Introduction to WHODrug Global

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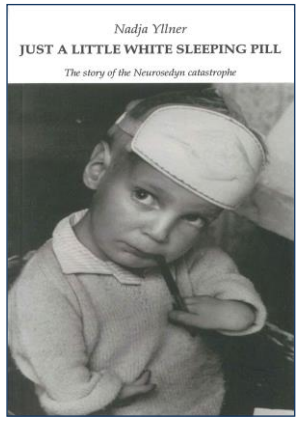
2023-09-20

Uppsala Monitoring Centre

The WHO-Programme for International Drug Monitoring (WHO-PIDM)



Thalidomide disaster in 1961

World Health Organization

In 1968 WHO creates the Programme for International Drug Monitoring (WHO-PIDM)

Uppsala Monitoring Centre

In 1978 the Swedish Government and WHO create the UMC as a Collaborating Centre to support the WHO-PIDM

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Redesignation of UMC as the WHO – Collaborating Centre for International Drug Monitoring in charge of supporting the WHO-PIDM – July 2021 to July 2025
Non-profit Pharmacovigilance activities

11/10/21, 4:13 PM WHOCC - WHO Collaborating Centres

World Health Organization

WHO Collaborating Centres
Global database

Ref.No. [Initiator]
SWE-28 [Headquarters]

Status
Active

Title of the centre:
WHO Collaborating Centre for International Drug Monitoring

Director / Head:

Institution:

The Uppsala Monitoring Centre

Address:
Box 1051
S-751 40

Town: Uppsala
Country: SWEDEN
Region: EURO
Phone: (46-18) 65 60 60
Fax: (46-18) 65 60 88
Web Site: http://www.who-umc.org
Date of Designation: 20/Jan/1977
Last Redesignation: 23/Jul/2021
Expiry: 23/Jul/2025

Terms of Reference:
1. Support WHO in the scientific development and in its activities in the WHO Programme for International Drug Monitoring relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem.
2. Under WHO's guidance, provide pharmacovigilance tools and services and deliver efficient access to information in the WHO global database of reported potential side effects of medicinal products.
3. Assist WHO by contributing to its capacity-building activities relevant to the framework of the WHO Programme for International Drug Monitoring.
4. Support WHO drug-risk mitigation strategies for LMICs in the WHO Programme for International Drug Monitoring.

Subjects:
1. Pharmaceuticals (including essential drugs and medicines)

Types of activity:
1. Collection and collation of information

WHO Outputs:
1.3.3 - Country and regional regulatory capacity strengthened, and supply of quality-assured and safe health products improved
1.3.1 - Provision of authoritative guidance and standards on quality, safety and efficacy of health products, including through prequalification services, essential medicines and diagnostics lists

Responsible Officer:

Technical Counterpart:

Access to annual progress reports and the current workplan (this is accessible to WHO Staff Members only):
Link to eWork

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Uppsala Monitoring Centre (Uppsala, Sweden)

Our job is:

- To Provide **technical, operational support, and scientific support** to the regulatory authorities and ministries of health of the **WHO-PIDM member countries** .
    - Via offering **VigiFlow** (and its associated services) and **VigiLyze** as **technological solutions** that contribute to strengthening the national pharmacovigilance systems of the WHO-PIDM member countries.
    - Via Detection and diffusion of signals (English and soon in Spanish)
    - Via prodviding training and courses in pharmacovigilance (English and Spanish, Portuguese soon)
- To host and maintain the WHO global database of ADRs and AEFIs (**VigiBase**).
- To coordinate PHPID calculation in the **ISO IDMP** drug identification harmonization project, which can be available to countries through **WHODrug.**
- To Actively participate in global harmonization efforts in collaboration with **ISO** and **ICH** with the aim of promoting safer medicines for all.

ISO: *International Organization for Standardization*
IDMP: *Identification of Medicinal Products*
ICH: *International Council for the Harmonization of Technical Requirements for Pharmaceutical Products for Human Use*

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What is WHO Drug Global?

- WHODrug Global is the international reference for pharmaceutical product information and contains information on nearly **4 million different pharmaceutical products** from **168 countries** (as of March 2023).
- It is a **dictionary of pharmaceutical products** developed and maintained by the UMC that is used to identify names and analyse information related to pharmaceutical products.
- It is used by around **2,500 organizations around the world** , from regulatory authorities and pharmaceutical companies, to research centers and universities.
- The use of WHODrug Global is required by reference organizations such as the regulatory authorities of the United States (**US FDA**), Japan (**PMDA**), South Korea (**KIDS**), Türkiye (**TITCK**), Mexico (**COFEPRIS**) and Colombia (**INVIMA**). And it is recommended by several organizations in different countries including Brazil (ANVISA), Ecuador (ARCSA), Peru (DIGEMID) and Uruguay (MoH).
- Updates on WHODrug Global are released **twice a year,** on March 1 and September 1.
- Available in: **English, Chinese, Spanish** and **Portuguese**

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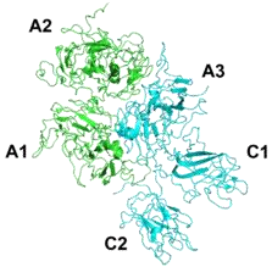
Types of Medications included in WHODrug Global

Vaccines

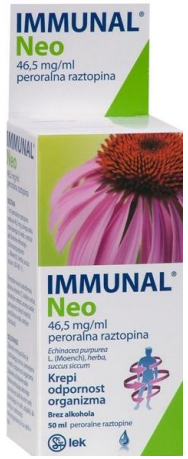
Homeopathic products

Vitamins/supplements

Biological products

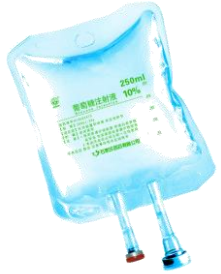


herbal products



Conventional medications

Chemotherapy regimens

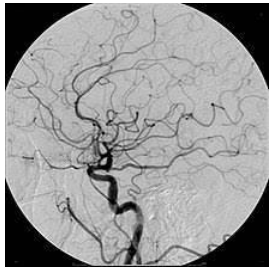


Analgesics

Medical devices with medicines

Traditional Medicine

Contrast media



“ Umbrella records ” that represent groups or types of medications

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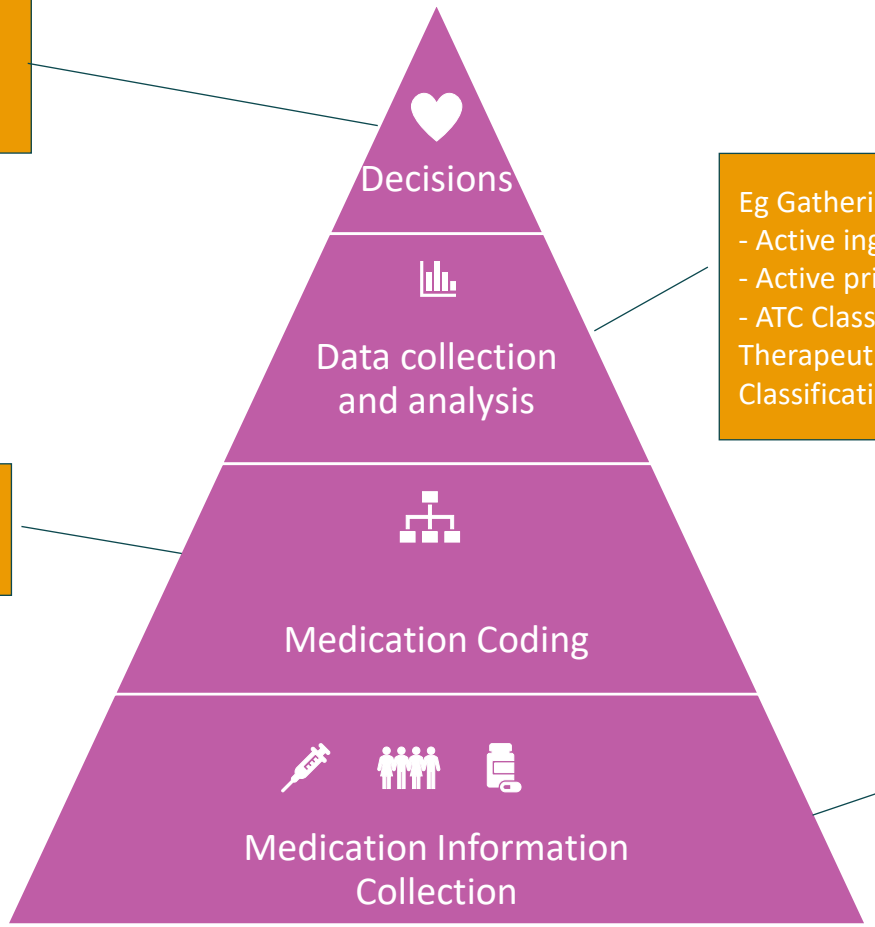
WHODrug Global – enables detailed analysis of pharmaceutical products information

Appropriate therapeutic decisions based on evidence.



Eg Gathering information by:
- Active ingredient(s)
- Active principle (s) (salts)
- ATC Classification (Anatomical, Therapeutic, Chemical Classification System)

WHO Drug Global

The names of the products are structured hierarchically based on their active ingredients and are assigned a unique identifier (the drugs Code).

Eg Report of adverse reactions concerning drugs or vaccines in post-marketing VF or clinical trials

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Product Information in WHODrug Global

- product name
- unique identifier codes
  - Drug code → active ingredient, salt variation and product name
  - MPID → drug code info + country, ATC, MAH, form, strenght
- Active principle
- ATC Classification
- country of sale
- Market Authorization Holder
- Pharmaceutical form
- Concentration

Product Name C3	Name Specifier	Drug Code	Active Ingredients	ATC	Country of Sales	MAH	Pharmaceutical Form	Strength
Loxonin MPID 80844		008907 02 002	☐ Loxoprofen sodium	**M01AE,** Propionic acid derivatives *umc-assigned* **M02AA,** Antiinflammatory preparations, non-steroids for topical use *official*	Brazil • China • Colombia • Dominican Republic • Ecuador • Indonesia • Japan • Korea (the Republic of) ... ↘	Alfa • Daiichi Sankyo • Dong wha • Sankyo • Sankyo co ltd • Sankyo pharma • Sankyo Pharma Brasil Ltda. • Sankyo pharma venezuela s.a. • Siegfried rhei ... ↘	GELS AND SOLS • TABLETS	1 % • 60 mg

WHODrug Insight

WHODrug Global Viewer

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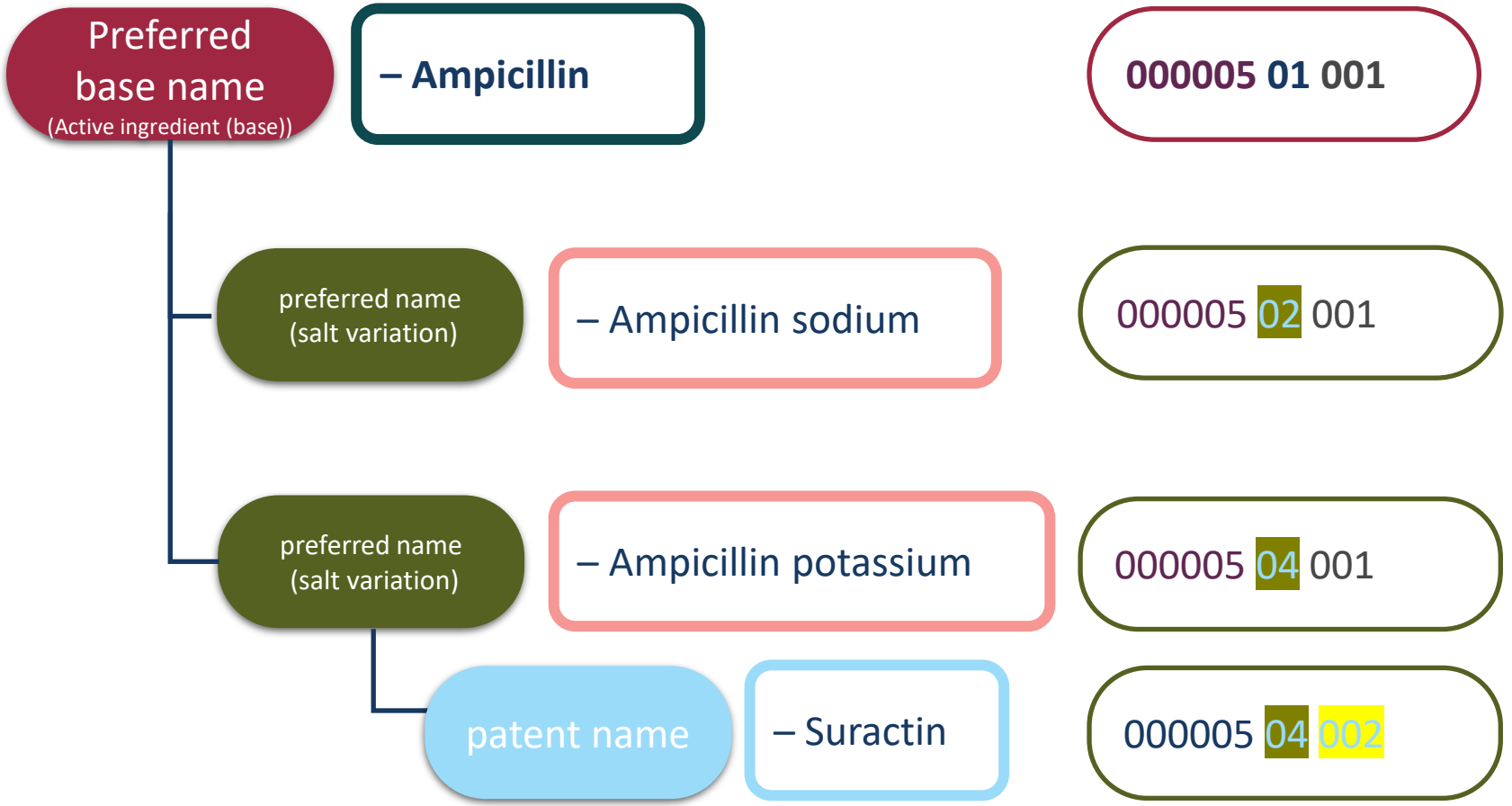
The hierarchical structure of a product in WHODrug Global



Drug names that have a code ending with 001 are called “ Preferred ”. Names ” (refer to active ingredients and salts (and their variants).

-The " Drug " Code ” is a unique identifier of the drug name.
-Provides information on the active ingredient(s), the salts (and their variants) and the name of the medication

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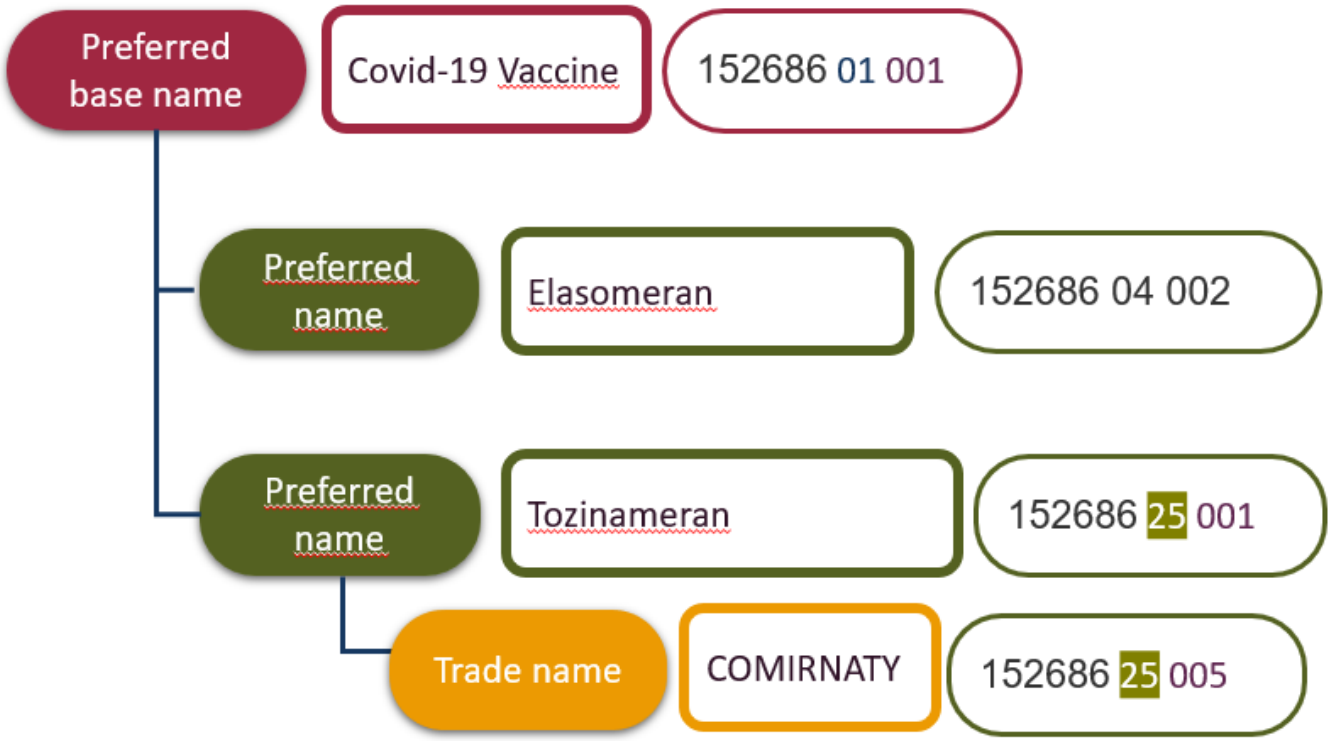
Vaccines – hierarchy at WHODrug



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C3 format and WHODrug MPID

WHODrug

Acqta (Drug code 003843 02 107) Ingredient: loperamide clorhydrate ATC: A07DA, Antipropulsives	MPID	Country of sales	MAH	Pharm form	strenght
	287968	-	-	-	-
	1316064	México	-	-	-
	287967	México	Rayere	-	-
	291217	México	Rayere	liquids	-
	287966	México	Rayere	tablets	-
	4963027	México	Rayere	tablets	2 mg

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ATC Classification of drugs in WHODrug Global

In WHODrug Global, drug names are classified according to:

1. ATC Classification (Anatomical, Therapeutic, Chemical Classification System).
   - www.whocc.no/atc_ddd_index
2. Herbal ATC classification, for herbal products.
3. ATC codes created by UMC

All product names on WHODrug Global are classified to reflect authorized indications for use

Why did the patient take gabapentin?

Nauralgia →N02BG, Other analgesics and antipyretics (umc -assigned)
Seizures → N03AX, Other antiepileptics (official)
Restless legs s → N07XX, Other nervous system drugs (umc -assigned)

Standardized Drug Groupings

Very useful for analyzing information already coded with WHODrug

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Definition

An SDG is any grouping of medicines having one or several properties in common

"The individual grouping can be based on indication, chemical properties, pharmacodynamic properties and/or pharmacokinetic properties as well as any other property of interest."

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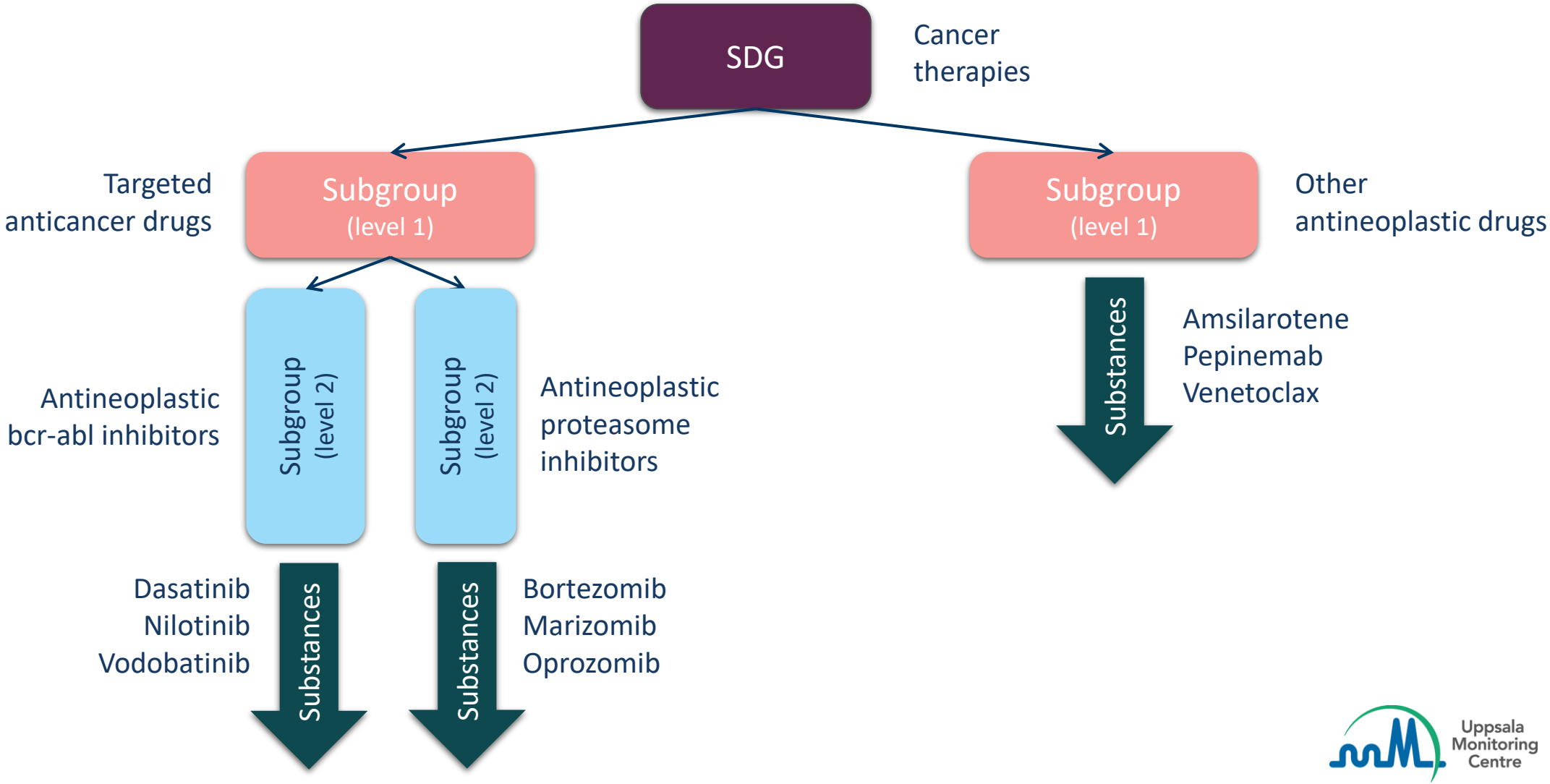
SDG Structure – with subgroups



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SDGs, what do you use them for?

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Use of WHODrug Global in the world

Examples of reference regulatory authorities

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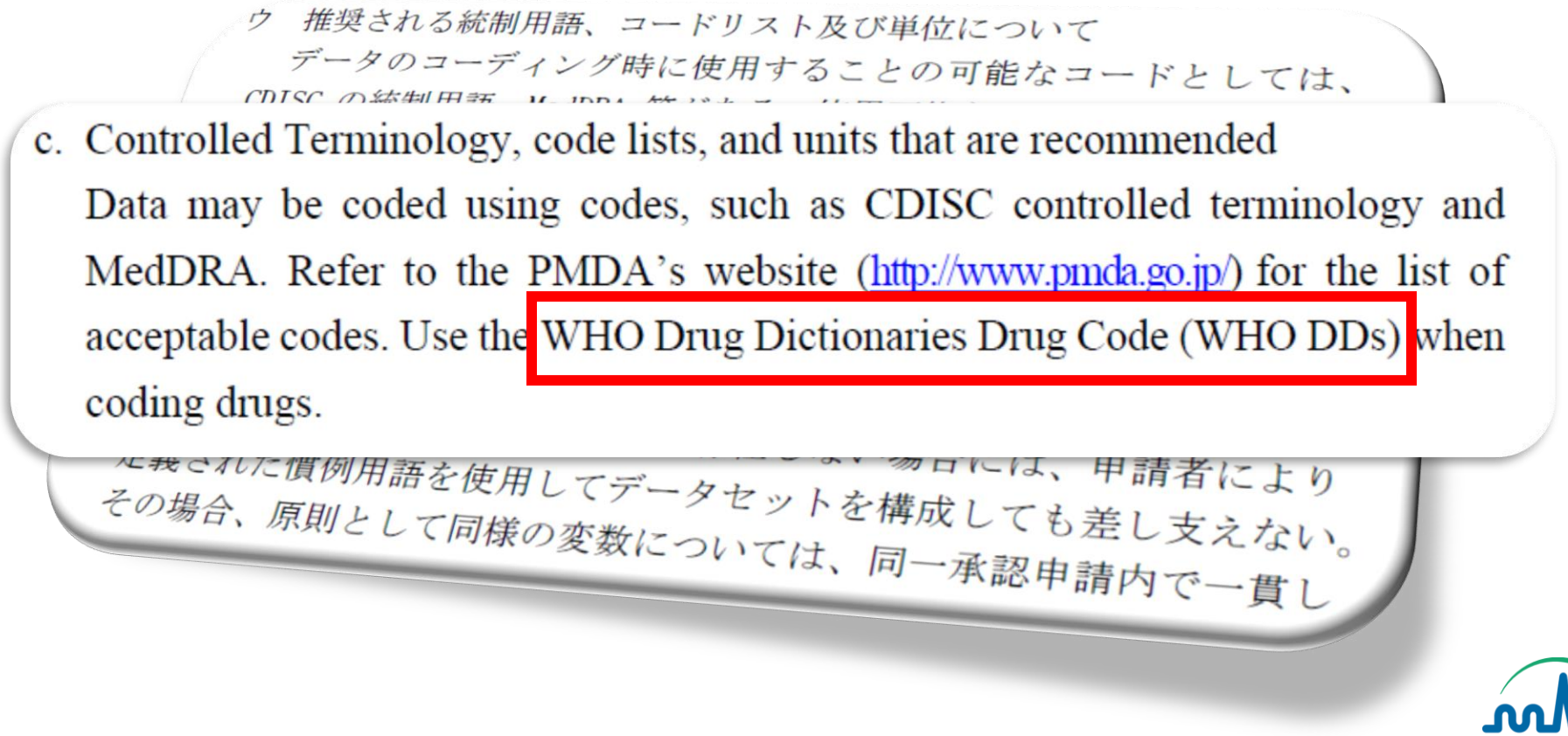
– Building a global safety culture

Pharmaceuticals and Medical Devices Agency (PMDA) Japan

Notification of practical operations for electronic submission of information derived from clinical studies [1]



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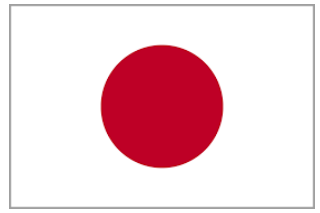
PMDA Japan – Information Standards Catalog [2]



PMDA Data Standards Catalog (2019-11-01) - Terminology Standards

Terminology Standard	Version(s)	Date Support Begins (YYYY-MM-DD)	Date Support Ends (YYYY-MM-DD)	Notes
CDISC Controlled Terminology	Between 2009-02-17 (inclusive) and 2011-06-10 (exclusive)	2016-10-01	2017-06-30	When using the version indicated in "Version(s)" column, consult PMDA at the consultation on data preparation of the submission of electronic study data.
CDISC Controlled Terminology	2011-06-10 or later	2016-10-01		
MedDRA	8.0 or later	2016-10-01		
WHO Drug Dictionary Enhanced/ WHODrug Global (since 2017 March)	2008:4 (2008-12-01) or later	2016-10-01		

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Food and Drug Administration (FDA) United States of America

Federal Register Notice [3]

Federal Register / Vol. 82, No. 204 / Tuesday, October 24, 2017 / Notices 49211

I. Background

On December 17, 2014, FDA published a final guidance for industry entitled "Providing Regulatory Submissions in Electronic Format—Standardized Study Data" (eStudy Data Guidance), posted on FDA's Study Data Standards Resources Web page at *https://www.fda.gov/forindustry/datastandards/studydatastandards/default.htm*. The eStudy Data Guidance implements the electronic submission requirements of section 745A(a) of the Federal Food, Drug, and Cosmetic Act for study data contained in NDAs, ANDAs, BLAs, and certain INDs to CBER or CDER by specifying the format for electronic submissions. The initial timetable for the implementation of electronic submission requirements for study data was December 17, 2016 (24 months after issuance of final guidance for NDAs, BLAs, ANDAs, and 36 months for INDs). The eStudy Data guidance states that a **Federal Register** notice will specify the transition date for all version updates (with the month and day for the transition date corresponding to March 15).

FDA currently supports the use of WHODG for the coding of concomitant medications in studies submitted to CBER or CDER in NDAs, ANDAs, BLAs, and certain INDs in the electronic common technical document format. Generally, the studies included in a submission are conducted over many years and may have used different WHODG versions to code concomitant medications. The expectation is that sponsors and applicants will use the most current B3-format annual version of WHODG at the time of study start. However, there is no requirement to recode earlier studies. The transition date for support of the most current B3-format annual version of WHODG is March 15, 2018. Although the use of the current B3-format annual version of WHODG is supported as of this **Federal Register** notice and sponsors or applicants are encouraged to begin using it, the use of the most current B3-format annual version will only be required in submissions for studies that start after March 15, 2019. The Catalog will list March 15, 2019, as the "date requirement begins." The Study Data Technical Conformance Guide provides addition information and recommendations on the coding of concomitant medications (*https://*

be updated to list March 15, 2019, as the "date support ends." Studies that start after March 15, 2019, will be required to use the most current B3-format annual version of WHODG.

Dated: October 18, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–23029 Filed 10–23–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0278]

Trand Doan Nguyen; Denial of Hearing; Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is denying Trang Doan Nguyen's (Nguyen's) request for a hearing and is issuing an order under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) debarring Nguyen for 5 years from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on a finding that Nguyen was convicted of a misdemeanor under Federal law for conduct relating to the development or approval of a drug product or otherwise relating the regulation of a drug product under the FD&C Act and that the type of conduct underlying the conviction undermines the process for the regulation of drugs. In determining the appropriateness and period of Nguyen's debarment, FDA has considered the relevant factors listed in the FD&C Act. Nguyen has failed to file with the Agency information and analyses sufficient to create a basis for a hearing concerning this action.

DATES: The order is effective October 24, 2017.

ADDRESSES: Any application by Nguyen for special termination of debarment under section 306(d) of the FD&C Act (application) may be submitted as follows:

Electronic Submissions

- *Federal eRulemaking Portal: https://www.regulations.gov.* [illegible] the instructions for sub[illegible]

solely responsible for ensuring that your application does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your application, that information will be posted on *https://www.regulations.gov*.

- If you want to submit an application with confidential information that you do not wish to be made available to the public, submit the application as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For a written/paper application submitted to the Dockets Management Staff, FDA will post your application, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: Your application must include the Docket No. FDA–2011–N–0278. An application will be placed in the docket and, unless submitted as "Confidential Submissions," publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit an application with confidential information that you do not wish to be made publicly available, submit your application only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of your application. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *www.regulati*[illegible] Submit[illegible]s to the[illegible]

"The expectation is that sponsors and applicants will use the most current annual B3 format version of WHODG at the time of study initiation."

"...use of the current annual version of WHODG B3 format is supported by this Federal Register notice and sponsors or applicants are encouraged to begin using it"

"...use of the most current annual version of the B3 format will only be required for study submissions beginning after March 15, 2019."

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US FDA – Information Standards Catalog [4]

FDA Data Standards Catalog v7.3 (09-14-2021)

For full description of column headings, see Instr. & Column Descriptions tab

Use	Terminology Standard	Terminology Standards Development and/or Maintenance Organization	Version(s)	FDA Center(s)	Date Support Begins (MM/DD/YYYY)	Date Support Ends (MM/DD/YYYY)	Date Requirement Begins (MM/DD/YYYY) [10] [11]	Date Requirement Ends (MM/DD/YYYY)	Examples of Use	Statutory, Regulatory, or Guidance Authority	Information Sources	
Medication	WHODrug Global	Uppsala Monitoring Centre	Current Version-B3 format	CBER, CDER	03/15/2018		03-15-2019		Use in SDTM CMDECOD and CMCLAS	Standardized Study Data	WHODrug Global	Study Data Technical Conformance Guide

WHODrug Global

Version(s)

Current Version-B3 format

Date Requirement Begins (MM/DD/YYYY)

03-15-2019

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US FDA
Compliance Guide for Clinical Study Information [5]

6.4.2 WHODrug Global

6.4.2.1 General Considerations

World Health Organization (WHO) Drug Global[56] is a dictionary maintained and updated by Uppsala Monitoring Centre. WHODrug Global contains unique product codes for identifying drug names and listing medicinal product information, including active ingredients and therapeutic uses.

Typically, WHODrug Global is used to code concomitant medications. The variable --DECOD should be populated with the active substances from the WHODrug Global Dictionary, and --CLAS populated with the drug class.

When using WHODrug Global, --CLAS is recommended to be populated with the Anatomic Therapeutic Chemical (ATC) class most suitable per intended use, and the remainder of the ATC classes, if any, placed in SUPPCM. Alternately, the use of the SUPPCM or FACM domains to populate all ATC Classes associated with the --DECOD value is acceptable. ATC classes should be submitted at the fourth level or most specific available as defined within WHODrug Global.

Generally, studies included in a submission are conducted over many years and may have used different WHODrug Global versions to code concomitant medications. The expectation is the most current B3-format annual version of WHODrug Global at the time of study start will be used to code concomitant medications. There is no requirement to recode earlier studies to align with the WHODrug Global version of later studies.

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US FDA – Validation Rules [7]

version 1.5, finalized March 2021

FDA Validator Rule ID	Publisher	Publisher ID	FDA Validator Rule Message	FDA Validator Rule Description	Domains
SD1344	FDA	FDAB017	Value for --DECOD not found in WHODrug dictionary	Value for the Standardized Medication Name (--DECOD) variable must be populated using a Drug Name from the WHO Drug dictionary version specified in the define.xml.	CM
SD1345	FDA	FDAB017	Value for --CLAS not found in WHODrug dictionary	Value for the Medication Class (--CLAS) variable must be populated using ATC Text from the WHO Drug dictionary version specified in the define.xml.	CM
SD1346	FDA	FDAB017	Value for --CLASCD not found in WHODrug dictionary	Value for the Medication Class Code (--CLASCD) variable must be populated using ATC Code from the WHO Drug dictionary version specified in the define.xml.	CM

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KIDS – South Korea [8]

WHODrug Global (C3 format) as the standard terminology for drug coding in ICSR submission to the regulatory authority.

Mandatory for post-market authorization pharmacovigilance (updated February 22, 2021).

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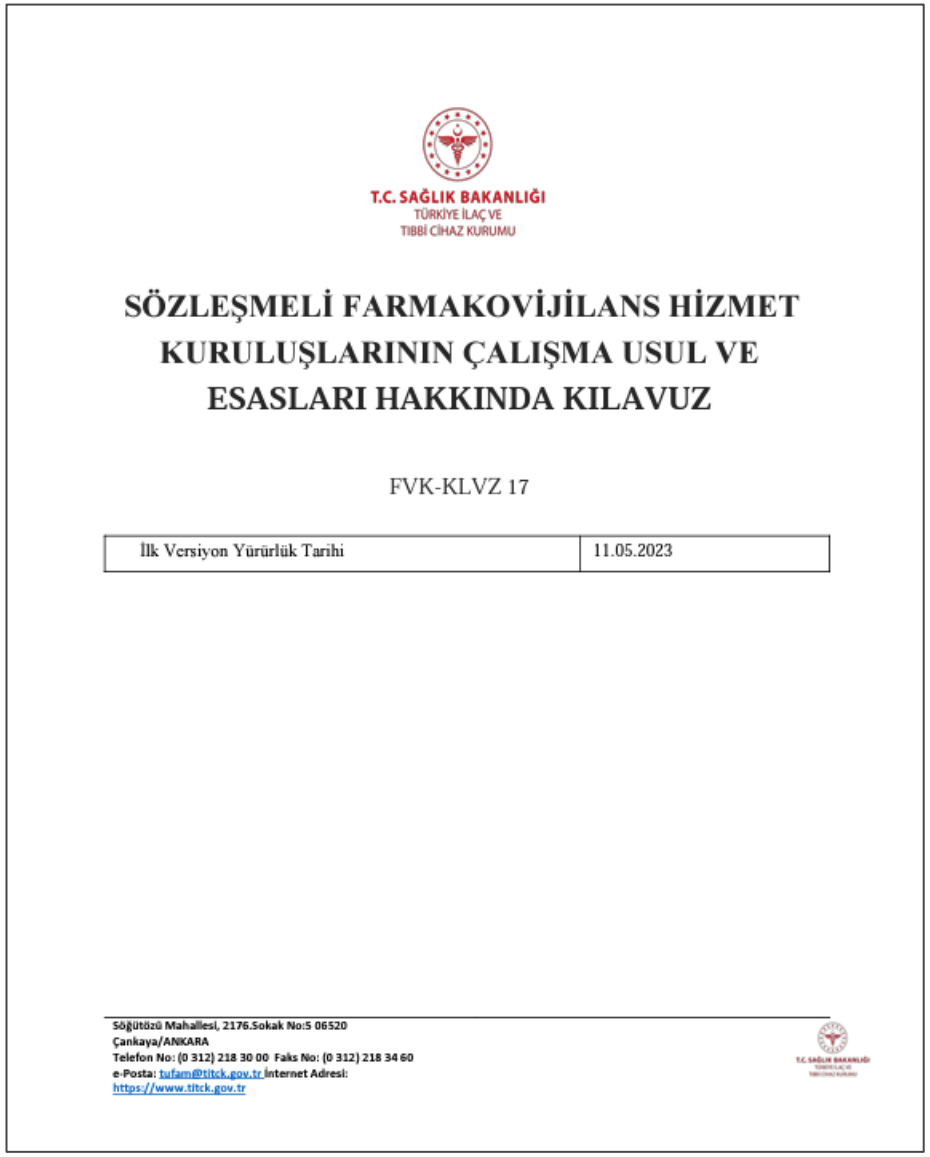
TITCK – Türkiye [9]

Guide FVK-KLVZ-17

WHODrug Global as the required terminology for drug coding in ICSR submission to the regulatory authority.

“The safety database must comply with E2B(R3) and be fully validated.

…The database should include the latest version of MedDRA and the WHO Drug Dictionary or the Extended EudraVigilance Medicinal Product Dictionary (Xtended “EudraVigilance Medicinal Product Dictionary ;XEVMPD).”…



T.C. SAĞLIK BAKANLIĞI
TÜRKİYE İLAÇ VE
TIBBİ CİHAZ KURUMU

SÖZLEŞMELİ FARMAKOVİJİLANS HİZMET KURULUŞLARININ ÇALIŞMA USUL VE ESASLARI HAKKINDA KILAVUZ

FVK-KLVZ 17

İlk Versiyon Yürürlük Tarihi	11.05.2023

Söğütözü Mahallesi, 2176.Sokak No:5 06520
Çankaya/ANKARA
Telefon No: (0 312) 218 30 00 Faks No: (0 312) 218 34 60
e-Posta: tufam@titck.gov.tr İnternet Adresi:
https://www.titck.gov.tr

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COFEPRIS – Mexico [10]

WHODrug Global (C3 format) as the standard terminology for drug coding in ICSR submission to the regulatory authority.

Mandatory for clinical trials and post-market authorization pharmacovigilance from January 1, 2024 (announced in November 2022).

Applies to:
-Suspected medication
-Interacting medication
-Concomitant medication
-Medication not administered
-Parents' medication history
(in a parent-child report)
-Patient medication history.

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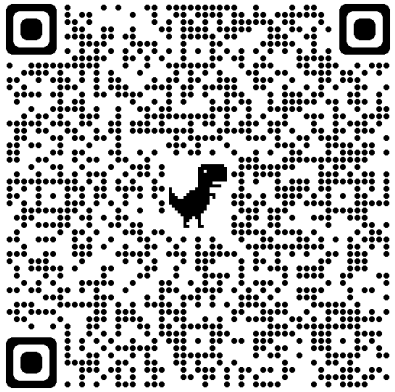
ANVISA - Brazil [11]

WHODrug Global recommendation as the coding standard for ICSR submissions from industry to the NRA.



gov.br Ministério da Saúde

Órgãos do Governo | Acesso à Informação | Legislação | Acessibilidade | Entrar

Agência Nacional de Vigilância Sanitária - Anvisa

O que você procura?

Assuntos > Notícias > 2022 > Simpósio discute melhorias para o monitoramento de eventos adversos

FARMACOVIGILÂNCIA

Simpósio discute melhorias para o monitoramento de eventos adversos

Realizada na sede da Anvisa, em Brasília (DF), atividade integrou as comemorações pelo Dia Mundial de Segurança do Paciente.

Publicado em 16/09/2022 14h35 | Atualizado em 16/09/2022 19h27

Compartilhe:

A Anvisa, o Uppsala Monitoring Centre (UMC) e empresas da indústria farmacêutica discutiram, nesta quinta-feira (15/9), melhorias para o sistema brasileiro de farmacovigilância, responsável pela identificação e monitoramento de eventos adversos relacionados ao uso de medicamentos. O debate ocorreu no segundo e último dia de atividades do 1º Simpósio Internacional de Farmacovigilância, realizado na sede da Agência, em Brasília (DF).

O principal assunto apresentado foi o uso de dicionários de medicamentos como forma de aprimorar o conteúdo de relatos sobre produtos envolvidos em casos de eventos adversos ou de problemas detectados após o uso de fármacos.

Os dicionários em questão são o MedDRA - Medical Dictionary for Regulatory Activities (Dicionário Médico para Atividades Regulatórias) e o WHODrug, que consiste em um sistema global de informações padronizadas, mantido pelo UMC, centro colaborador da Organização Mundial da Saúde (OMS) para o monitoramento da segurança de medicamentos no mundo.

Esses dicionários ajudam na identificação de medicamentos e vacinas com base em dados codificados. A codificação é única para cada produto. Isto contribui para a melhoria do monitoramento de fármacos em todo o mundo, permitindo análises sobre eventos adversos e troca de informações entre países.

Os dois dicionários já são utilizados no Brasil, sendo que o MedDRA é de uso obrigatório desde 2020. Atualmente, está em processo de discussão a incorporação do uso mandatório do WHODrug como mais uma ferramenta de melhoria do monitoramento de eventos adversos no país. Essa ferramenta é utilizada por 2.500 organizações em todo o mundo.

No caso da indústria, essas notificações devem ser feitas pelo VigiMed Empresas, sistema destinado ao uso exclusivo de empresas do setor regulado, adotado pela Anvisa desde 2018 para a gestão das notificações de suspeitas de eventos adversos.

Durante o evento destacou-se que a codificação de medicamentos e vacinas facilita a identificação de produtos em uma base de dados composta por quatro milhões de produtos de 168 países.

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INVIMA - Colombia [12]

WHODrug Global recommendation (C3 format) as the coding standard for ICSR submissions from industry to the NRA.

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ARCSA - Ecuador [13]

Guideline:
IE-B.5.1.4-FCV-02 Notification of adverse events to medications for holders of Sanitary Registry

WHODrug Global recommendation (C3 format) as the coding standard for ICSR submissions from industry to the NRA.


Agencia Nacional de Regulación, Control y Vigilancia Sanitaria

INSTRUCTIVO EXTERNO

NOTIFICACIÓN DE SOSPECHAS EVENTOS ADVERSOS AL USO DE MEDICAMENTOS PARA ESTABLECIMIENTOS FARMACÉUTICOS Y TITULARES DE REGISTRO SANITARIO

Versión [1.0]

Coordinación General Técnica de Vigilancia y Control Posterior
Dirección Técnica de Farmacovigilancia, Tecnovigilancia y Vigilancia de Productos Sanitarios.
Mayo, 2023

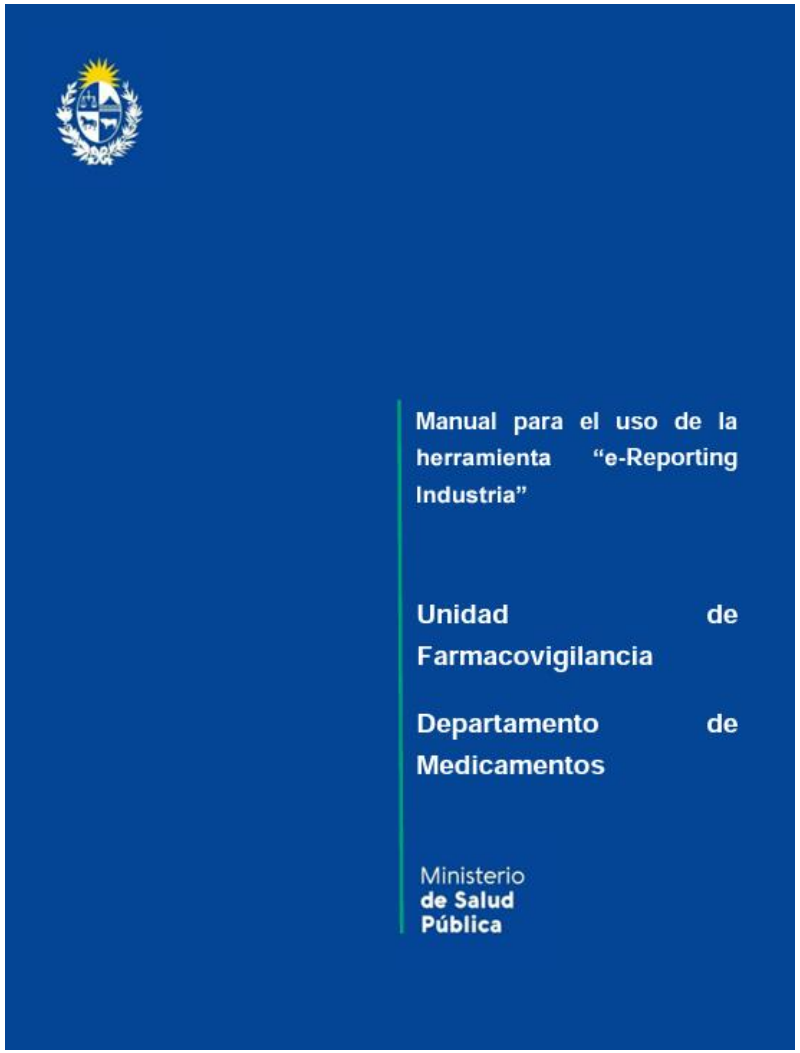
LA AGENCIA NACIONAL DE REGULACIÓN, CONTROL Y VIGILANCIA SANITARIA SE RESERVA EL DERECHO DE ESTE DOCUMENTO, EL CUAL NO DEBE SER USADO PARA OTRO PROPÓSITO DISTINTO AL PREVISTO EN EL MISMO; DOCUMENTOS IMPRESOS O FOTOCOPIADOS SON COPIAS NO CONTROLADAS, VERIFICAR SIEMPRE CON LA ÚLTIMA VERSIÓN VIGENTE EN EL REPOSITORIO INSTITUCIONAL

Gobierno del Ecuador
GUILLERMO LASSO
PRESIDENTE

Ministry of Public Health - Uruguay [14]

Guideline:
Manual for the use of the industry eReporitng tool

WHODrug Global recommendation (C3 format) as the coding standard for ICSR submissions from industry to the NRA.



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DIGEMID - Peru [15]

Guideline:
Reporting guidance document for the industry.

WHODrug Global recommendation (C3 format) as the coding standard for ICSR submissions from industry to the NRA.

DOCUMENTO DE ORIENTACIÓN

eReporting industria para titulares de registro sanitario y titulares del certificado de registro sanitario

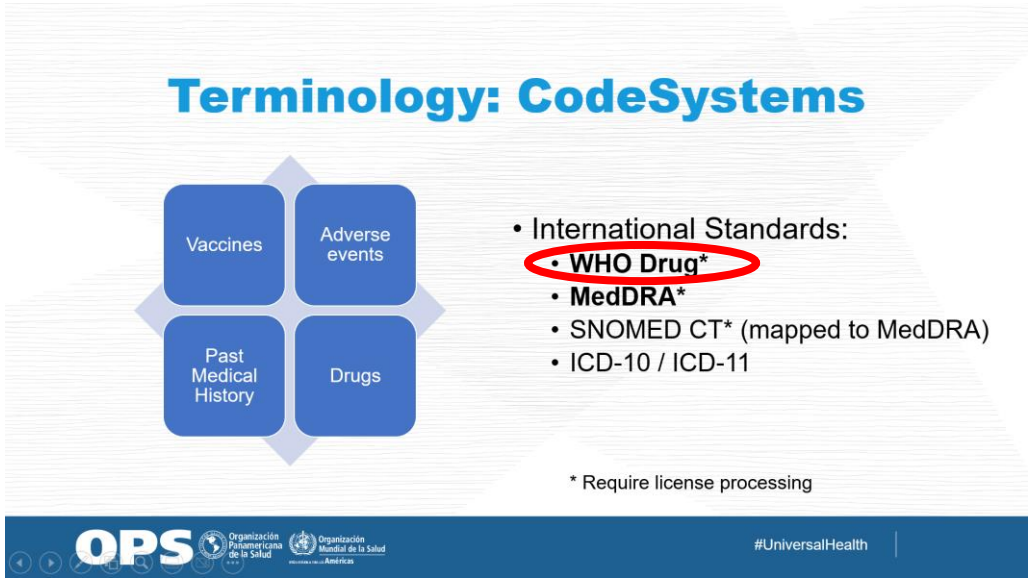
Versión N.º 1 – mayo 2022

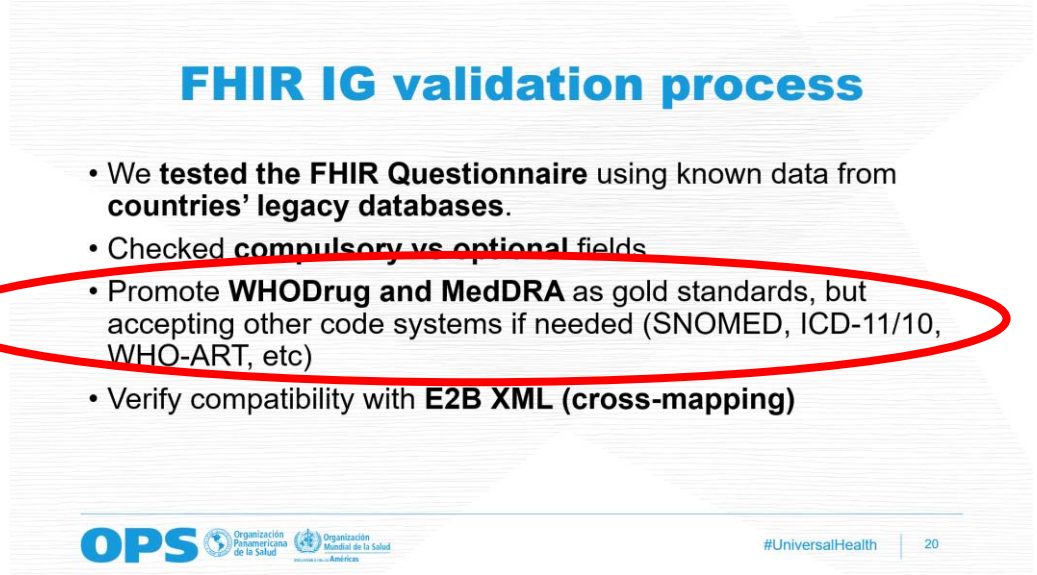
Centro Nacional de Farmacovigilancia y Tecnovigilancia

Uppsala Monitoring Centre

PAHO (Pan American Health Organization)

WHODrug Global is recommended as the preferred vaccine and drug coding standard in the context of AEFI reporting to regulatory authorities and Expanded Immunziation Programs.





References

1) Notification on Practical Operations of Electronic Study Data Submissions *(provisional English translation),* PMDA, July, 2015

2) PMDA Data Standards Catalog , PMDA, last updated November 1, 2019

3) Notice in the Federal register, US FDA, Vol. 82, No. 204, October 24, 2017

4) FDA Data Standards Catalog , US FDA, v. 7.3, last updated September 14, 2021

5) Study Data Technical Conformance Guide, US FDA, v. 4.8.1, last updated October, 2021

6) Study Data Tabulation Model Implementation Guide (*SDTMIG*), CDISC, v. 3.3, last updated November 20, 2018 (*access requires CDISC account*)

7) FDA Validator Rules, US FDA, v. 1.5, last updated March 2021

8) https://nedrug.mfds.go.kr/bbs/34/35/#

9) https://www.titck.gov.tr/faaliyetalanlari/ilac/farmakovijilans

10) https://www.gob.mx/cofepris/articulos/comunicado-del-centro-nacional-de-farmacovigilancia-a-la-industria-farmaceutica

11) https://www.gov.br/anvisa/pt-br/assuntos/noticias-anvisa/2022/simposio-discute-melhorias-para-o-monitoramento-de-eventos-adversos

12) https://www.youtube.com/watch?v=cwOqMma7b2M

13) https://www.controlsanitario.gob.ec/documentos-vigentes/

14) https://www.gub.uy/ministerio-salud-publica/comunicacion/comunicados/implementacion-herramienta-reporting-industria

15) https://www.digemid.minsa.gob.pe/webDigemid/farmacovigilancia-y-tecnovigilancia/

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Use of WHODrug Global in the world

The UMC and WHODrug Global in the ISO - IDMP project, part of the ICH E2B R3 standard for the transmission of ICSRs

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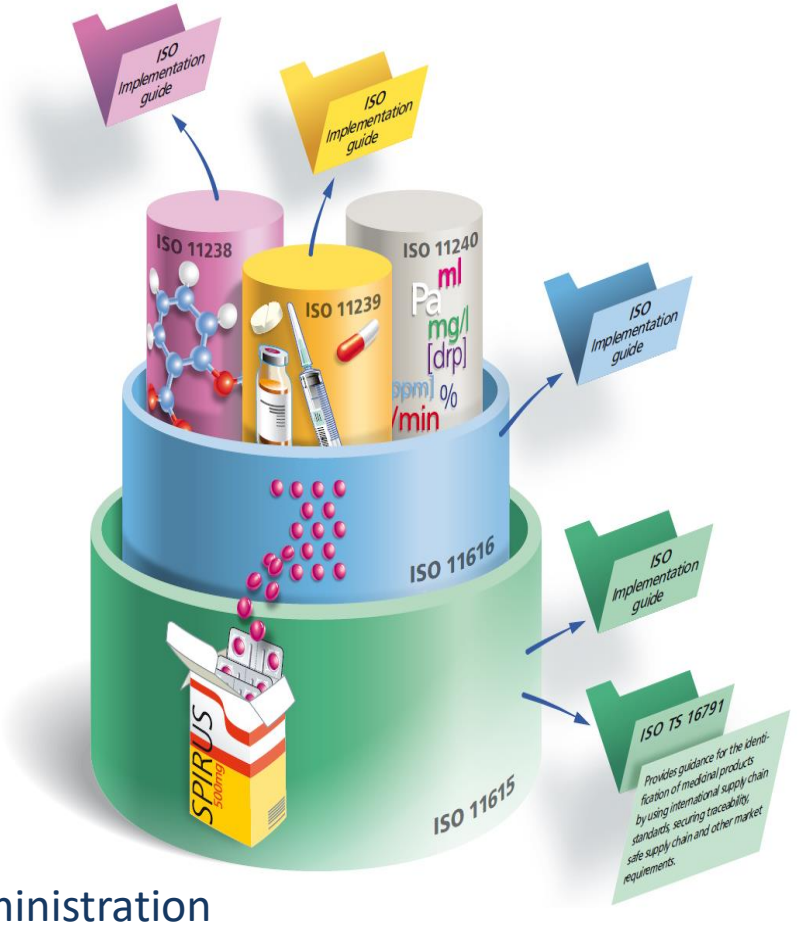
– Building a global safety culture

What is ISO-IDMP?

The objective of the IDMP project is to create a *Medicinal Product Identifier* (MPID) calculated from information from a set of five ISO standards that:

Will allow a medicinal product to be uniquely and unequivocally identified.

The ISO standards used are:



- ISO 11238 – Substance Identification
- ISO 11239 – Pharmaceutical dose forms, units of presentation and routes of administration
- ISO 11240 – Units of measurement
- ISO 11616 – Pharmaceutical Product Identification (PhPID)
- ISO 11615 – Medicinal Product Identification (MPID)

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ISO – IDMP, a collaborative project

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Making medicines **safer for patients**

Thank you for your attention!

Any questions, plese write to us at:

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