies that already have a WHODrug license will be able to review their products in WHODrug Insight or in the advance coding manual module e-Reporting or in the WHODrug viewer of the E2B databases, in order to identify errors, variations or missing products.

You must make the modification request if you identify products that need to be updated due to:

- Errors in the information contained in the product in WHODrug (trade name, generic name, strength, pharmaceutical form).

- The ownership does not correspond and there is evidence that the transfer of legal rights has already been authorized.

2. Modification/registration request

Change requests are handled directly with the UMC through the *WHODrug Change Request* portal via the following link:

https://changerequest.who-umc.org/External

It is also possible to request the addition of a new product or products that are not in WHODrug. To do this you must access the corresponding section in *WHODrug Change Request*.

It is very important to point out that the information contained in WHODrug corresponds to the registrations as authorized by the CAS, so the reference document that you must provide in WHODrug Change Request to validate the information of the product you are requesting modification, is a version to share of the market authorization received from CAS.

Therefore, the marketing authorization holders or legal representatives in Mexico who hold the ownership of a product will be the only ones who can request the modification/registration of their products in WHODrug.

It is necessary that for any modification/deletion request made in *WHODrug Change Request* you send an email to xmlvigiflow@cofepris.gob.mx informing about this request and attach a simple copy of the sanitary registration of the product(s) requested for modification/registration.

Note: modification requests due to change of ownership/legal representation in Mexico, do not exempt from complying with numeral 7.4.2.8 of NOM-220-SSA1-2016 through the corresponding procedure to the DEFFV.

3. Handling of requests by UMC

The UMC will review the request and validate with the reference document provided. Applicants will be able to check the status of requests and result on the same *WHODrug Change Request* page.

4. **Modification/registration confirmation**

Applicants must verify the update/registration of their product either in *WHODrug Insight* or in the advance coding manual module e-Reporting Industry (for users of this module). It is worth mentioning that WHODrug subscribing organizations with E2B databases, will be able to view the upgrade in the WHODrug viewer of their database until the next upgrade (March or September), but will be able to verify it without problem in *WHODrug Insight* and evaluate internally to adjust their E2B database from the WHODrug Insight information.

For organizations with E2B databases that have requested an update/registration of a product, so that they can use the updated record to submit reports of SRAM, RAM, ESAVI and any other safety issues for this product, especially expedited ones (e.g. serious and 2 or more serious, similar cases at the same location, with the same drug and same batch number), as an exception the following will apply:

- If you will submit an initial report, you may use the manual module of e-Reporting Industry.
- If you will submit a follow-up report of a case that was initially submitted through the manual module of e-Reporting Industry, you may do it through the same way.

Advanced WHODrug coding in e-Reporting Industry manual module

The e-Reporting Industry manual module will have advanced WHODrug coding functionality. A group of four laboratories (national, transnational and CRO) will be formed to review, test and provide feedback to the UMC and CNFV on this advanced functionality. A first test version will be reviewed in December 2022.

During the production phase, this advanced coding will be accompanied by a WHODrug license validation system through which the organization that already has a WHODrug license will be able to enable it in the corresponding License Management section in e-Reporting Industry.

Discontinuation of the ICH E2B (R2) format

By December 1st 2023, the DEFFV will no longer accept reports in XML E2B (R2) format on the e-Reporting Industry E2B module. These reports will be invalid for reporting compliance purposes. Companies that currently have this format must begin transitioning their database to the E2B (R3) format to request CNFV testing with this format in order to be able to use the E2B upload module.

Organizations with E2B (R2) databases that currently report to the CNFV with this standard will be able to request the CNFV to start the testing phase to comply with the E2B (R3) standard in order to authorize the approval to go into production. This can be done by sending a request to xmlvigiflow@cofepris.gob.mx

Companies that fail to transition their database to the E2B (R3) format, by December 1, 2023 will not be able to use the E2B module of e-Reporting Industry and will have to use only the manual module to comply with the report.

As a reference, it should be noted that the EMA established June 30, 2022 as the final date for not accepting ICSRs in ICH E2B (R2) format.

Mandatory coding requirement in WHODrug

The deadline for all Marketing Authorization Holders or their legal representatives in Mexico, establishments where health research is performed, distributors and marketers to code their reports with WHODrug will be **January 1, 2024**. To do so, all of the above mentioned must have enabled the corresponding license in the MedDRA/WHODrug license validation system within e-Reporting Industry.

There will be no extension for coding compliance with WHODrug, because of this, all Market Authorization Holders, or their legal representatives, stablishments where health research, distributors and marketers must take all necessary and appropriate measures in order to obtain the WHODrug license with the UMC.

Companies with E2B bases that do not manage to configure and implement WHODrug, will be able to comply with the notification only through the manual module of e-Reporting Industry, but will no longer be able to use the XML-E2B module, until they achieve the configuration that allows them to code with WHODrug in their bases.

WHODrug manual

This document will give specific attention to the technical component of the configuration of pharmacovigilance databases for the implementation of WHODrug, the operation within e-Reporting Industry, as well as the in-depth process of product modification/registration requests in WHODrug. Among the aspects it will contain are:

- Applicable ICH E2B (R3) fields for WHODrug
  The *Technical guidance for use of WHODrug Global in XMLs uploaded in VigiFlow eReporting for Industry for E2B (R3) compliance* developed by the UMC is currently available and can be started to be used. Appendix 1. This document can now be considered for application in WHODrug implementation.
- Good Coding Practice in WHODrug
  - The guidance document *How to use the WHODrug C3 format for drug coding*, developed by the UMC, is currently available and can be started to be used. Appendix 2. This document can now be considered for application in WHODrug implementation.
- Process for requesting and attending to changes in market authorization status (who, how, when, response time). WHODrug Change Request Guide

This manual will be reviewed by the UMC and also by the group of selected companies. Subsequently by the design area for publication on the Cofepris website. It is expected to be published by January 2023.

Communication and training

Cofepris website

All official communications issued by the Executive Direction of Pharmacopeia and Pharmacovigilance will be through the website https://www.gob.mx/cofepris

- Press releases

https://www.gob.mx/cofepris

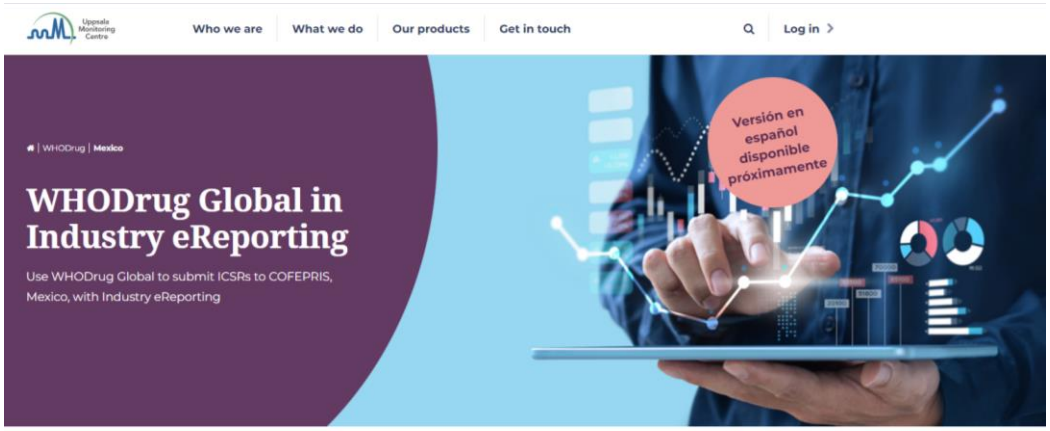
- Emission or updating of guidelines and requirements

https://www.gob.mx/cofepris/documentos/guias-lineamientos-y-requerimientos-de-farmacovigilancia

- Manuals related to e-Reporting Industry

https://www.gob.mx/cofepris/acciones-y-programas/como-notificar-una-sospecha-de-reaccion-adversa?state=published

UMC website dedicated to WHODrug implementation in Mexico



The Federal Commission for Protection against Sanitary Risks (Comisión Federal para la Protección contra Riesgos Sanitarios, COFEPRIS) requires the pharmaceutical industry in Mexico to submit suspected adverse drug reactions via the UMC-hosted **Industry eReporting**. Since March 2022, the platform supports medical coding, including drug coding via WHODrug Global, and enables full compliance with established and future-proofed standards.

https://who-umc.org/whodrug/mexico/

Provides guidance on WHODrug Global implementation specifically on the following aspects:

- General information
- Use of WHODrug in e-Reporting Industry in Mexico
- Official communications from Cofepris on WHODrug implementation in Mexico
- Support and training
- License application

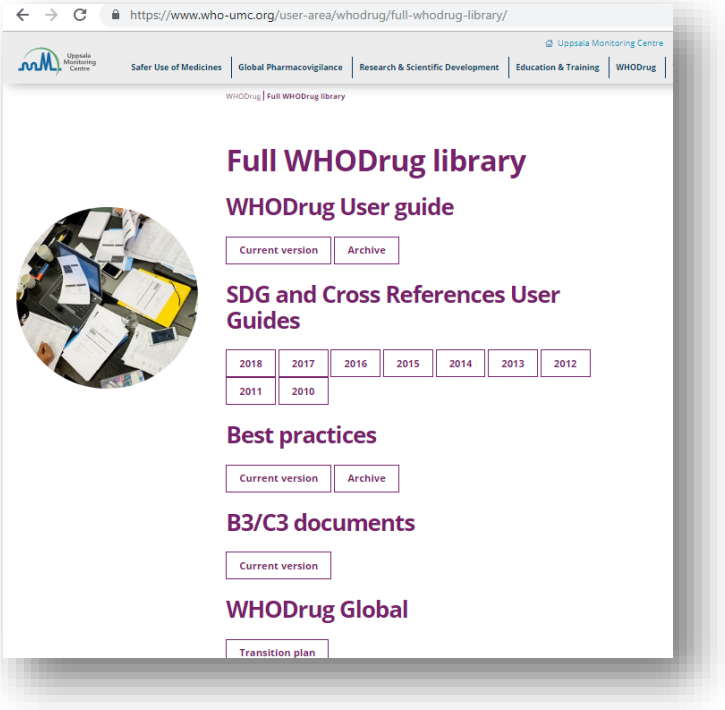
This website is also available in Spanish https://who-umc.org/whodrug/mexico/es/

Documents - WHODrug Global Library

Users of WHODrug Global licenses (login and password required) have the following tools at their disposal.

- User Guides
- Coding Best Practices Manual

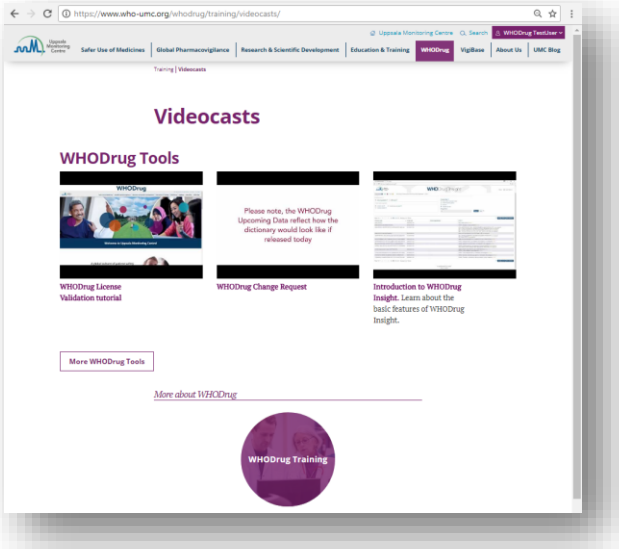
- WHODrug Global News
- Other documents of interest



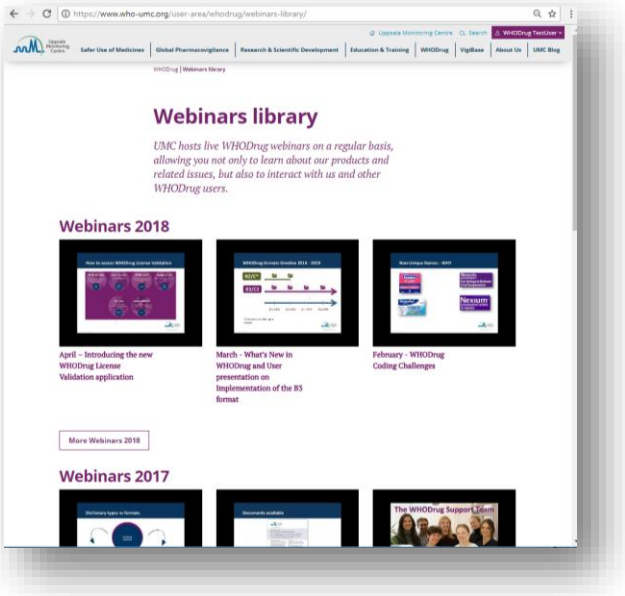
https://www.who-umc.org/user-area/whodrug/full-whodrug-library/

Video tutorials and webinars

This site hosts multimedia material related to training sessions that are very useful for users.



https://www.who-umc.org/whodrug/training/videocasts/



https://www.who-umc.org/user-area/whodrug/webinars-library/

Training events in Mexico

WHODrug users, in addition to the training resources mentioned above, will be able to participate in two events to be organized by the UMC and Cofepris in 2023.

1) Promotional and training activity in LATAM

Proposed date: April 2023
Host: Mexico City
Organization: UMC/Cofepris
Objective: to promote the use of WHODrug and Good Coding Practices.
Modality: hybrid
Target audience: UFV of the pharmaceutical industry, CEFV, CICFV and CIFV

2) 1st MedDRA User Group Meeting & UMC WHODrug User Group Meeting in LATAM

Proposed date: October 2023
Host: Mexico City
Organization: UMC/MSSO/Cofepris
Objectives:

- To present MSSO services, coding and analysis in MedDRA and change request processes.

- Share ideas and best practices between WHODrug experts and current users, as well as discuss solutions on how to use the drug dictionary. Coding Best Practices.
- Expose implementation experiences in Latin America (Brazil, Colombia and Argentina).

Target audience: MedDRA and WHODrug users.

Licenses

Purchase of licenses

Cofepris does not manage or provide WHODrug licenses and has no involvement in the evaluation, assessment, analysis, costing and determination of the type of license that corresponds to each company, nor does it receive any remuneration derived from the use of WHODrug.

It is the UMC through its WHODrug sales and support area that performs the following activities, in strict adherence to its non-profit guidelines as a Collaborating Center for the WHO-Programme for International Drug Monitoring:

- Provide information regarding WHODrug licenses
- Perform the market analysis of each company to determine the corresponding license and its cost
- Provide technical support to WHODrug users
- Provide face-to-face/virtual training to WHODrug users

The WHODrug subscription types currently operated by the UMC are defined on the basis of user type:

- Regulatory authorities (free license)
- Non-profit academia (free license)
- Private Pharmaceutical Industry (license fee)
- Software developers (license fee)

For questions related to WHODrug license subscription types, please contact UMC directly through the following options:

Web form: https://who-umc.org/whodrug/whodrug-subscription/

Email: subscription@who-umc.org

Continuation of the IDMP implementation project

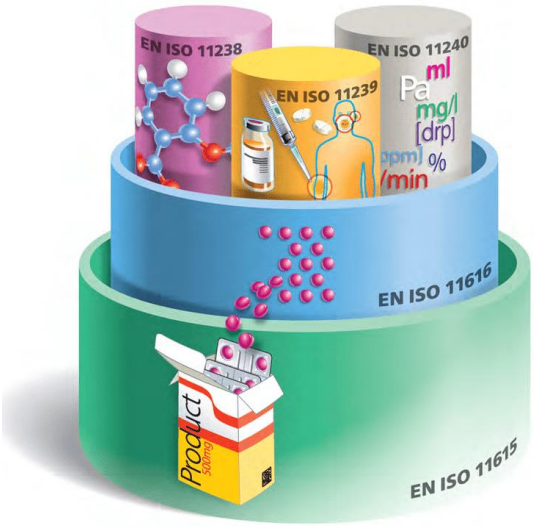
The UMC will be the organization in charge of coordinating the ISO-IDMP drug identification harmonization project.

The ISO-IDMP project was initiated in 2012 and aims to create a Medicinal Product Identifier (IDMP) calculated from information from a set of five ISO standards, which will allow a medicinal product to be uniquely and unequivocally identified.

Several initiatives by regulatory authorities and pharmaceutical companies have begun to promote the harmonization of global identifiers. The need for global identifiers is based on the inadequacy of case analysis where only free text information is available and the level of specificity depends on what has been reported by the initial reporter.

The ISO standards to be used for this project are:

- **ISO 11238** – Substance Identification
- **ISO 11239** – Pharmaceutical dose forms, units of presentation and routes of administration
- **ISO 11240** – Units of measurement - strenght
- **ISO 11616** – Pharmaceutical Product Identification (PhPID). Pharmaceutical product identifier code, set of one or more of the following standards 11238, 11239, 11240
- **ISO 11615** – Medicinal Product Identification (MPID)



Source: unicom-project.eu

With the implementation of WHODrug Global, we intend to expand the scope of this dictionary to include the ISO IDMP, PhPID Global and the global active

ingredient ID, in order to preserve the coding and analysis tasks in a single dictionary. The UMC will be the organization that will provide the future generation and maintenance of the global PhPID and will provide support for the calculation of the ISO IDMP.

WHO initiated global implementation of PhPID in 2019. Shortly thereafter, the European UNICOM project for IDMP implementation started and, with the launch of COVID-19 vaccines, the need for global harmonization of drug information and global PhPIDs became even more evident.

To continue exploring the application of PhPID globally, a *Global IDMP Working Group* (GIDWG) was formed in October 2021 to carry out projects leading to the establishment of a framework for the global implementation of ISO IDMP standards and the maintenance of global standards.

IDMP benefits in the drug and vaccine cycle

- Medicines and vaccine safety monitoring
  - Unambiguous global identification will improve pharmacovigilance by uniquely identifying specific drugs in adverse reaction reports.
  - Improved global detection of drug and vaccine safety signals to which adverse events are referenced.
- Transparency
  - Communicate medicine data globally
  - Opportunity to communicate and build trust with the public and other stakeholders about the quality and safety of medicines
- Mitigation of drug shortages
  - It enables the identification of pharmaceutically equivalent products in all regions, allowing communication to other regulatory authorities to help mitigate drug shortages.
- Interoperability
  - Harmonized source of product information based on vocabularies and standards that are consistent worldwide.
  - Supports the exchange of drug information between pharmaceutical companies, academia, the healthcare sector and regulatory authorities.

Contacts

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- Aspects of WHODrug implementation in Mexico
- Support of test XML review requests already configured with WHODrug
- Support of XML revision requests with E2B (R3) standard
- Copy of requests for modification/registration of products in WHODrug that are made directly through the WHODrug Change Request tool.

subscription@who-umc.org

- WHODrug license details
- License requests and modifications

WHODrug@who-umc.org

- WHODrg Global implementation information
- Drugs and vaccines modification request information in WHODrug

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Appendices

Appendix 1

Technical guidance for use of WHODrug Global in XMLs uploaded in VigiFlow eReporting for Industry for E2B (R3) compliance
English and Spanish version

Appendix 2

How to use the WHODrug C3 format for drug coding
English and Spanish version

Note: The appendices may be updated as required by the needs of use in Mexico, therefore the CNFV reserves the right to update the versions at any time.