WP 1 Workshop Brussels 3-5 March 2020

WP 1: IDMP-related standards and terminologies
Presentation ICSR

Presenter: Anja van Haren

This project has received funding from the European Union's
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Acronyms

- ADR = Adverse Drug Reaction
- EDQM=European Directorate for the Quality of Medicines & HealthCare
- EEA=European Economic Area
- EMA = European Medicines Agency
- ICH: ICH= International Council on Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
- ICSR= Individual Case Safety Report
- HCP=Health Care Professional
- MPID=Medicinal Product Identifier
- NCA=National Competent Authority
- PhPID=Pharmaceutical Product Identifier
- PhV=Pharmacovigilance
- WHO-DD=WHO Drug Dictionary
- XEVMPD = Extended EudraVigilance Medicinal Product Dictionary

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Pharmacovigilance definition:
Science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem (WHO)

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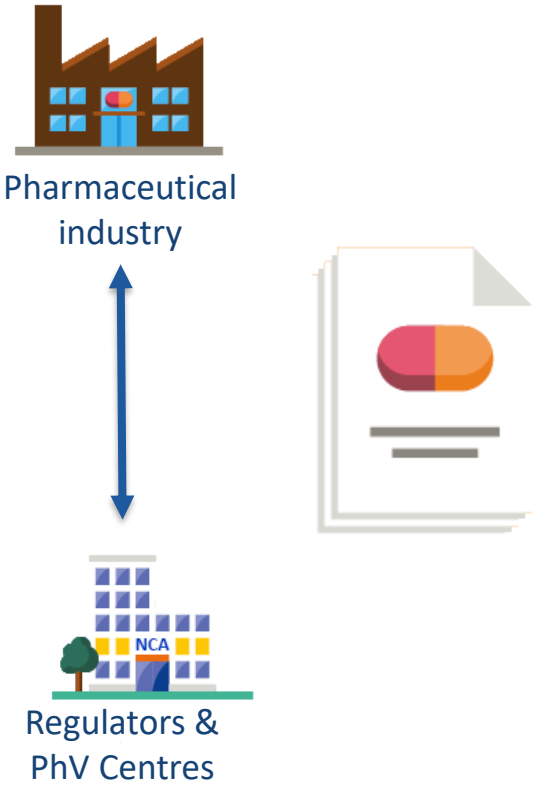
Pharmacovigilance as driver for developing IDMP



Exchange ICSRs (Individual Case Safety Reports):

'Format and content for the reporting of one or several suspected adverse reactions to a medicinal product that occur in a single patient at a specific point of time'

Why is IDMP needed for ICSRs:

1: Improve efficiency ICSR processing

2: Improve accuracy of data analysis of ICSRs

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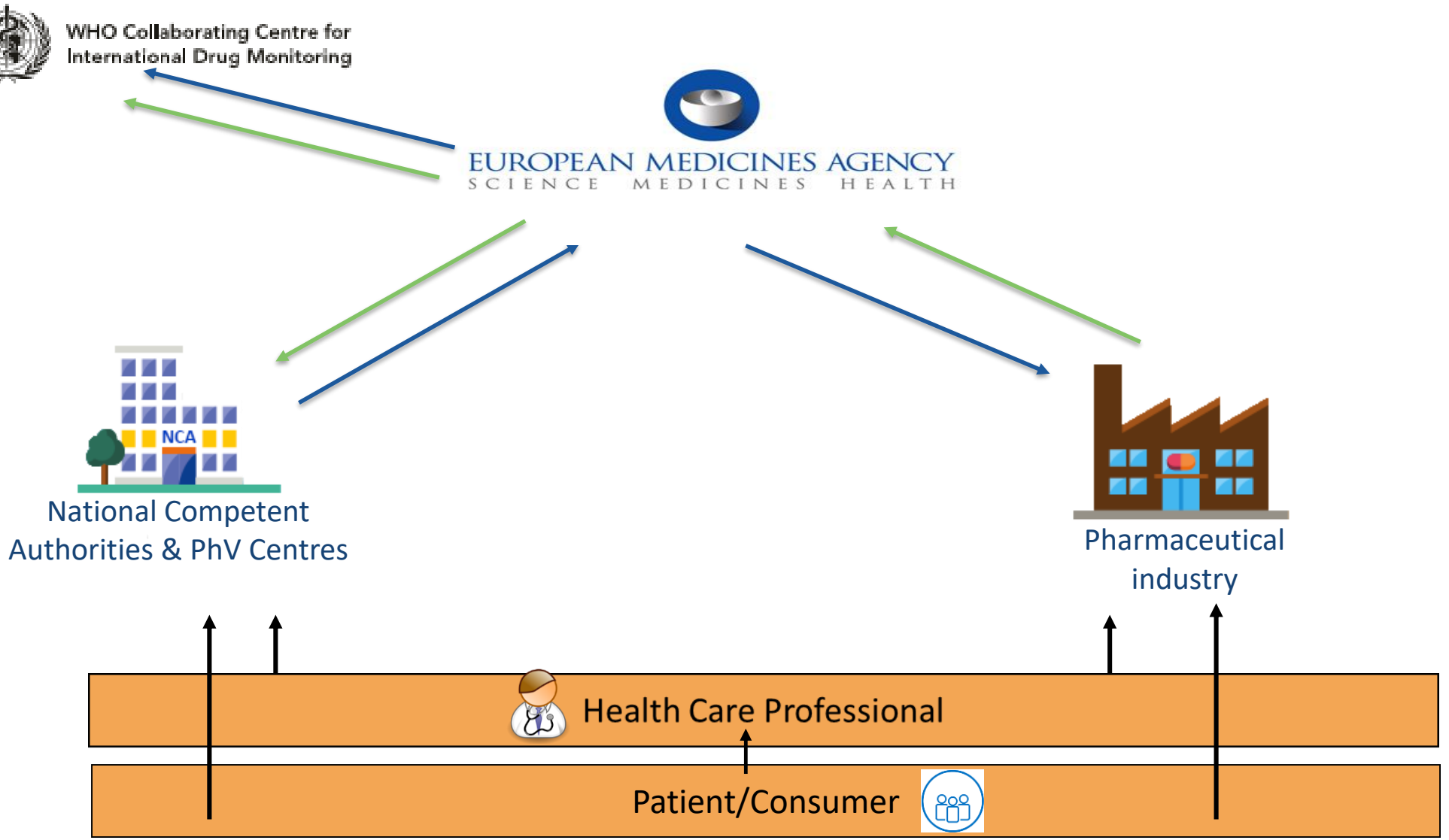
Flow of EU ICSRs



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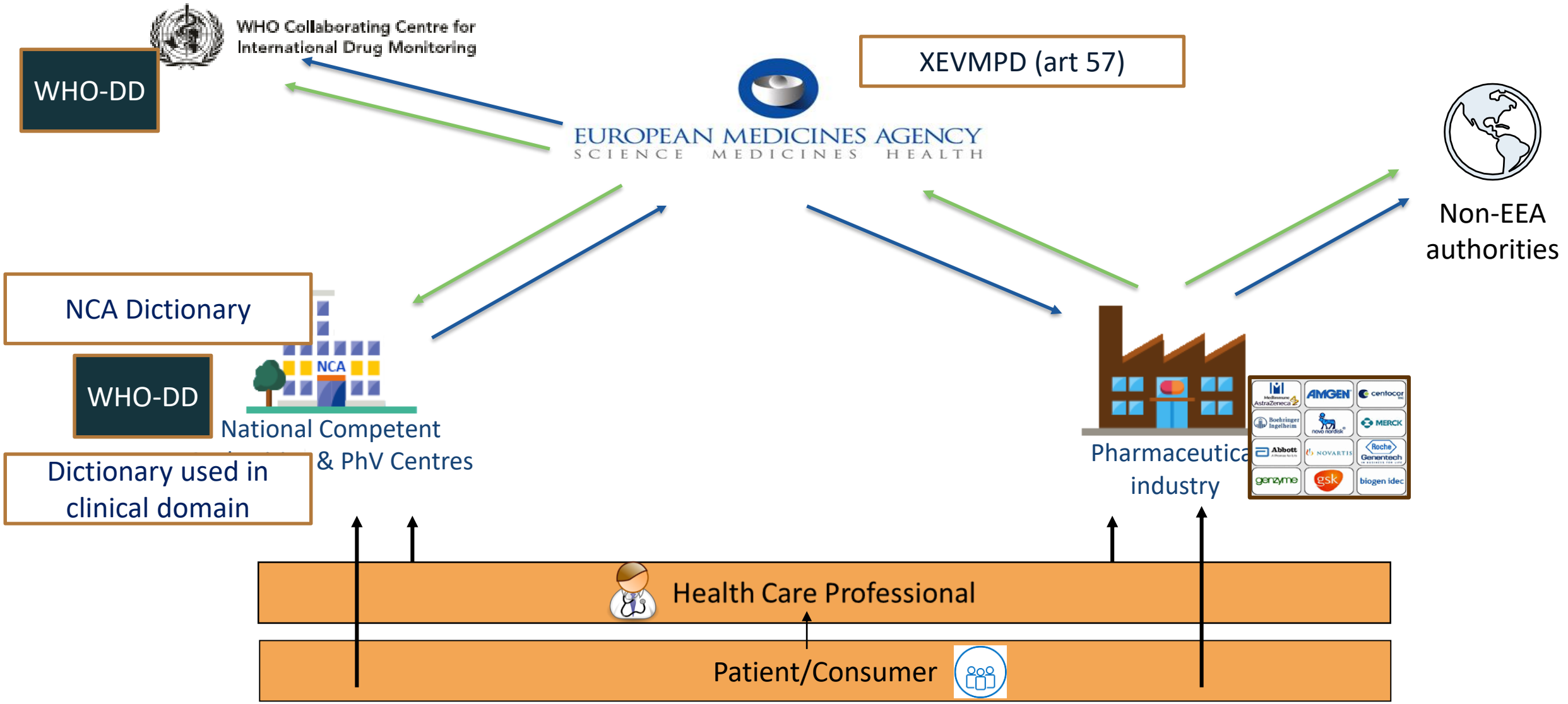
Flow of EU ICSRs and drug dictionaries used



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Drug information in ICSR

Currently free text; level of specificity depends on what initial reporter (HCP/patient) has stated

Drug brand name may not have same ingredient in another country

Reported medicine:
‘ Trexan’ (Brand name)

?

Substance: naltrexone

Substance: methothrexate

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Drug information in ICSR

Paracetamol

Paracetamol tablet

Paracetamol hydrochloride

Paracetamol 500mg tablet

Paracetamol sodium

Paracetamol Bigpharma 200mg tablet

Acetaminophen

Paracetamol 250mg suppository

Acetaminophen 500mg tablet

Paedmol Bigpharma 200mg drink

Paracetamol Worldpharma chewable tablet

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A closer look at the ISO ICSR standard

Front end: ISO standard

INTERNATIONAL STANDARD ISO/HL7 27953-2:2011(E)

First edition 2011-12-01

Health informatics — Individual case safety reports (ICSRs) in pharmacovigilance —

Part 2:

Human pharmaceutical reporting requirements for ICSR

Informatique de santé — Rapports de sécurité de cas individuel (ICSRs) en pharmacovigilance —
Partie 2: Exigences pharmaceutiques humaines à rapporter pour un rapport de sécurité de cas individuel (ICSR)

ISO/HL7 27953-2:2011(E)

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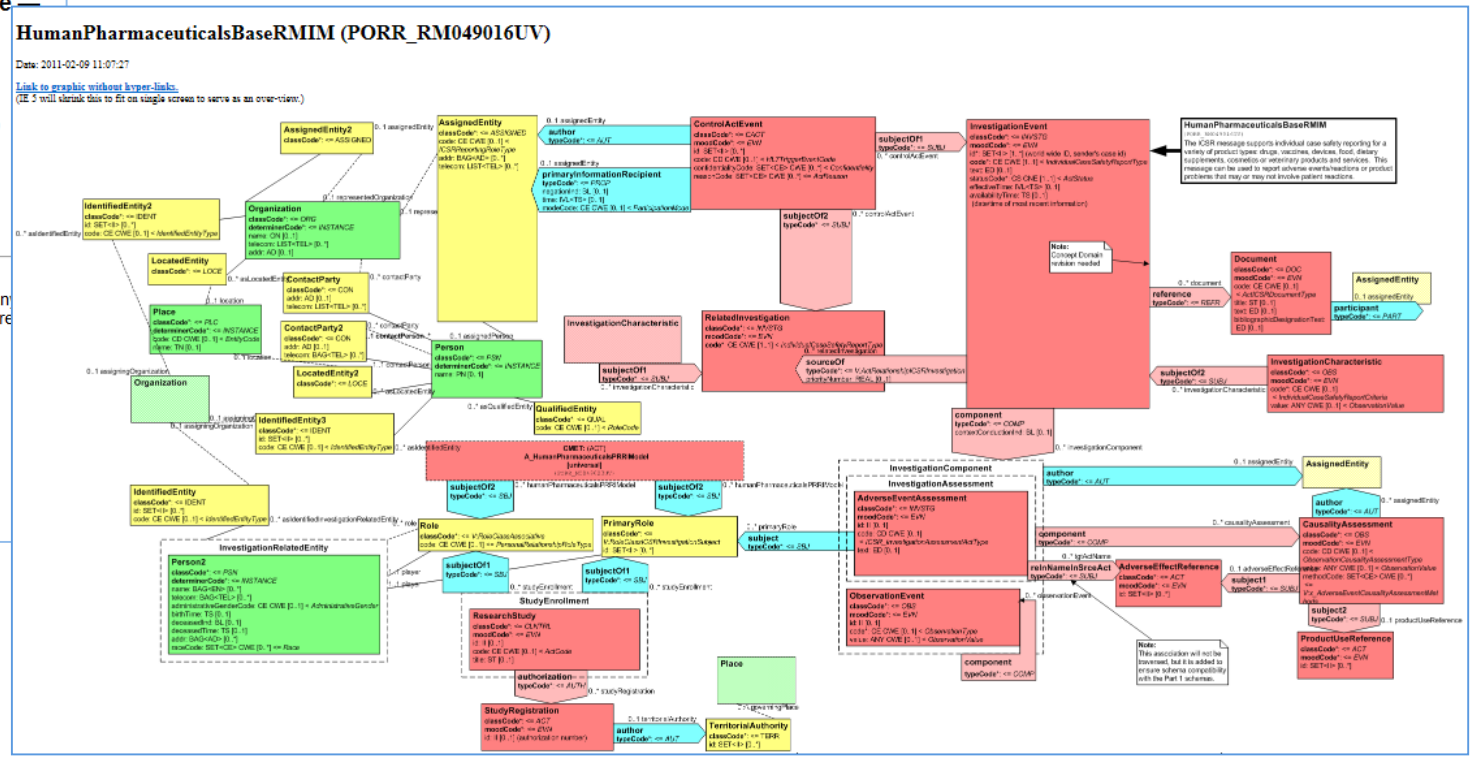

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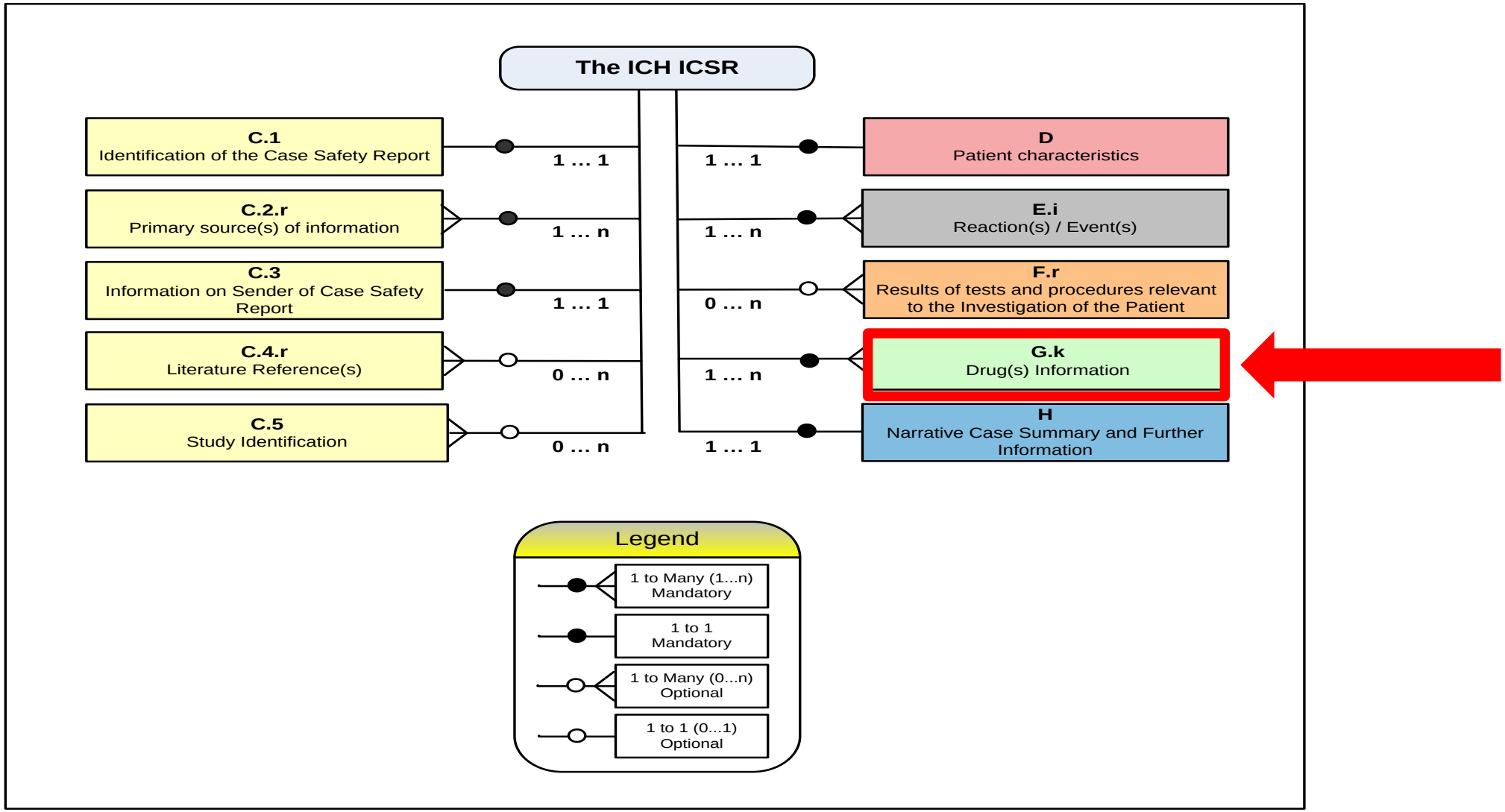

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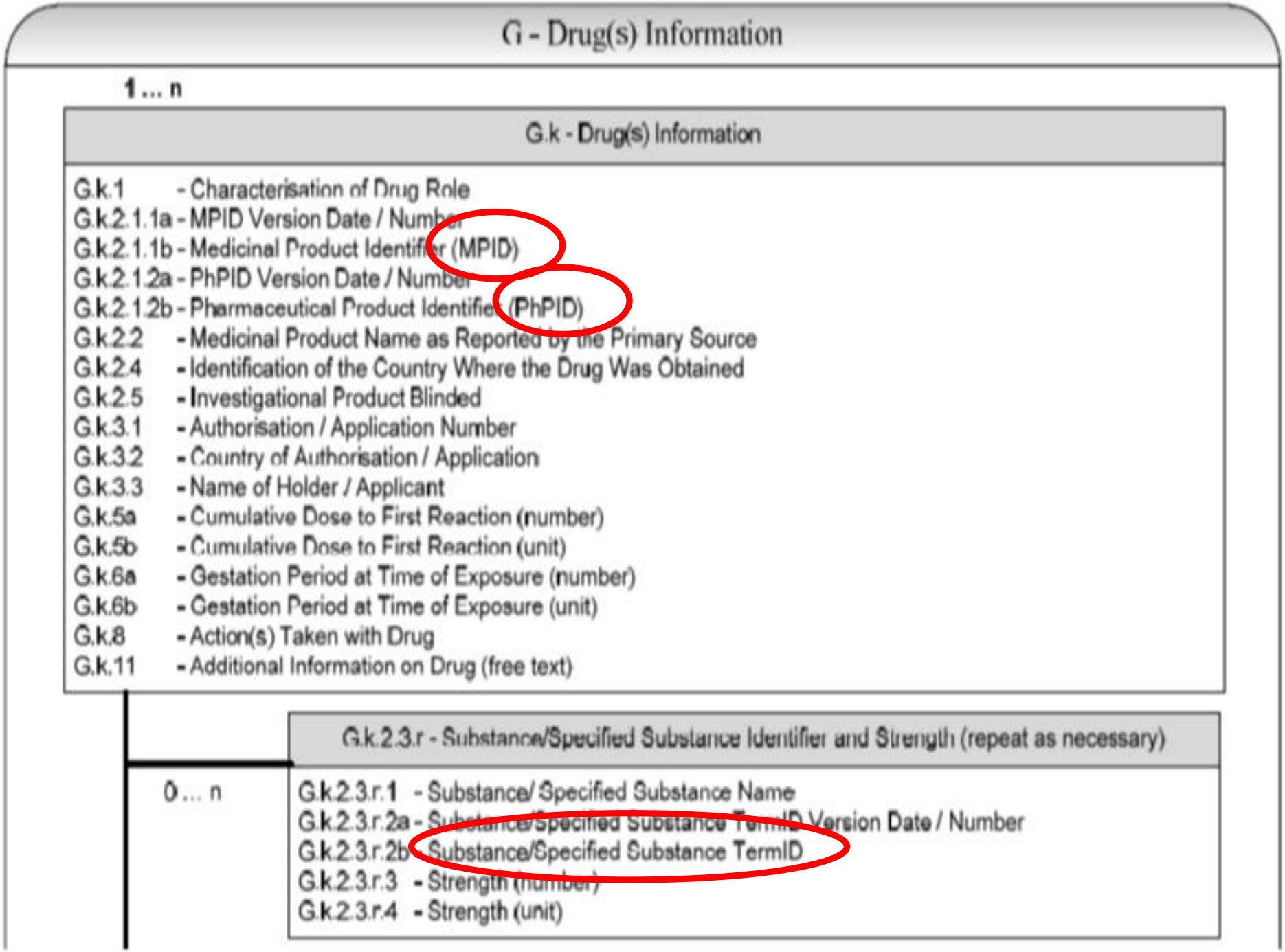
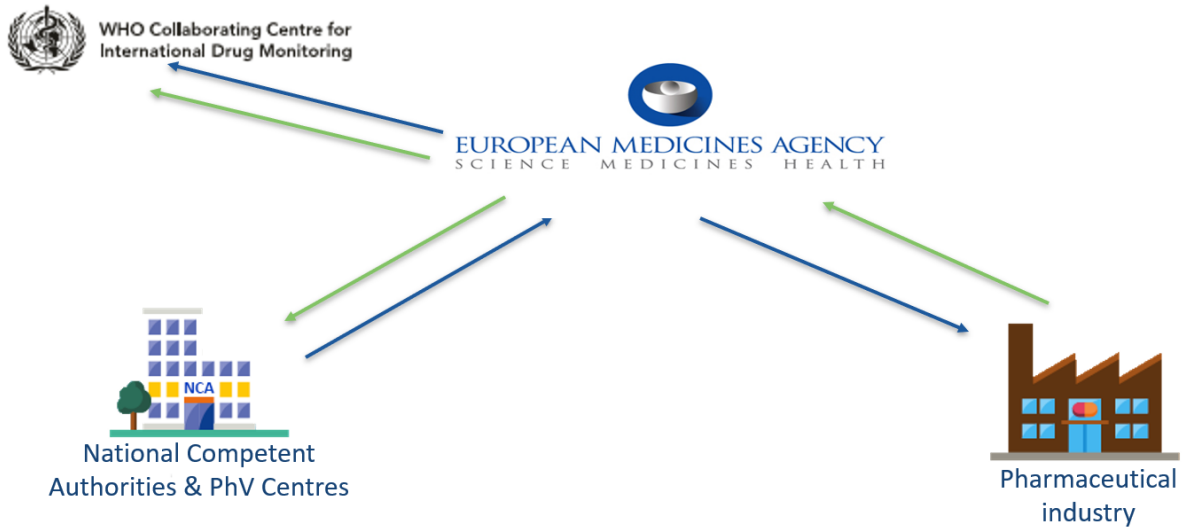

G - Drug(s) Information
1 ... n
G.k - Drug(s) Information
G.k.1 - Characterisation of Drug Role
G.k.2.1.1a - MPID Version Date / Number
G.k.2.1.1b - Medicinal Product Identifier (MPID)
G.k.2.1.2a - PhPID Version Date / Number
G.k.2.1.2b - Pharmaceutical Product Identifier (PhPID)
G.k.2.2 - Medicinal Product Name as Reported by the Primary Source
G.k.2.4 - Identification of the Country Where the Drug Was Obtained
G.k.2.5 - Investigational Product Blinded
G.k.3.1 - Authorisation / Application Number
G.k.3.2 - Country of Authorisation / Application
G.k.3.3 - Name of Holder / Applicant
G.k.5a - Cumulative Dose to First Reaction (number)
G.k.5b - Cumulative Dose to First Reaction (unit)
G.k.6a - Gestation Period at Time of Exposure (number)
G.k.6b - Gestation Period at Time of Exposure (unit)
G.k.8 - Action(s) Taken with Drug
G.k.11 - Additional Information on Drug (free text)
G.k.2.3.r - Substance/Specified Substance Identifier and Strength (repeat as necessary)
0 ... n
G.k.2.3.r.1 - Substance/ Specified Substance Name
G.k.2.3.r.2a - Substance/Specified Substance TermID Version Date / Number
G.k.2.3.r.2b - Substance/Specified Substance TermID
G.k.2.3.r.3 - Strength (number)
G.k.2.3.r.4 - Strength (unit)

EU legislation

The EU legislation* requires use of the ISO ICSR 27953-2:2011 message (in ICH E2B(R3) format) and use of standard terminologies within that message:
- terminologies resulting from ISO IDMP standards
- MedDRA

ISO ICSR (in ICH E2B(R3) format) is used by EMA EudraVigilance database since Nov 2017 and many more PhV databases in EU

Will be the only ICSR message accepted in EU from June 2022 (for exchange between NCA-EMA-pharmaceutical industry)



Note:
ISO ICSR message is not legally required for exchange of adverse events between consumer/health care professional and PhV centre/industry

* COMMISSION IMPLEMENTING REGULATION (EU) No 520/2012 of 19 June 2012

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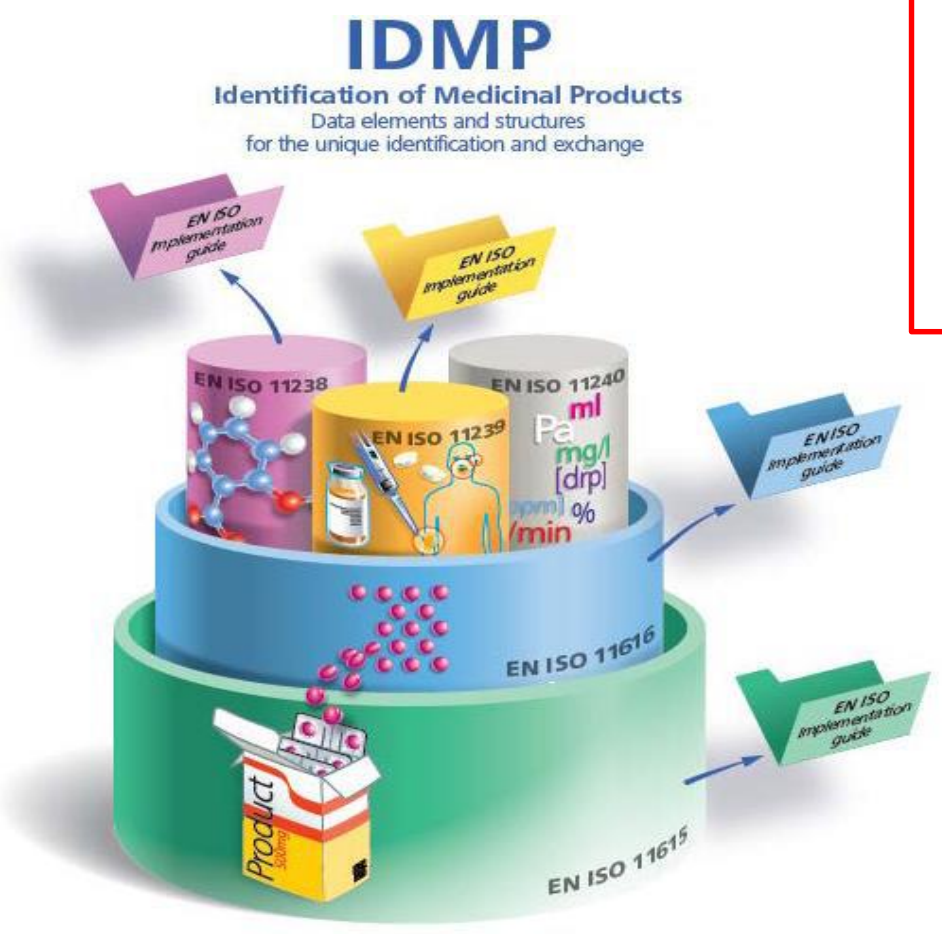
Use of IDMP in the ICSR



Waiting for identifiers

- **Medicinal product information (MPID/PCID) - ISO 11615**
- **Pharmaceutical product information (PhPID) - ISO 11616**
- **Substances (Substance ID/Specified Substance ID) - ISO 11238**

- **Units of measurement (UCUM) - ISO 11240** ✓ **used**
- **Pharmaceutical dose forms, units of presentation, routes of administration and packaging - ISO 11239**

✓ **Use of EDQM Dose forms & routes of administration mandatory in EU from June 2022 onwards**

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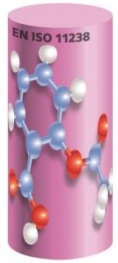
Summary

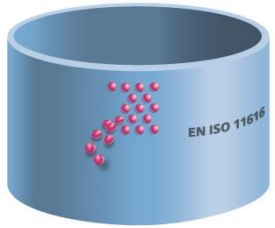
The ISO ICSR standard in ICH E2B(R3) format is widely used by medicines regulators, pharmacovigilance centres and pharmaceutical industry

- will become mandatory in EU in June 2022

- Has placeholders for transmitting IDMP identifiers
  Different levels can be used within the ICSR – depending upon what information on medicine is available

- Use of MPID, PhPID and (Specified)Substance identifiers will improve efficiency of ICSR processing as well as data analysis





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Thank you for your attention