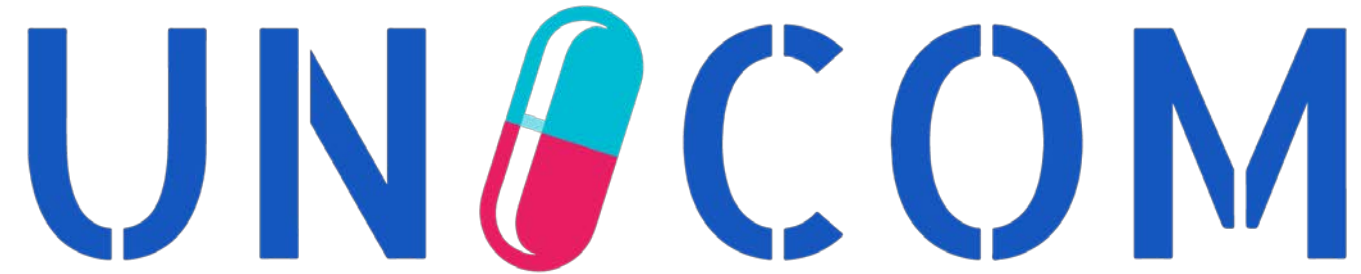


## WP-1 / community of expertise

November/December 2021





## Using IDMP in Adverse Event reporting and Individual Case Safety Reports (ICSR)

Anja van Haren  
Barry Hammond  
Sarah Vaughan



## SOME RULES FOR THE VIRTUAL MEETINGS

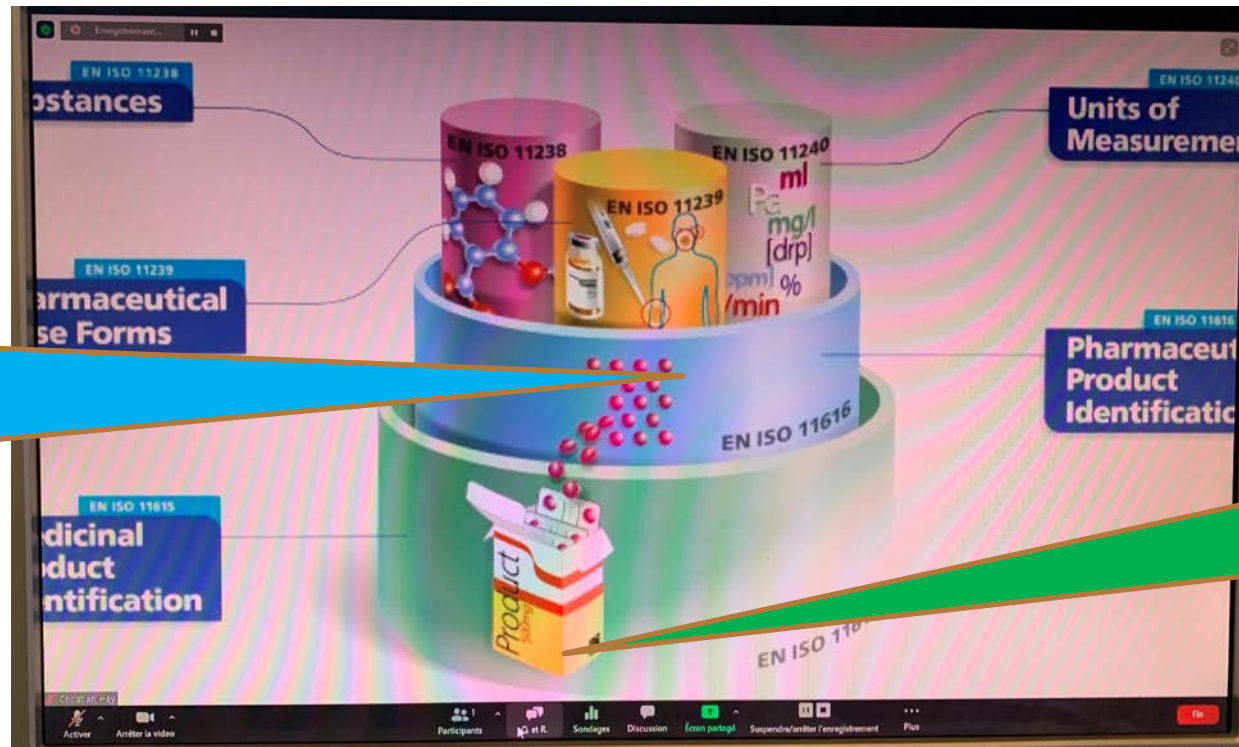
- ✓ **Everybody is on mute**
- ✓ **You post your question in the Q&A facility**
- ✓ **When you speak, please keep concise**
- ✓ **You may show your approval !**

After (and during) the introduction presentations, any UNICOM related question / comment may be shared with Q&A



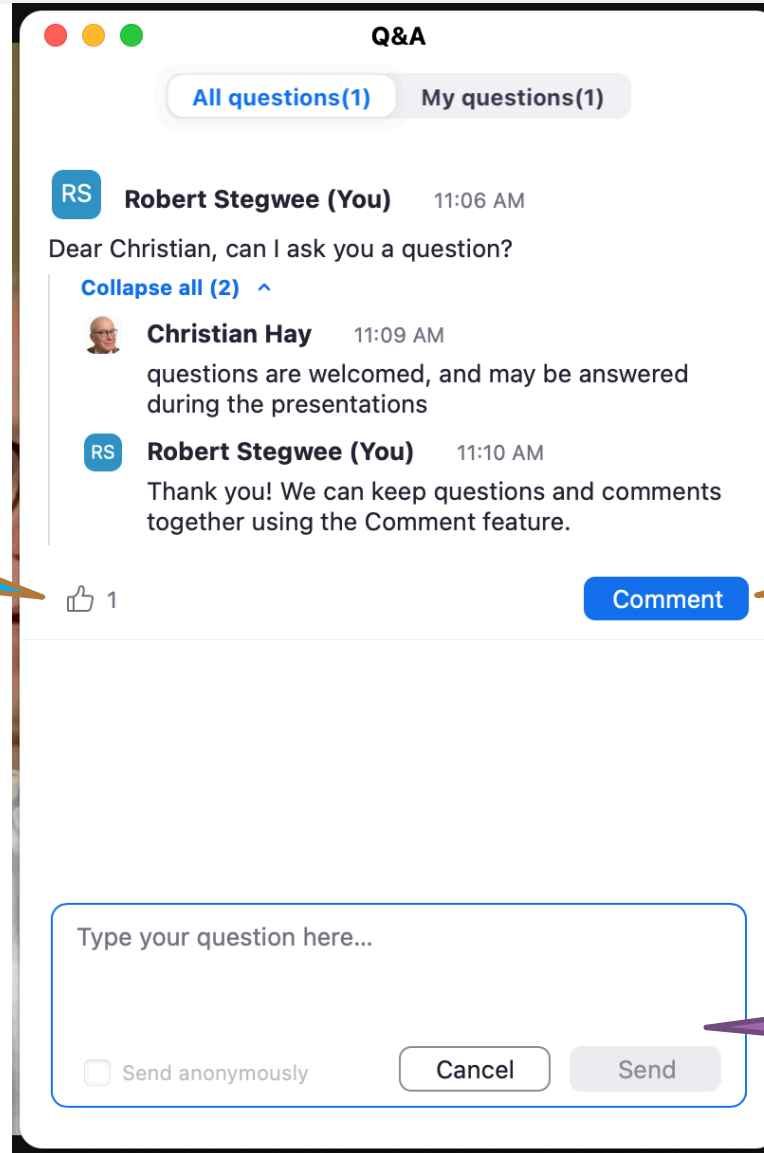
Asking a question or making a comment: please use the Q&A facility

1. Move the mouse on the screen to have the options bar appearing



2. You then select «Q&A» and write your question

You can support a question by clicking the «thumbs up» which moves it up on the list for the presenters



The screenshot shows a Q&A interface with the following elements:

- Buttons for "All questions(1)" and "My questions(1)".
- A question from **Robert Stegwee (You)** at 11:06 AM: "Dear Christian, can I ask you a question?"
- A "Collapse all (2)" link.
- An answer from **Christian Hay** at 11:09 AM: "questions are welcomed, and may be answered during the presentations".
- A response from **Robert Stegwee (You)** at 11:10 AM: "Thank you! We can keep questions and comments together using the Comment feature."
- A thumbs up icon with the number "1" below it.
- A blue "Comment" button.
- A text input field with the placeholder "Type your question here...".
- A checkbox for "Send anonymously".
- "Cancel" and "Send" buttons.

You can comment on a question or answer to engage in a conversation

Typing and sending a new question does not retain the context of your comment



- ▶ Security is our priority
- ▶ This session is password protected



Recording of this session will be made available on UNICOM's youtube channel.

At the end of the virtual session, a questionnaire will be sent to the participants, to help us understand participant's reactions and needs



Introductions to our esteemed colleagues and today's speakers



Anja van Haren



Barry Hammond



Sarah Vaughan

...and our panellist



Julie James



Jane Millar

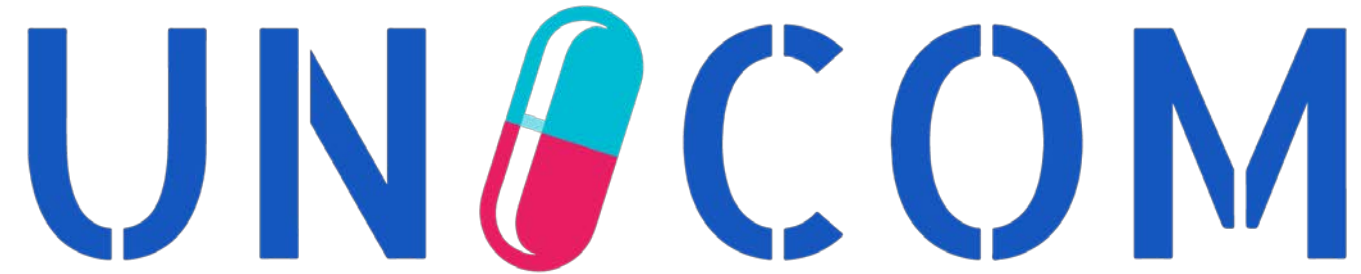


Questions in the Q & A facility, please

For feedback, please go to : <https://forms.gle/g7reYNcGJ75QdndN9>

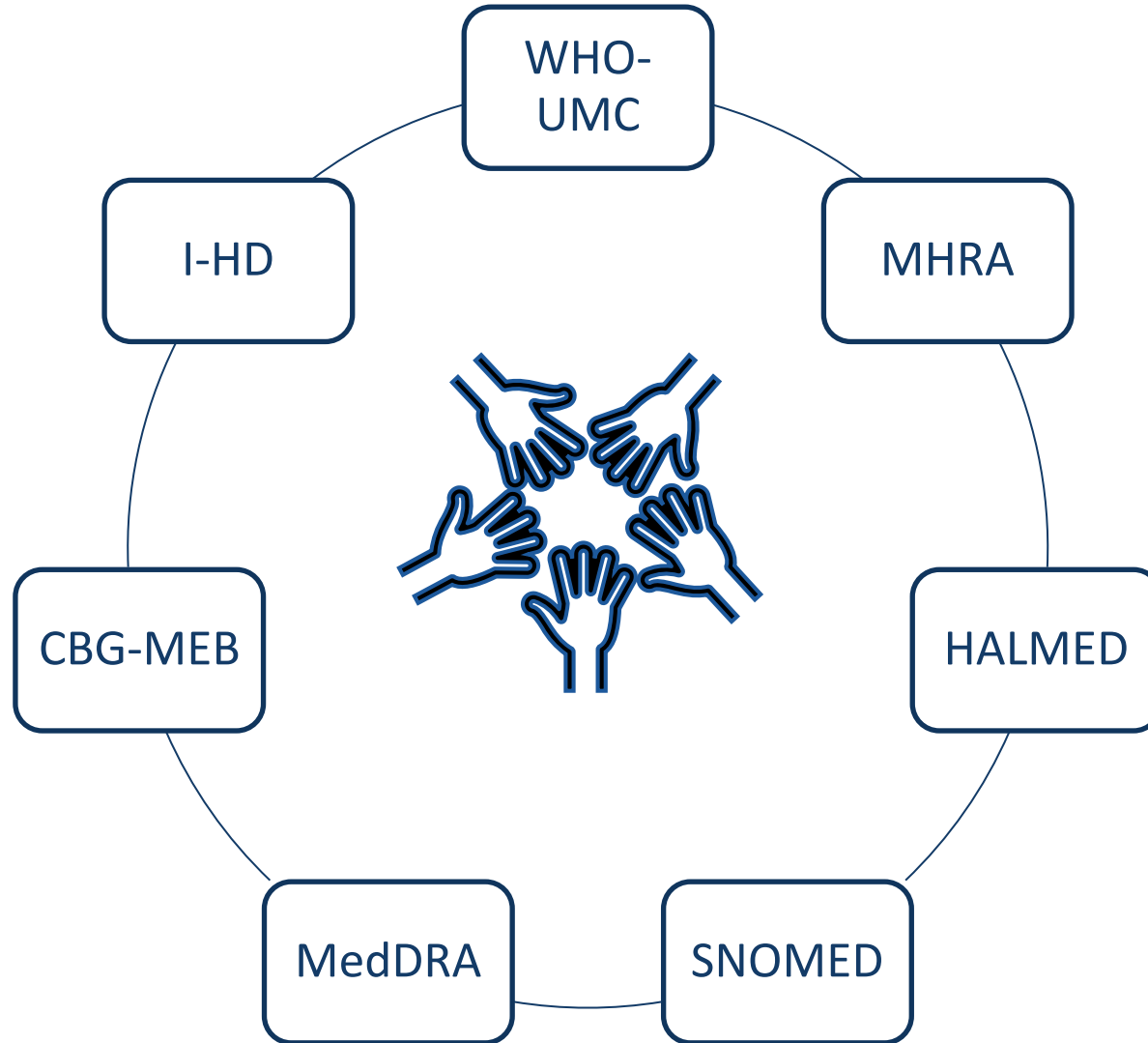
*Thanks for your time*

UN  COM



## Using IDMP in Adverse Event reporting and Individual Case Safety Reports (ICSR)





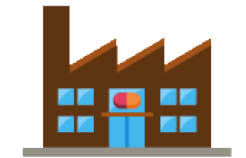
- ▶ ADR = Adverse Drug Reaction
- ▶ EDQM=European Directorate for the Quality of Medicines & HealthCare
- ▶ EEA=European Economic Area
- ▶ EMA = European Medicines Agency
- ▶ ICH= International Council on Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
- ▶ ICSR= Individual Case Safety Report
- ▶ HCP=Health Care Professional
- ▶ MAH= Marketing Authorisation Holder
- ▶ 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

- 1) Pharmacovigilance as driver for IDMP
- 2) Steps taken to develop the IDMP coding guidance for ICSRs
- 3) Principles and guidance for selecting IDMP identifiers
- 4) Points for discussion

## Pharmacovigilance definition:

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





Pharmaceutical  
industry



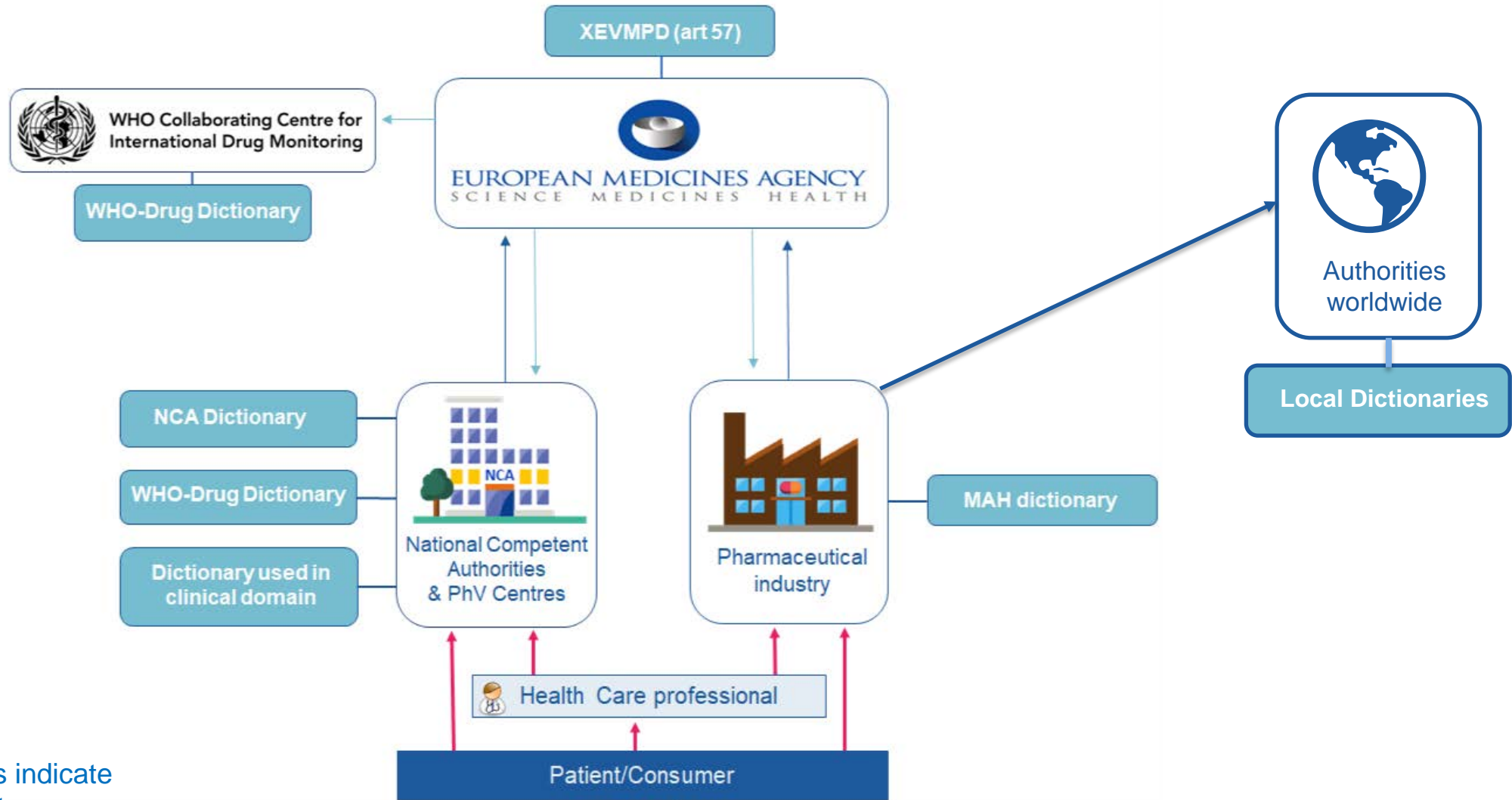
Regulators &  
PhV Centres

## 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:

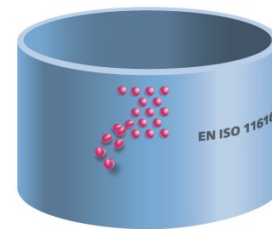
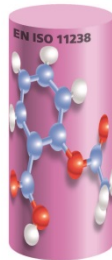
- 1: Improve efficiency of ICSR processing
- 2: Improve accuracy of data analysis of ICSRs
3. Improve collation of data globally facilitating earlier signal detection



Note:  
Light and dark blue arrows indicate exchanges in ICSR format.

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 for exchange between regulators and MAHs in June 2022
- ▶ ICSR has placeholders for transmitting IDMP identifiers
  - Different levels can be used within the ICSR – depending upon what information on medicine is available
- ▶ Use of Medicinal Product Identifiers (MPID), Pharmaceutical Product Identifiers (PhPID) and (Specified) Substance identifiers will improve efficiency of ICSR processing as well as data analysis if done accurately and consistently



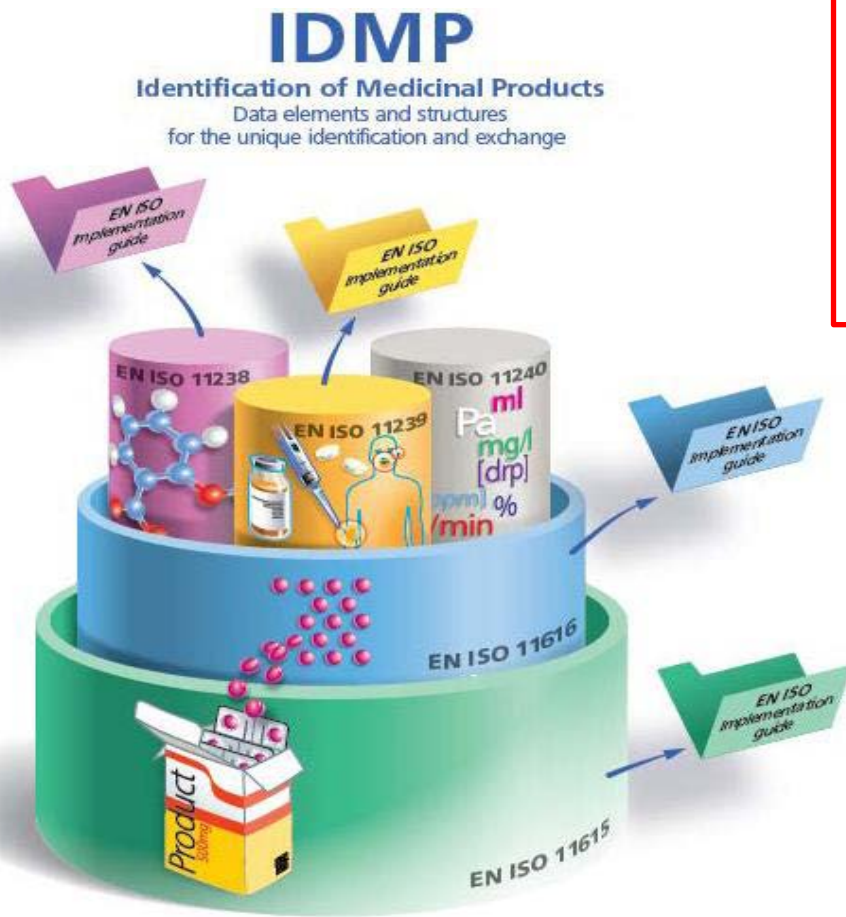
## Waiting for identifiers

- 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



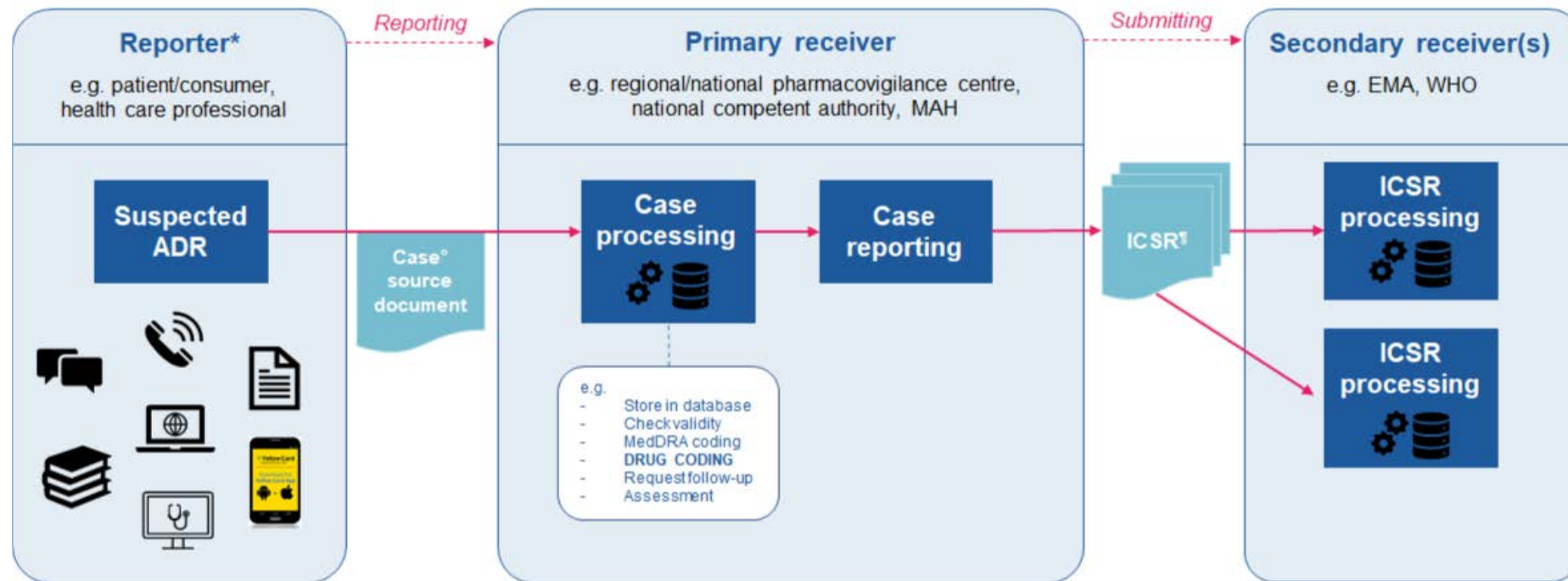
1) Pharmacovigilance as driver for IDMP

2) Steps taken to develop the IDMP coding guidance for ICSRs

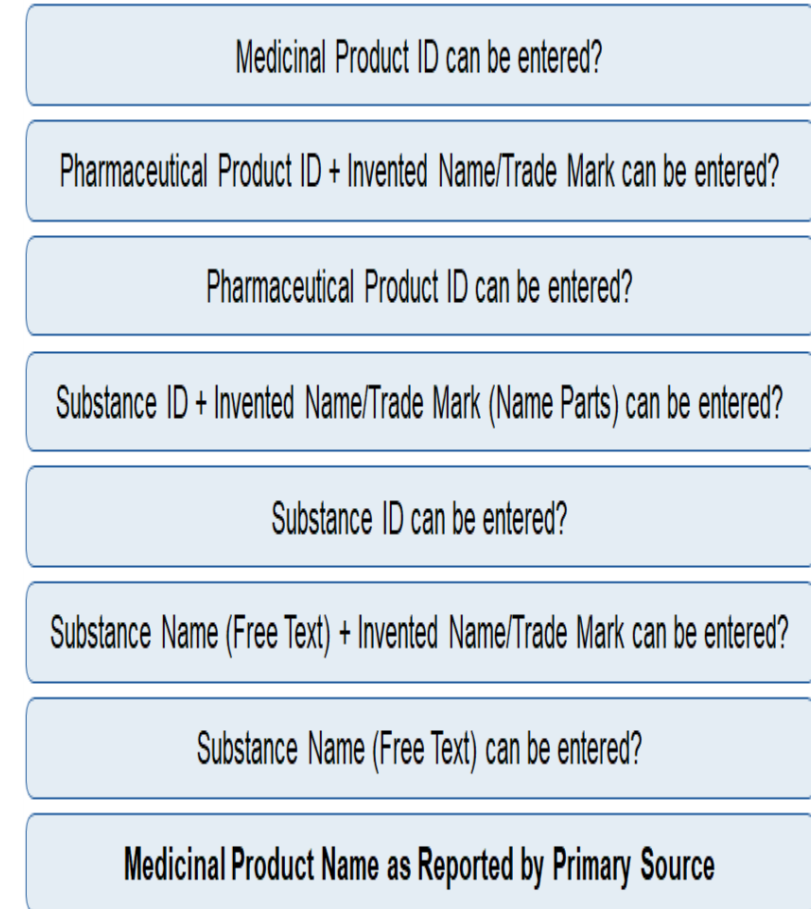
3) Principles and guidance for selecting IDMP identifiers

4) Points for discussion

- ▶ Purposive sample dataset based on drug verbatims from ‘primary receivers’ (3 MAHs, 3 EU NCAs) and secondary receivers (WHO, EMA)
- ▶ Data from the primary receivers originated from different reporting media (web forms, mobile apps, telephone triage, paper forms or clinical systems)

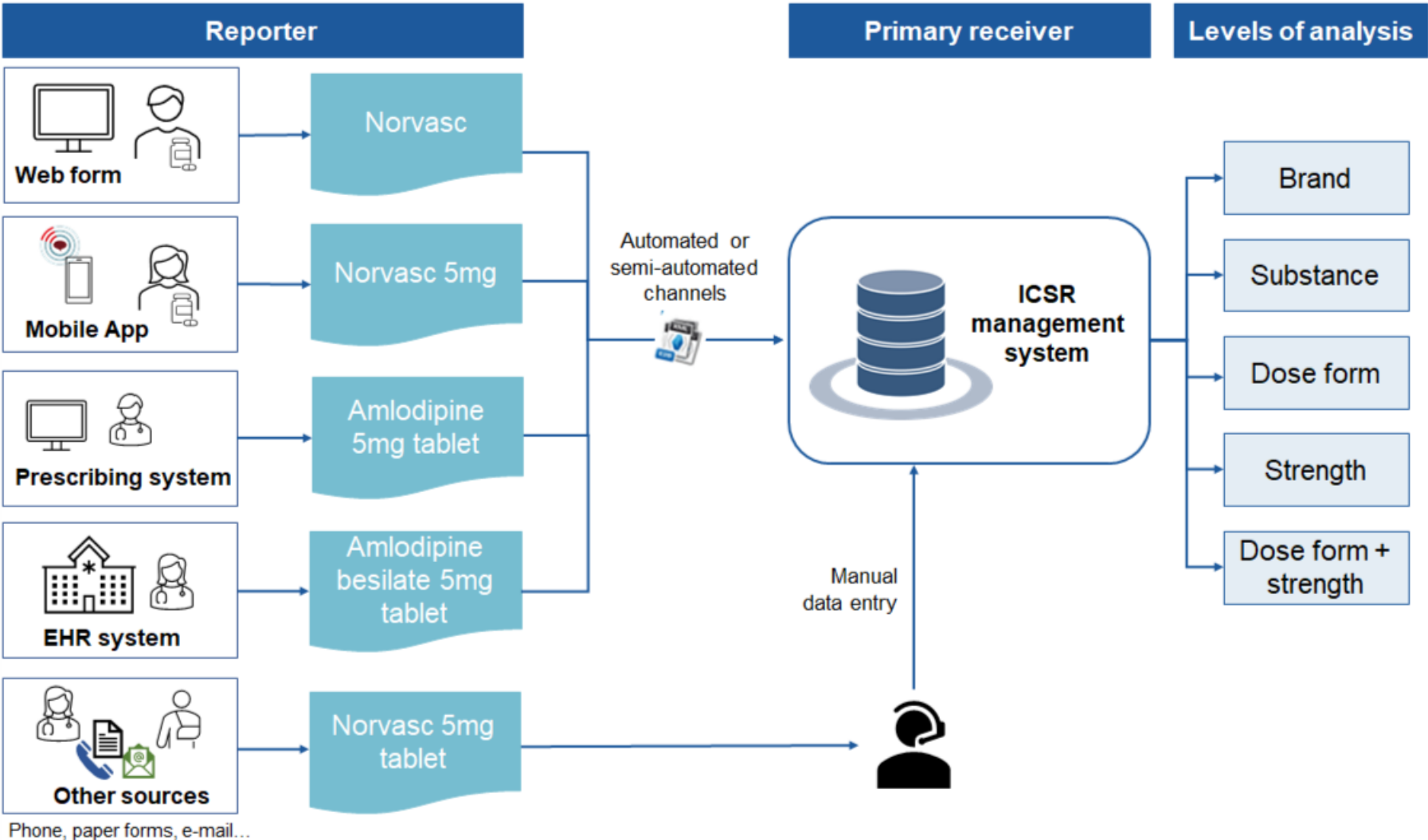


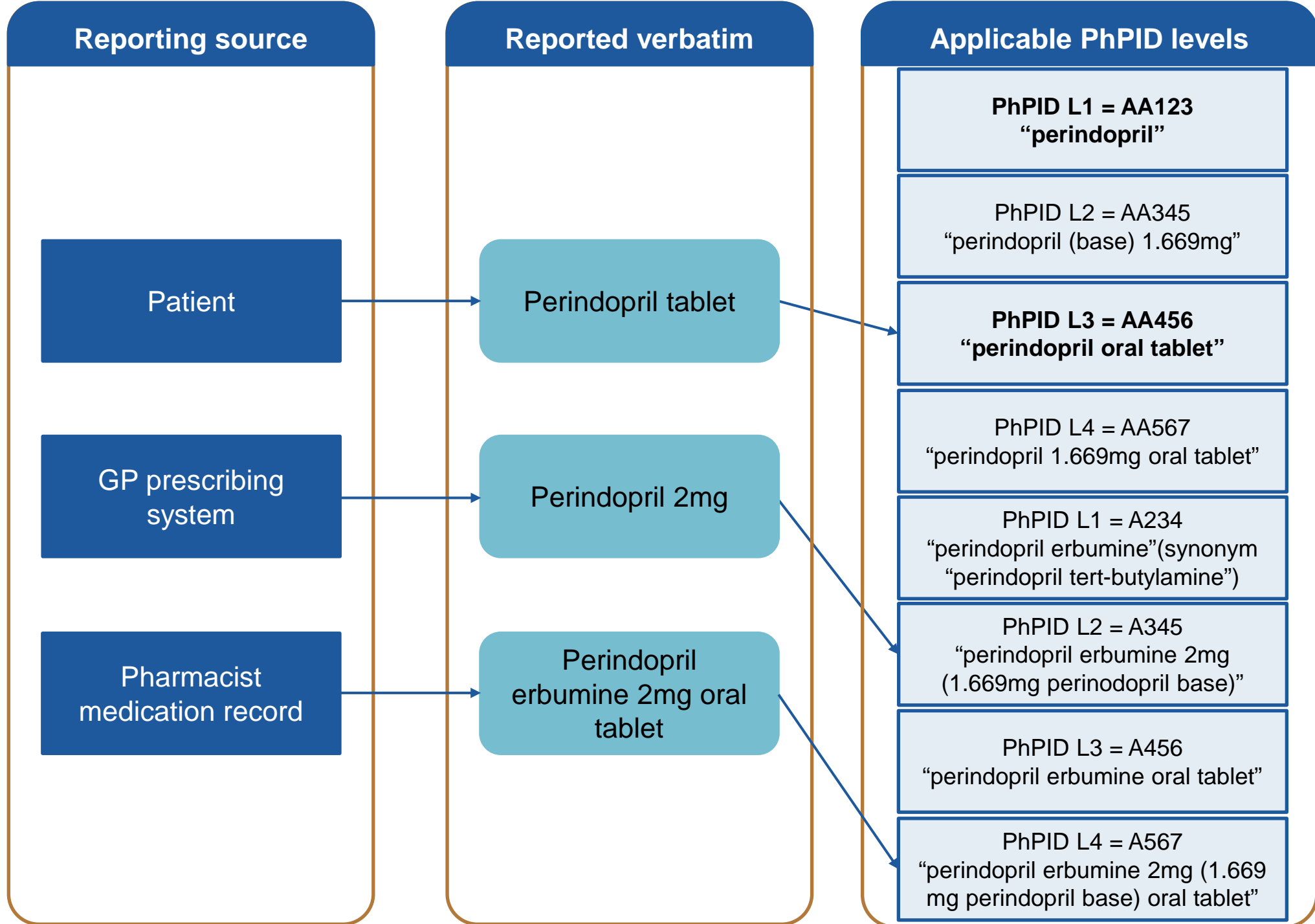
- ▶ Sample of 150 drug verbatims (as provided by the initial reporter) was coded with MPID or PhPID (+/- name parts) in line with:
  - ICH E2B(R3) Implementation Guide
  - EU ICSR Implementation Guide
- ▶ For each drug verbatim, it was considered:
  - if MPID or PhPID could be selected based on exact verbatim
  - whether a more specific PhPID or MPID could be assigned by imputing information based on assumptions
- ▶ If assumptions were made, these were specified
- ▶ Areas for developing further guidance were identified based on:
  - differences in coding results
  - challenges raised by reviewers



PhPID level	PhPID set for substance base	PhPID set for substance with salt
PhPID L1	Ibuprofen	Ibuprofen lysine
PhPID L2	Ibuprofen 400mg	Ibuprofen lysine 684mg (equivalent to ibuprofen 400mg)
PhPID L3	Ibuprofen tablet	Ibuprofen lysine tablet
PhPID L4	Ibuprofen 400mg tablet	Ibuprofen lysine 684mg (equivalent to ibuprofen 400mg) tablet

Note: details of generating PhPIDs are still under discussion, for example on how to express dose form and strength. Different proposals would result in a more or less granular PhPID.

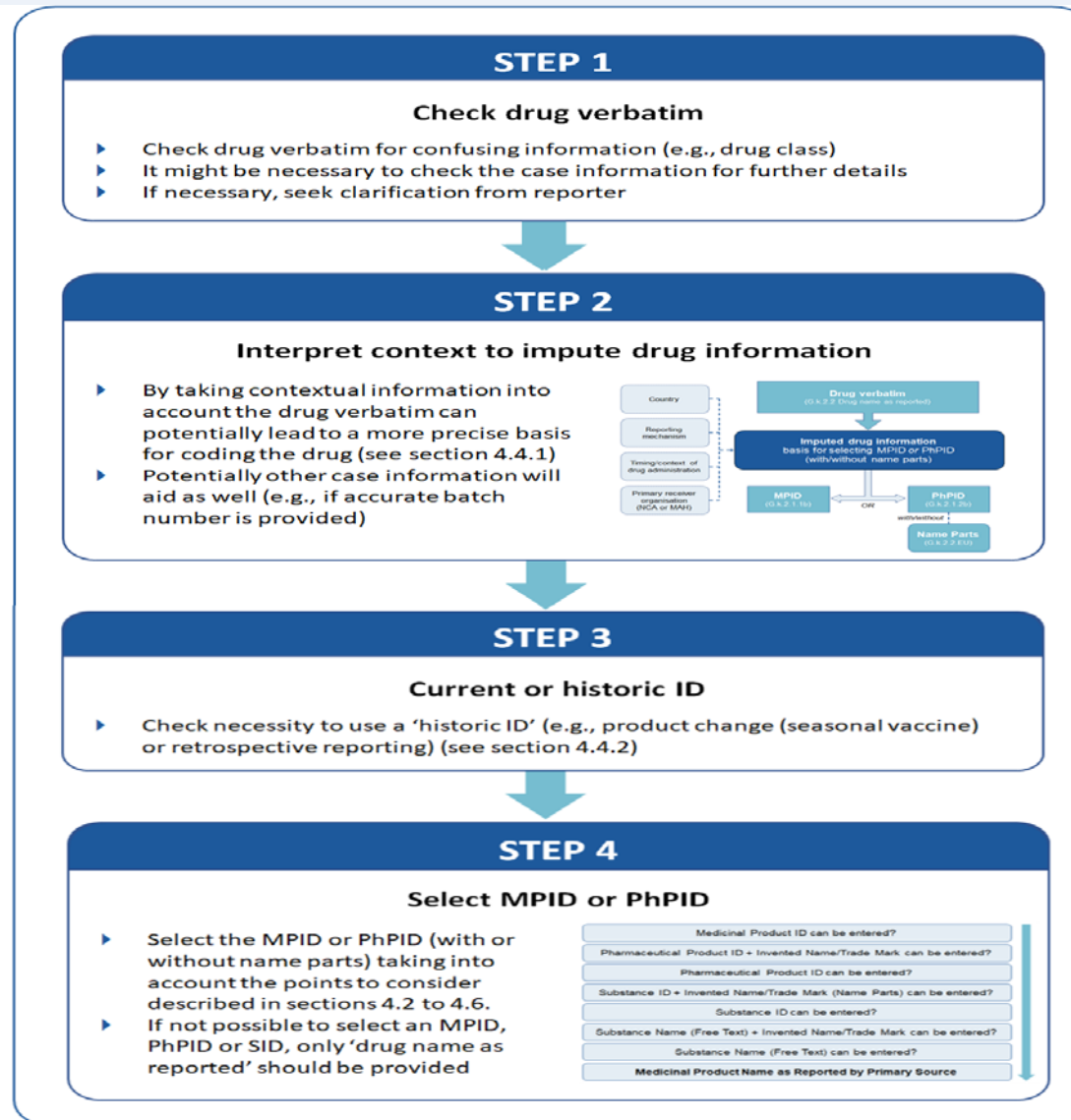




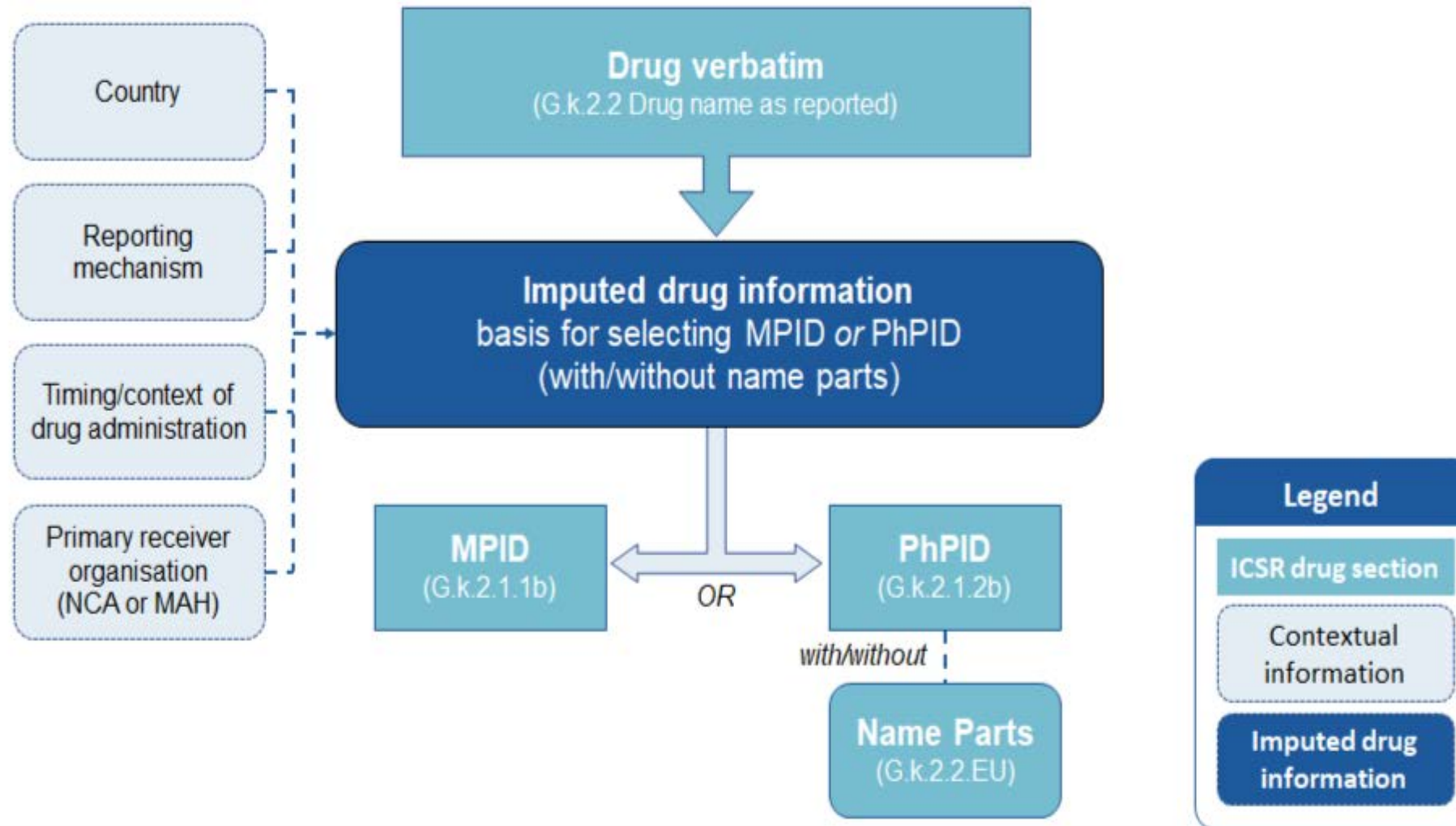
- ▶ Deliverable 8.7 'IDMP coding guidance for ICSRs' cannot be considered as worldwide agreed regulatory guidance.
- ▶ Since exchange of ICSRs is a highly regulated worldwide activity, agreement at level of ICH is needed before we can start using MPIDs, PhPIDs and (S)SIDs in the ICSR.
- ▶ To best support pharmacovigilance stakeholders, it is recommended to explore a possible role of global and/or regulatory organisations as an owner for IDMP ICSR coding guidance, to be responsible for its ongoing development and revision as the IDMP implementation progresses.



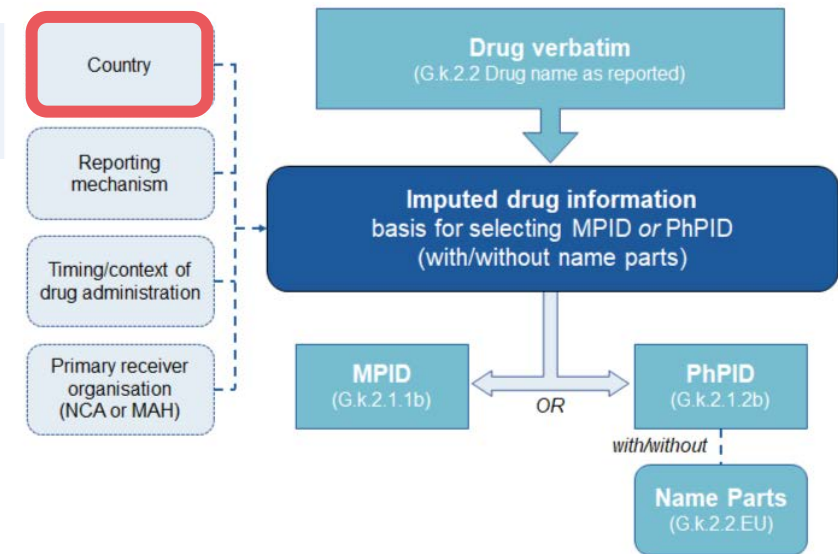
- 1) Pharmacovigilance as driver for IDMP
- 2) Steps taken to develop the IDMP coding guidance for ICSRs
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## Step 2: interpret context to impute drug information



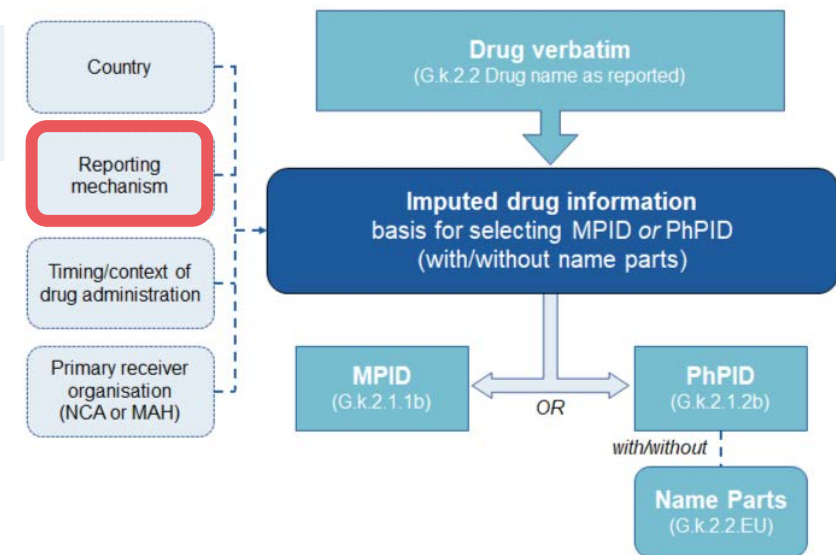
## Step 2: Country



### Example:

A suspected ADR is reported to LAREB (Dutch pharmacovigilance centre) with the drug verbatim '0.9 NaCl'. In the Netherlands there is only one 0.9 NaCl product marketed, namely 0.9 NaCl Baxter. As the case originates from The Netherlands and at that point in time there was only one product marketed, the receiver may assume that this report concerns 0.9 NaCl Baxter. Imputing this information may contribute to selection of a more precise level of PhPID or a MPID.

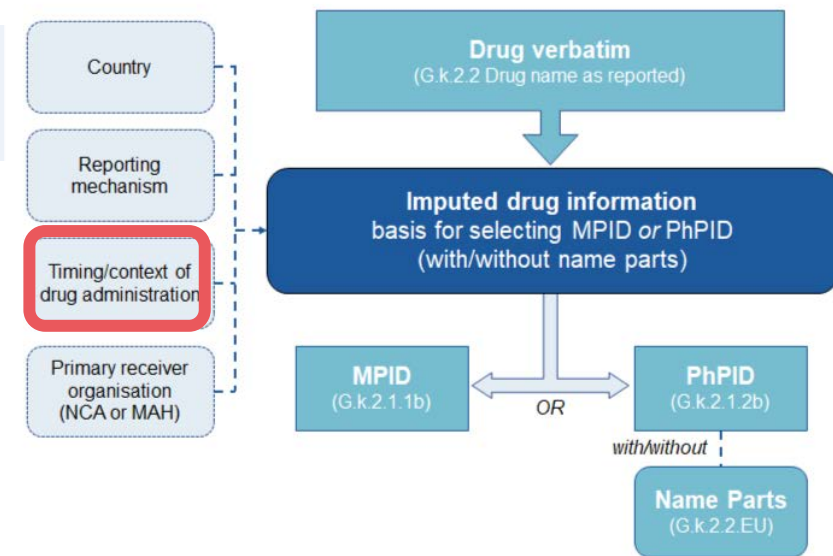
## Step 2: Reporting mechanism



### Example:

The electronic health record (EHR) system in country B facilitates ADR reporting to the national competent authority. This reporting mechanism provides reliable drug verbatims, which are retrieved directly from the patient's medication record that is using the National Medicinal Product Dictionary.

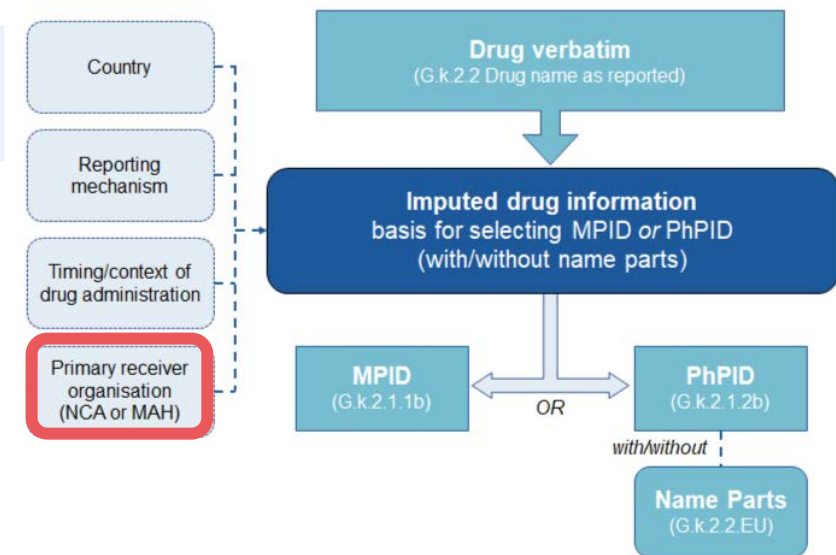
## Step 2: Timing/context of drug administration



### Example:

Country A has received a report of a suspected ADR associated with a covid-vaccine. The report does not specify the name of the vaccine. **At the time of vaccination, the only covid vaccine available in Country A was Comirnaty (Pfizer) mRNA vaccine.** By using this background knowledge, a PhPID Level 4 could be imputed. As long as only 1 MPID would be available for the Comirnaty (Pfizer) mRNA vaccine, even the MPID could be imputed. Without using contextual information, based on only 'covid vaccine' as drug verbatim it would not even be possible to code PhPID level 1.

## Step 2: Primary receiver organisation (NCA or MAH)



### Example:

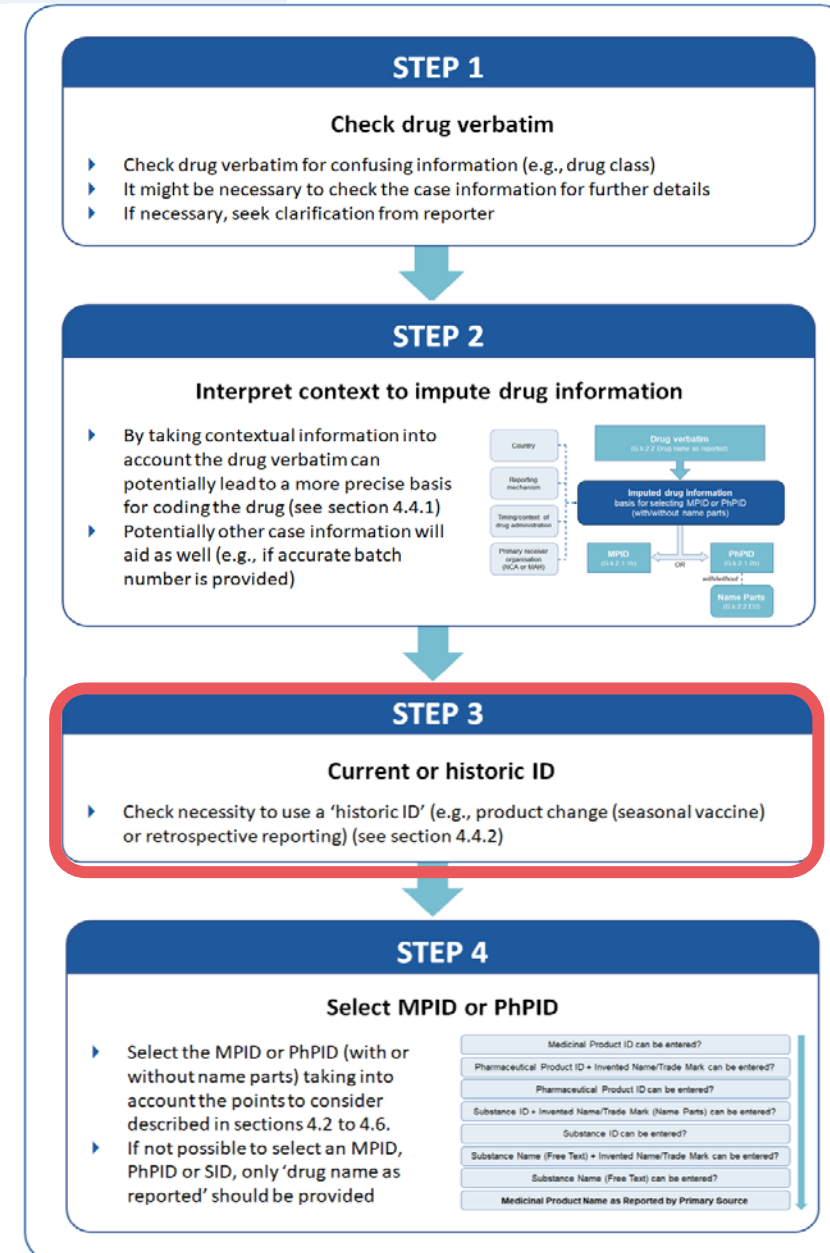
A consumer contacts Janssen Pharmaceuticals about an ADR with 'methylphenidate 18mg'. Methylphenidate is the suspected medication, therefore the MAH can assume that the report concerns their own methylphenidate product (Concerta 18mg tablets with prolonged release) and select the appropriate IDMP identifier (at least PhPID Level 4, or MPID if appropriate). However, if the ADR was reported to the national pharmacovigilance centre, other methylphenidate 18mg products should be taken into account and only the PhPID L2 would be coded.

## Step 3: Check necessity to use current or historic ID

New MPIDs can be assigned to a product following a substantial change.

Historic identifiers may be needed for:

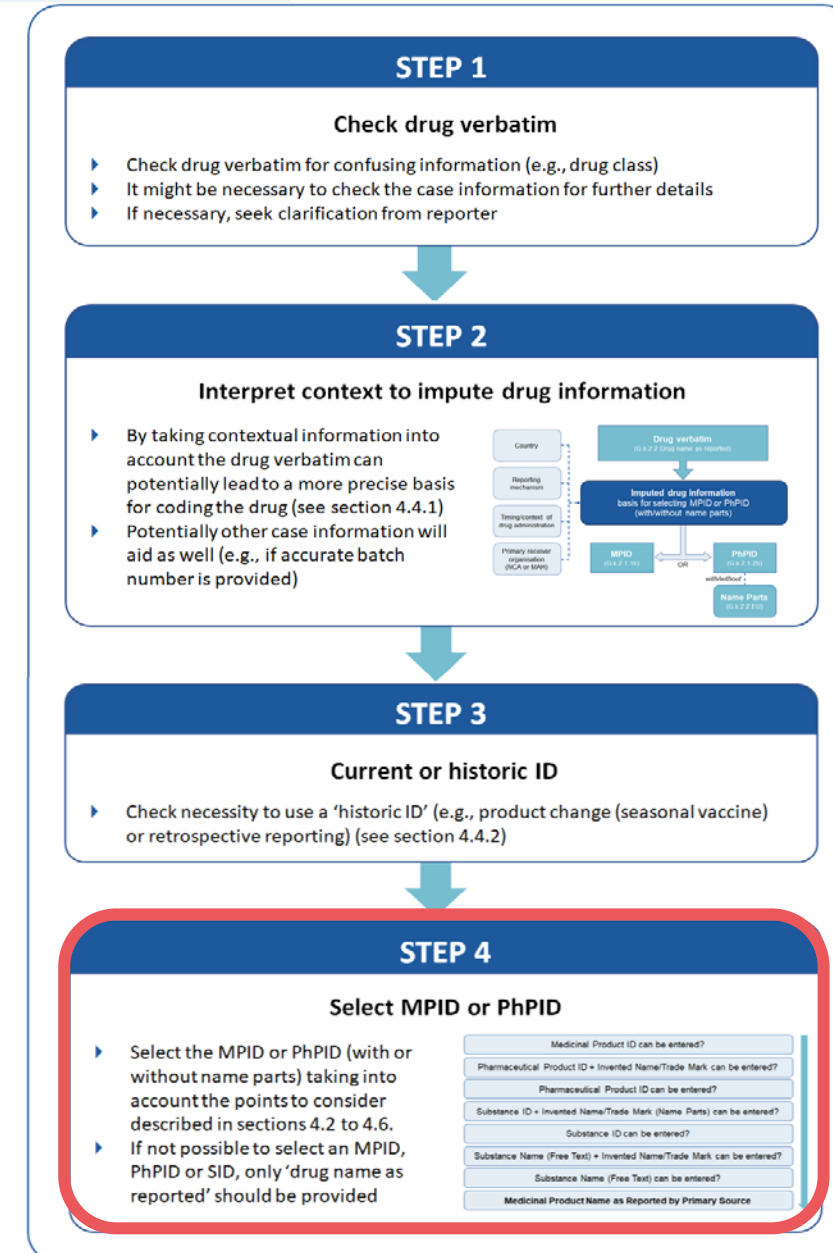
- retrospective ADR reporting (ADR occurred years ago but is reported now)
- ICSR section D.8 Relevant Past Drug History e.g. Seasonal flu vaccines



## Step 4: select MPID or PhPID (+/- name parts)

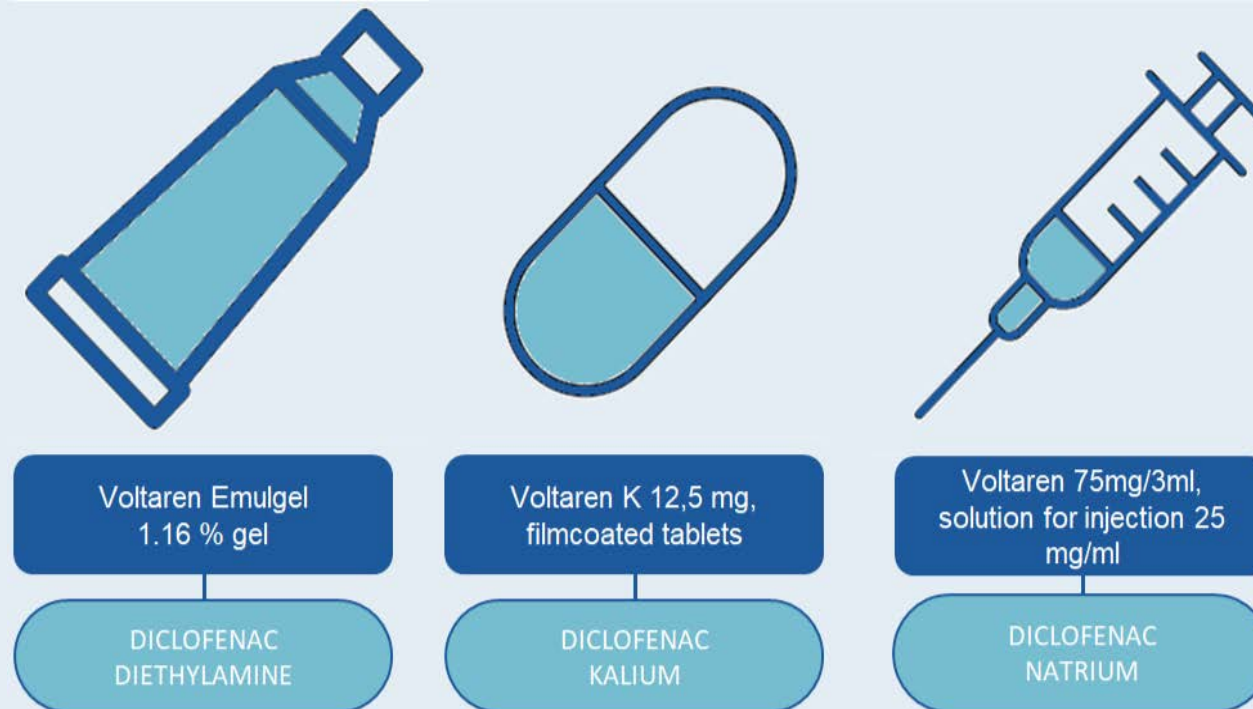
### Various scenario's with practical examples:

- Verbatims with brand name:
  - Brand name with different compositions depending on country
  - Brand name with different compositions in a single country
- Products with multiple active substances
- Drug verbatims with strength and dose
- Drug verbatims with route of administration and/or dose form 'intended site'
- Drug verbatims with acronyms, abbreviations and synonyms
- Excipients
- Combination packs ('kits')
- Drug classes, other therapies and non-medicinal products
- Verbatims with herbal drug names

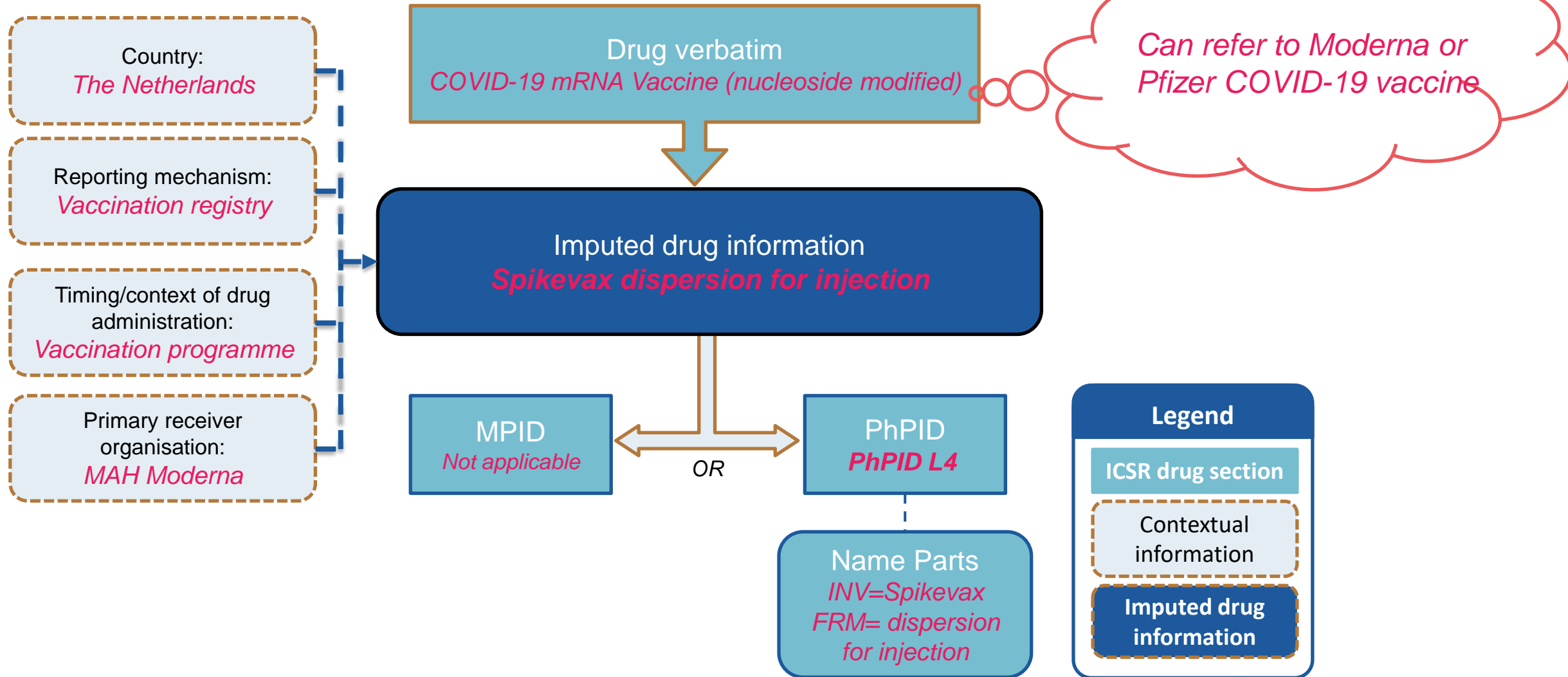


**Example:**

A report with drug verbatim 'Voltaren' should be coded with PhPID L1 for 'diclofenac' (if available) as this is common to all pharmaceutical forms/presentations.



# Example: Use of name parts



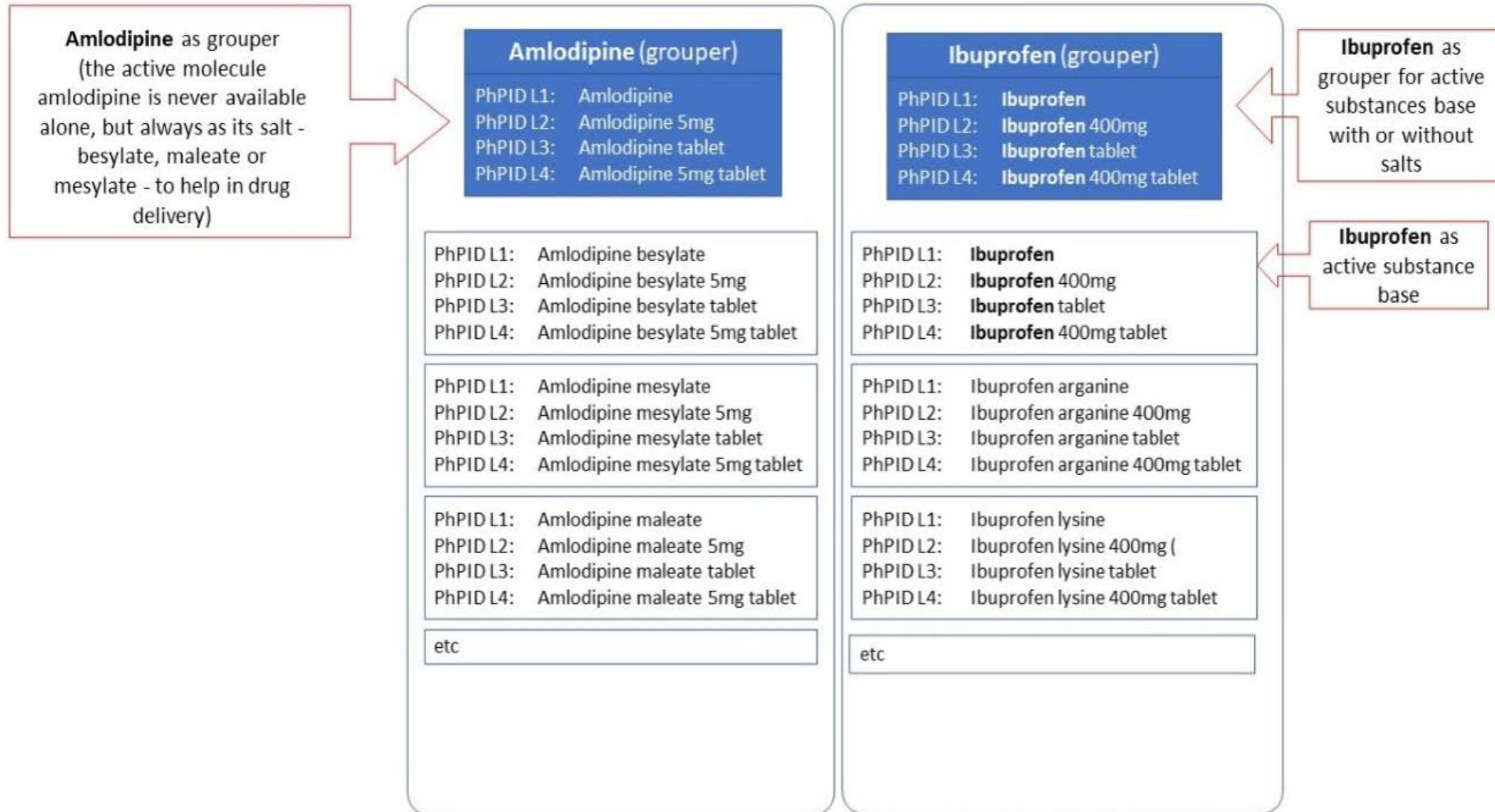
- 1) Pharmacovigilance as driver for IDMP
- 2) Steps taken to develop the IDMP coding guidance for ICSRs
- 3) Principles and guidance for selecting IDMP identifiers
- 4) Points for discussion

- ▶ 1. For pharmacovigilance coding and analysis purposes, it is recommended to have granular PhPIDs available globally. It is also essential that PhPID grouping concepts and relationships will be available and maintained.
- ▶ 2. It is recommended to investigate and assess the potential benefit of a new ICSR data element 'imputed drug information' as an alternative for using name part data elements in the ICSRs.
- ▶ 3. To best support pharmacovigilance stakeholders, it is recommended to explore a possible role of global and/or regulatory organisations as an owner for IDMP ICSR coding guidance, to be responsible for its ongoing development and revision as the IDMP implementation progresses.
- ▶ 4. It is recommended to improve pharmacovigilance data collection methods by using drug identification information via the 2D-data matrix or barcode on the medicine package.

- ▶ 5. As IDMP implementation activities progress, the need for IDMP versioning in the ICSR and potential versioning strategies should be explored further.
- ▶ 6. A potential benefit of implementing different grouping concepts (as available in for example SNOMED CT and WHO Drug) for pharmacovigilance analysis should be further investigated.
- ▶ 7. It is recommended that the design and interface of drug coding tools used in pharmacovigilance systems should support display of contextual information as well as historic identifiers.
- ▶ 8. As there can be ambiguity and a lack of clarity to exactly what the reporter was meaning, the option to code using drug concepts with an “open world view” as exists in ontologies such as SNOMED CT might be a consideration for the future.
- ▶ 9. Requirements for a medicinal product dictionary for pharmacovigilance could be a potential work item for standardization.

- ▶ 1. For pharmacovigilance coding and analysis purposes, it is recommended to have **granular PhPIDs available globally**. It is also essential that **PhPID grouping concepts and relationships** will be available and maintained.
  
- ▶ **Global PhPID**
  - ▷ Essential for consistency, interoperability
  - ▷ Larger safety database -> faster signal detection -> safer medicines -> improved healthcare
  
- ▶ Requirements for Global PhPID
  - ▷ Global substance ID – proposals progressing
  - ▷ Global dose form terminology - Exploring options for EDQM vs IDMP dose form characteristics
  - ▷ Global agreement on strength - progressing
  - ▷ Global governance, generation, maintenance, SLA/responsiveness, accessibility, funding – WHO-UMC role proposed

- ▶ **1. For pharmacovigilance coding and analysis purposes, it is recommended to have granular PhPIDs available globally. It is also essential that PhPID grouping concepts and relationships will be available and maintained.**
  
- ▶ Appropriate PhPID granularity for use cases
  - ▷ Prescribing equivalence vs Pharmacovigilance vs pharmacoepidemiology
  - ▷ Base vs salt vs specified substance levels
  
- ▶ PhPID Grouping Concepts
  - ▷ IDMP standards are based on ability to capture detailed, thorough and precise information during drug development and submission
    - PhPIDs defined based on knowing specific substance/specified substance, strength and dose form
  - ▷ In the 'Real World' of pharmacovigilance the information reported may be imprecise or incomplete
    - Substance may be reported as the specific salt or base present, or as a generic base term (unspecified but real, or generic term but not real)
  - ▷ Need multiple levels of analysis for pharmacovigilance signal detection
    - Signal detection may start at a high level and then drill down
    - May want to analyse data initially by grouping 'base and all salts' together or by drug class
    - Can then drill down to more granular PhPIDs, MPIDs, PCIDs and potentially Batch IDs if needed
  - ▷ PhPID grouping concepts can be added to enhance analysis
    - May be able to build upon on existing concepts used by WHODrug and SNOMED-CT



▶ 2. It is recommended to investigate and assess the potential benefit of a new ICSR data element 'imputed drug information' as an alternative for using name part data elements in the ICSRs.

▶ IDMP coding directly from verbatim text alone may be limited

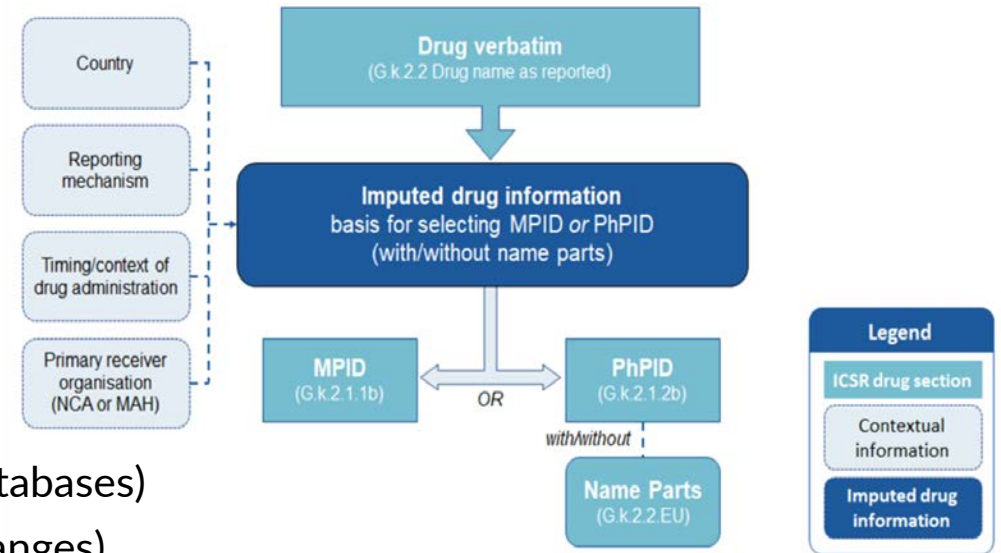
- ▷ Substance/PhPID 1 is often identifiable
- ▷ PhPID2/3/4 can sometimes be assigned
- ▷ MPID is rarely assignable from verbatim text alone

▶ Addition of contextual information can assist coding

- ▷ Country (narrows list of possible products)
- ▷ Reporting mechanism (structured entries via web/app; healthcare databases)
- ▷ Timing/History (current ADR vs old version of product, in case of changes)
- ▷ Primary Receiver (MAH may assume own product?)

▶ Further analysis of the Drug verbatim can also be helpful

- ▷ The current ICSR and IDMP both contain data elements for structured Name Parts
- ▷ Another option to consider is 'smart' text searching



- ▶ 2. It is recommended to investigate and assess the potential benefit of a new ICSR data element 'imputed drug information' as an alternative for using name part data elements in the ICSRs.

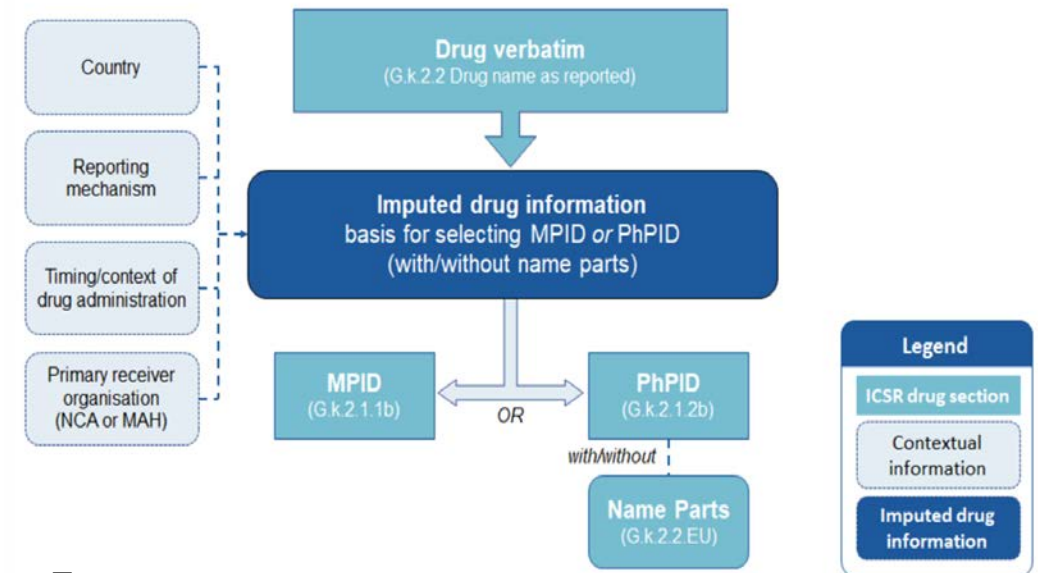
- ▶ Use of structured Name Parts

- ▷ Effective use of structured Name Parts requires

- Aligned data elements
    - Consistent assignment of the correct text to each Name Part
      - Across Regulators, Pharma, Healthcare, ICSRs/Pharmacovigilance

- ▷ Currently, in the Real World

- ICSR has 8 Name Parts; IDMP has 13!
    - Assignment of text to correct Name Part not always obvious, e.g. Forte
    - Resource intensive to correctly assign and match Name Part data elements

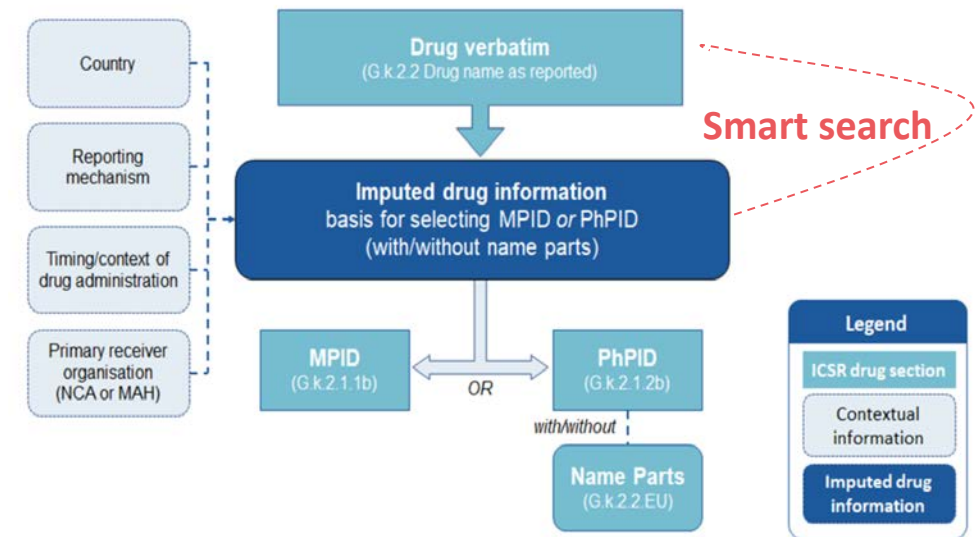


ICSR		PMS	
Concept name	Example	Concept name	Example
Container name	<i>Pre-filled syringe</i>	Container or pack part	<i>In a vial</i>
Device name	<i>InjectPen</i>	Device part	<i>inhaler</i>
Form name	<i>Soft capsules</i>	Pharmaceutical dose form part	<i>Slow release tablets</i>
Invented name	<i>TotalFlu</i>	Invented name part	<i>BeatCold</i>
Scientific name	<i>paracetamol</i>	Scientific name part	<i>diclofenac</i>
Strength name	<i>50 mg</i>	Strength part	<i>50 mg</i>
Trademark name	<i>Syncopharm</i>	Trademark or company name part	<i>PharmaX</i>
<b>Intended use name</b>	<i>Heartburn relief</i> <i>For children</i>	<b>Intended use part</b>	<i>Migraine relief</i>
		<b>Target population part</b>	<i>For children</i>
		Time/period part	<i>2013/2014 (influenza vaccine)</i> <i>One a Day</i>
		Flavour part	<i>Orange</i>
		Delimiter part	<i>/</i> <i>'and'</i>
		Formulation part	<i>Sugar free</i>

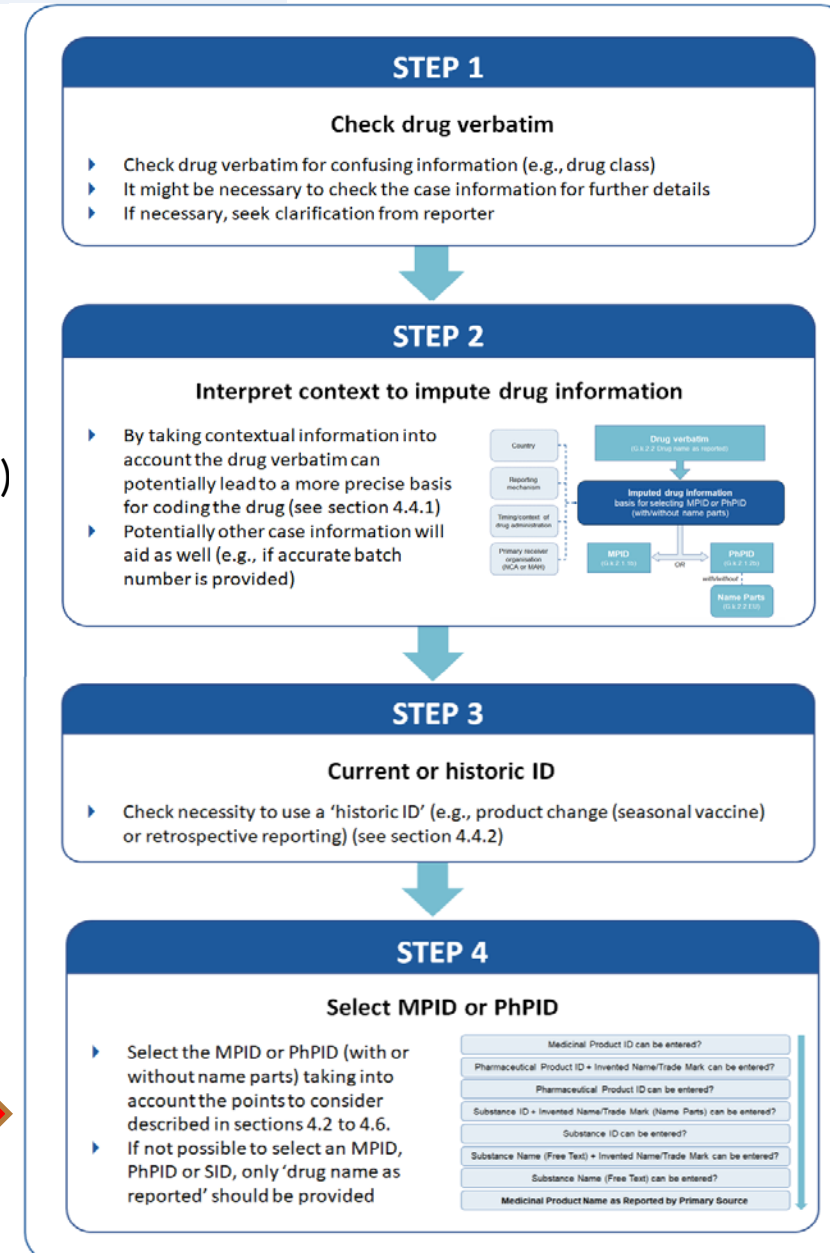
ICSR 'intended use' name part can contain information on target population which is a separate element in PMS

Grey PMS elements are not available in ICSR

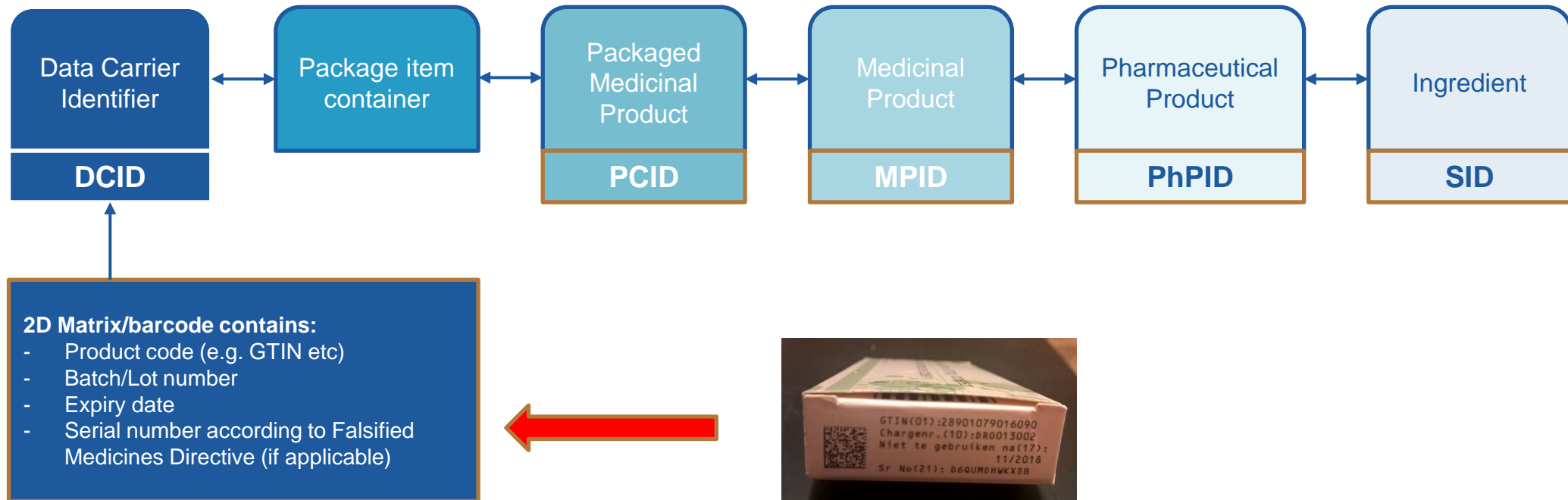
- ▶ 2. It is recommended to investigate and assess the potential benefit of a new ICSR data element 'imputed drug information' as an alternative for using name part data elements in the ICSRs.
- ▶ 'Smart' text searching – an alternative to Name Parts?
  - ▷ Name Parts concept initiated years ago before more powerful text searching and Natural Language Processing developed
  - ▷ Although Name Parts are included in the current ICSR (EU version), these have yet to be mandated
  - ▷ Opportunity to review options and potentially avoid resource intensive implementation of structured Name Parts



- ▶ 4. It is recommended to improve pharmacovigilance data collection methods by using drug identification information via the **2D-data matrix or barcode** on the medicine package.
- ▶ Currently the Drug Verbatim field is the starting point for ICSRs (Step 1)
  - ▷ May be free text or from a pick list or database
  - ▷ May apply contextual information and Name Parts to aid coding
  - ▷ Usually still limited ability to code to PhPID; rarely able to code to MPID (Step 4)
- ▶ Alternative – scan the 2D data matrix or barcode on the packaging
  - ▷ Current ICSR developed before widespread use of barcoding and imaging
  - ▷ Now widespread ability to scan/store barcodes on packaging
    - Supply chain, clinical settings, patients/apps
  - ▷ 2D data matrix contains precise and additional key information
    - Data carrier ID (DCID), e.g. GTIN
    - Batch/Lot ID
    - Expiry date
    - Serial number (e.g. for Falsified Medicines Directive)
  - ▷ IDMP model already includes a Data Carrier Identifier data element
    - **Key link to other IDMP identifiers**



- ▶ 4. It is recommended to improve pharmacovigilance data collection methods by using drug identification information via the **2D-data matrix or barcode** on the medicine package.
- ▶ Addition of 2D data matrix/barcode scanning to ICSR, clinical processes/databases and eHealth apps will enable direct links to IDMP identifiers and provide additional product information, e.g. Batch/lot number



- ▶ The ISO ICSR is undergoing a planned systematic review ballot.
  - ▷ Opportunity to suggest improvements or keep ICSR as it is
  - ▷ Closes **20-FEB-2022**
  
- ▶ Consider addition of 'Imputed Drug Information' field
  - ▷ Facilitates improved coding to IDMP IDs from verbatim text by inclusion of additional contextual information
  
- ▶ Consider use of smart text searches as alternative to use of specific Name Part data elements
  - ▷ Name Parts concept initiated years ago before more powerful text searching and Natural Language Processing developed
  - ▷ Although Name Parts are included in the current ICSR (EU version), these have yet to be mandated
  - ▷ Opportunity to review options and potentially avoid resource intensive implementation of structured Name Parts
  
- ▶ If Name Parts are to be implemented, then the ICSR data elements should be aligned with those of IDMP

**Thank you!**

**UN  COM**

# BACK-UP SLIDES

MPIDs will be generated by regional regulators and will be made publicly available.

Construction of an MPID will use a common pattern with 3 segments:

- ▶ Country code segment,
- ▶ Marketing Authorization Holder (Organisation Identifier) code segment
- ▶ Medicinal Product code segment (Unique Medicinal Product Identifier)

Examples: NL-MAH X-12345, ES-MAH Y-45678, etc

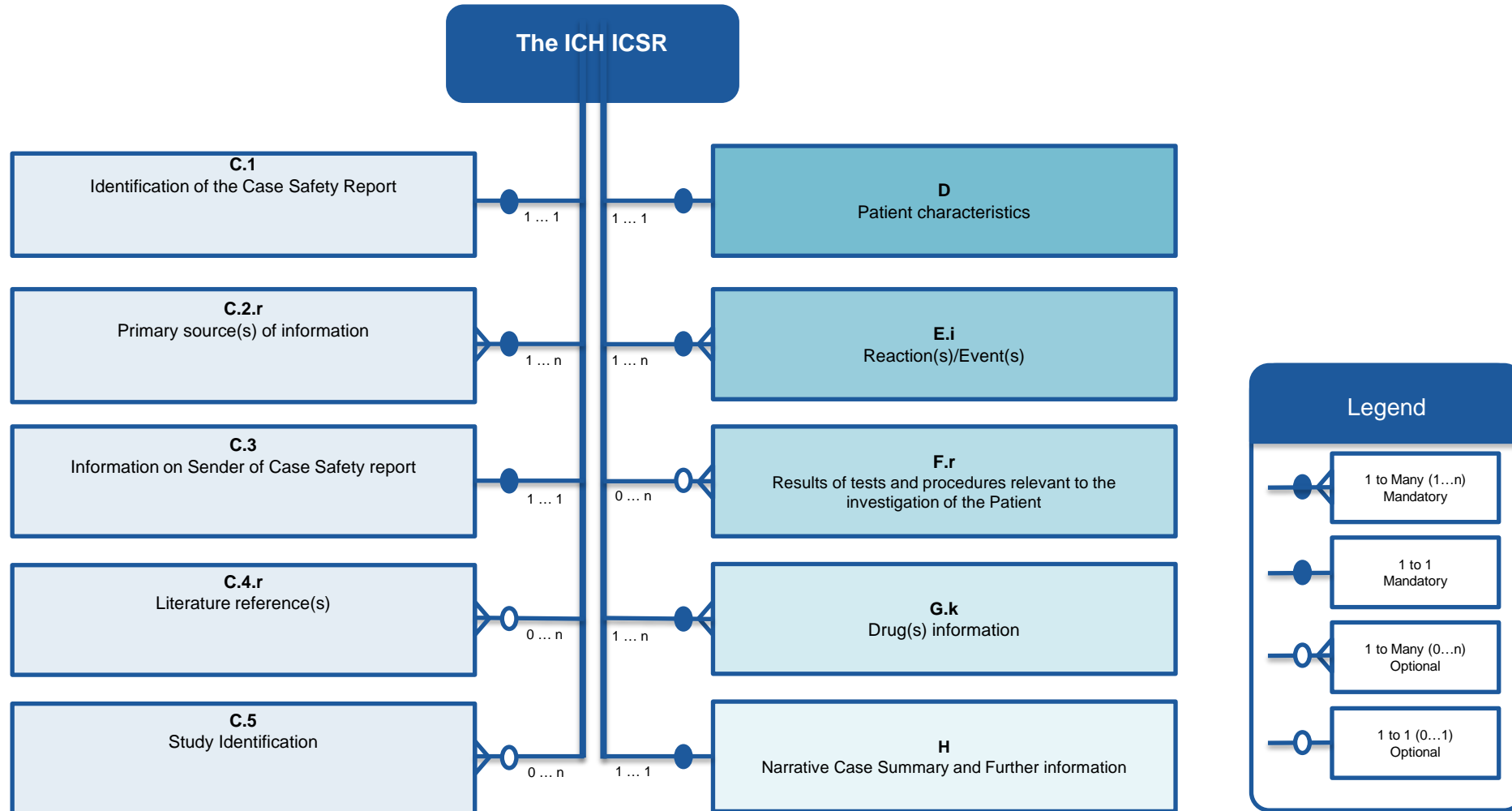
Triggers to assign a new MPID (based on ISO 11615 version 2015) are:

- ▶ Marketing authorization in relation to the jurisdiction;
- ▶ Legal status of supply (e.g., prescription only or “over the counter” sale);
- ▶ Medicinal Product name;
- ▶ The pharmaceutical dose form;
- ▶ The ingredient substance(s) and their strength;
- ▶ Device(s) where a Medicinal Product is combined with a medical device and where the pharmacological, immunological or metabolic action should be considered as the principal mode of action; the medical device is presented as part of the Medicinal Product;
- ▶ Therapeutic indication(s) as authorized for the Medicinal Product.

- ▶ A PhPID will be a non-semantic identifier generated by an algorithm based on the core elements for identification of a pharmaceutical product ((specified) substance, dose form, strength).

Example: 8663a93b-5627-7466-306d-fd794b7d268a

- ▶ Discussions are ongoing on having a global organization responsible for generating and maintaining PhPIDs.
- ▶ In theory, if the core elements ((specified) substance, dose form, strength) are standardised globally, PhPIDs can be generated by individual stakeholders themselves, using the MD5 hash generator (a free online tool).



## 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.2.2.EU – EU specific elements

0...n

G.k.2.2.EU.1	Name Part – Invented name
G.k.2.2.EU.2	Name Part – Scientific name
G.k.2.2.EU.3	Name Part – Trademark name
G.k.2.2.EU.4	Name Part – Strength name
G.k.2.2.EU.5	Name Part – Form name
G.k.2.2.EU.6	Name Part – Container name
G.k.2.2.EU.7	Name Part – Device name
G.k.2.2.EU.8	Name Part – Intended Use name
G.k.2.2.EU.9.r.1	Device Component name
G.k.2.2.EU.9.r.2	Device Component TermID version Date/Number
G.k.2.2.EU.9.r.3	Device Component TermID
G.k.2.2.EU.9.r.4	Device Batch Lot Number

### G.k.2.3.r – Substance/Specified Substance ID 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)

Continue on next

## G – Drug(s) Information

Continue from previous

### G.k.4.r – Dosage information (repeat as necessary)

G.k.4.r.1a	Dose (number)
G.k.4.r.1b	Dose (unit)
G.k.4.r.2	Number of Units in the interval
G.k.4.r.3	Definition of the Time interval Unit
G.k.4.r.4	Date and Time of Start of Drug
G.k.4.r.5	Date and Time of Last Administration
G.k.4.r.6a	Duration of Drug Administration (number)
G.k.4.r.6b	Duration of Drug Administration (unit)
G.k.4.r.7	Batch/Lot number
G.k.4.r.8	Dosage Text
G.k.4.r.9.1	Pharmaceutical Dose Form (free text)
G.k.4.r.9.2a	Pharmaceutical Dose Form TermID Version Date/Number
G.k.4.r.9.2b	Pharmaceutical Dose Form TermID
G.k.4.r.10.1	Route of Administration (free text)
G.k.4.r.10.2a	Route of Administration TermID Version Date/Number
G.k.4.r.10.2b	Route of Administration TermID
G.k.4.r.11.1	Parent Route of Administration (free text)
G.k.4.r.11.2a	Parent Route of Administration TermID Version Date/Number
G.k.4.r.11.2b	Parent Route of Administration TermID

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### G.k.7.r – Indication for Use in Case (repeat as necessary)

G.k.7.r.1	Indication as Reported by the Primary Source
G.k.7.r.2a	MedDRA Version for Indication
G.k.7.r.2b	Indication (MedDRA code)

0...n

### G.k.9.i – Drug reaction(s)/Event(s) Matrix (repeat as necessary)

G.k.9.i.1	Reaction(s)/Event(s) Assessed
G.k.9.i.3.1a	Time Interval between Beginning of Drug Administration and start of Reaction/Event (number)
G.k.9.i.3.1b	Time Interval between Beginning of Drug Administration and start of Reaction/Event (unit)
G.k.9.i.2a	Time interval between Last Dose of Drug and Start of Reaction/Event (number)
G.k.9.i.2b	Time interval between Last Dose of Drug and Start of Reaction/Event (unit)
G.k.9.i.4	Did Reaction Recur on Re-administration?

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### G.k.9.i.2.r – Assessment of Relatedness of Drug to Reaction(s)/Event(s) (repeat as necessary)

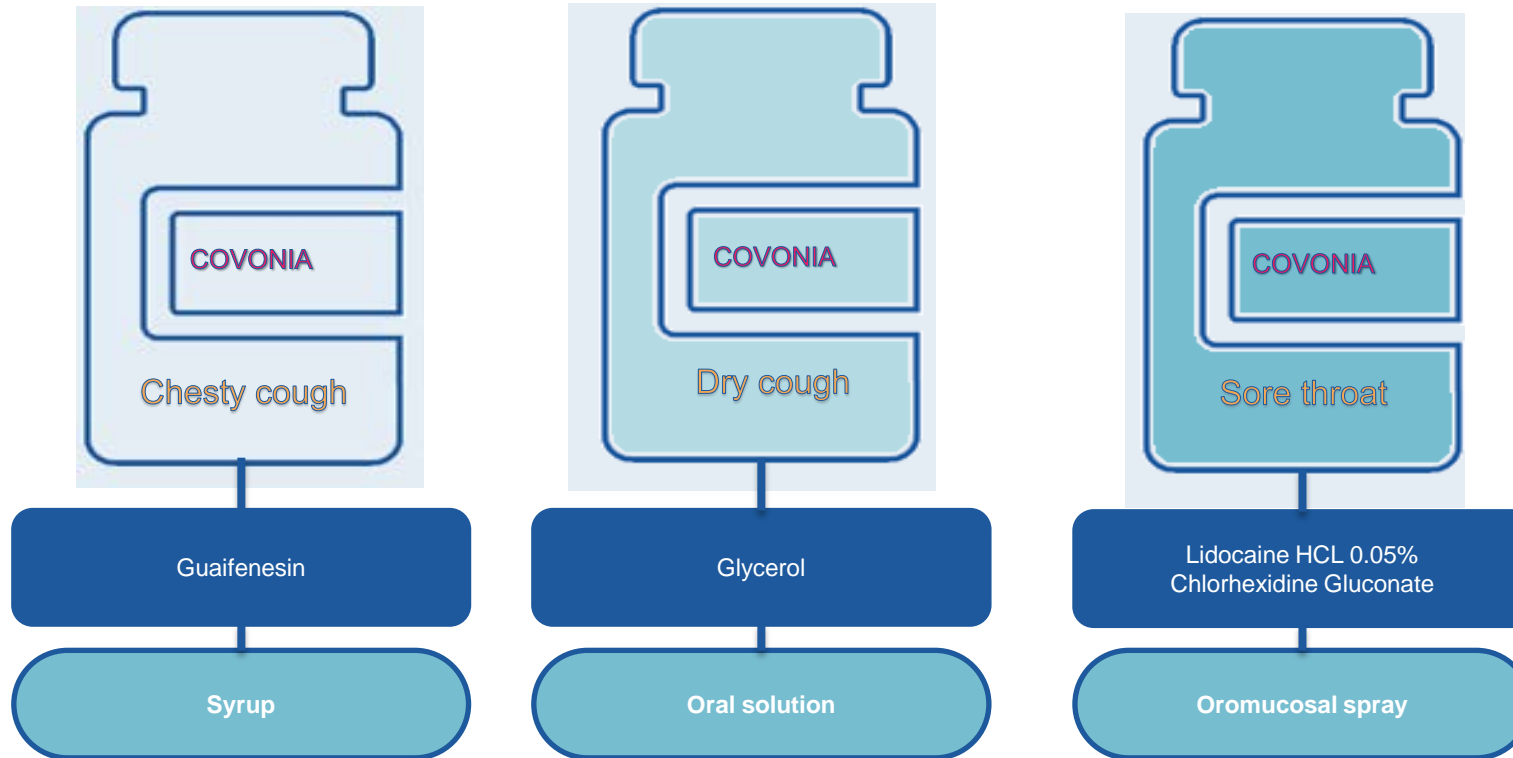
G.k.9.i.2.r.1	Source of Assessment
G.k.9.i.2.r.2	Method of Assessment
G.k.9.i.2.r.3	Result of Assessment

0...n

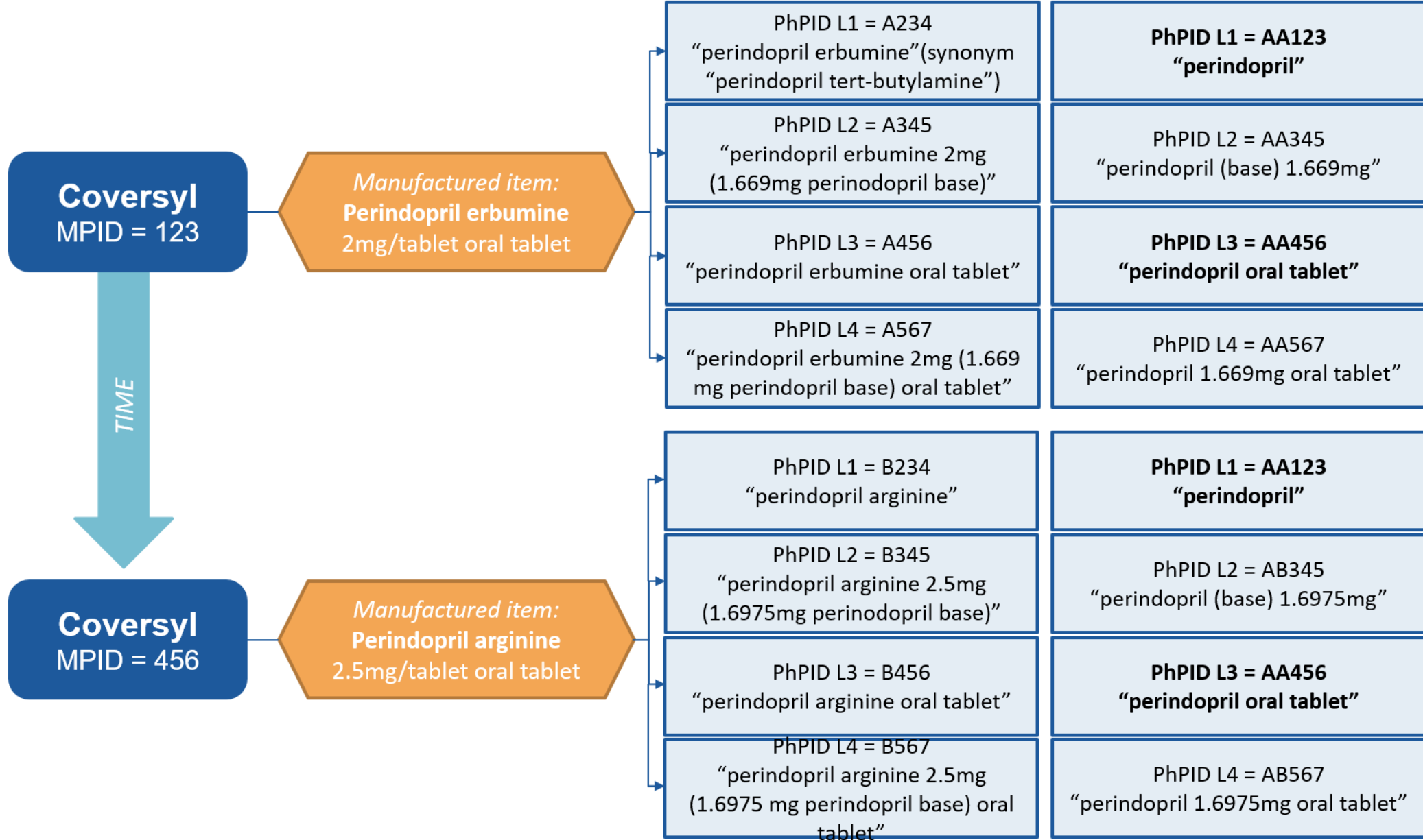
### G.k.10.r – Additional information on Drug (repeat as necessary)

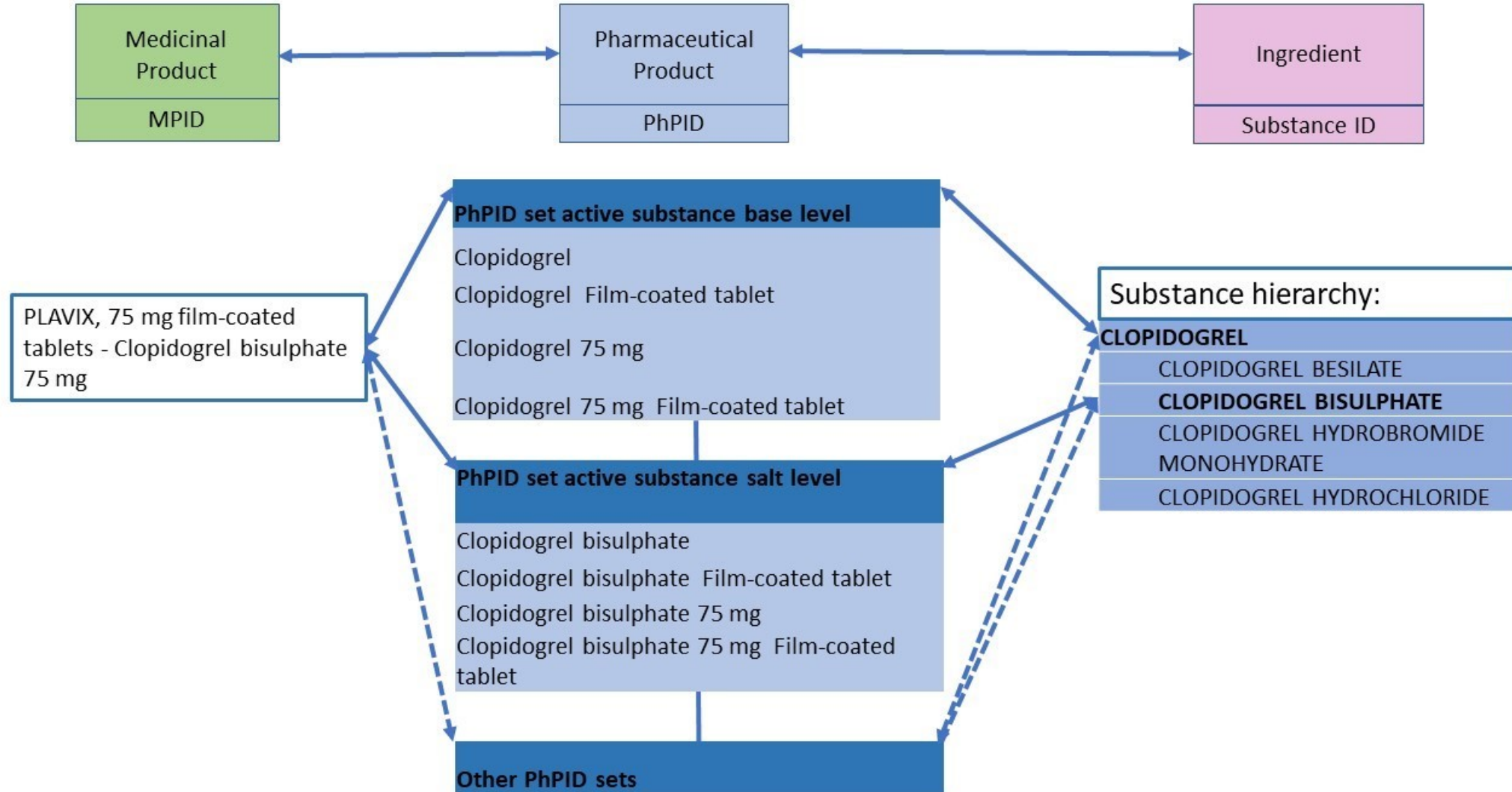
G.k.10.r	Additional Information on Drug (coded)
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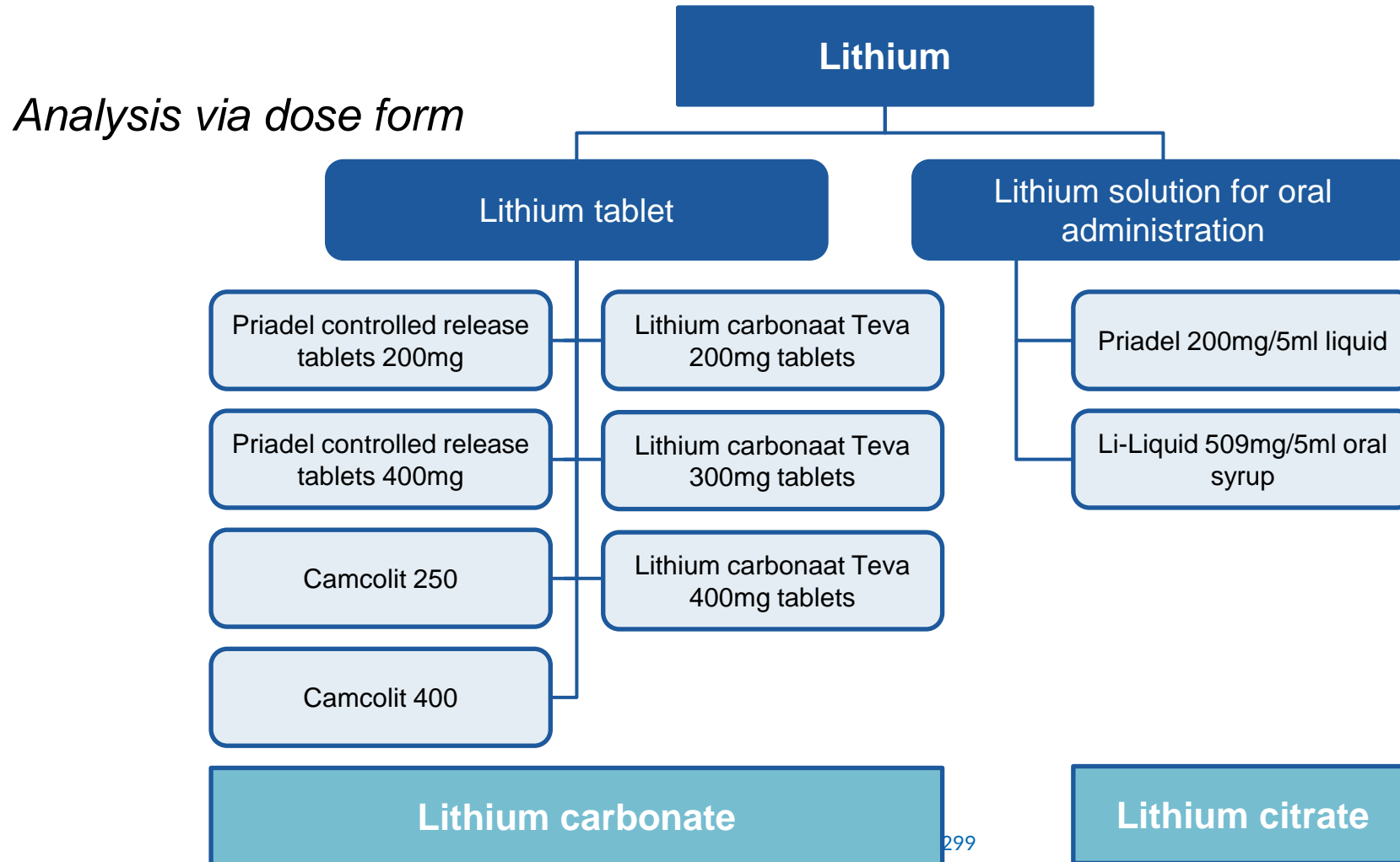


A report of a suspected ADR with a drug verbatim 'Covonia' without any further details cannot be coded: only data element G.k.2.2 'Medicinal Product Name as Reported by the Primary Source' (the drug verbatim) should be populated.

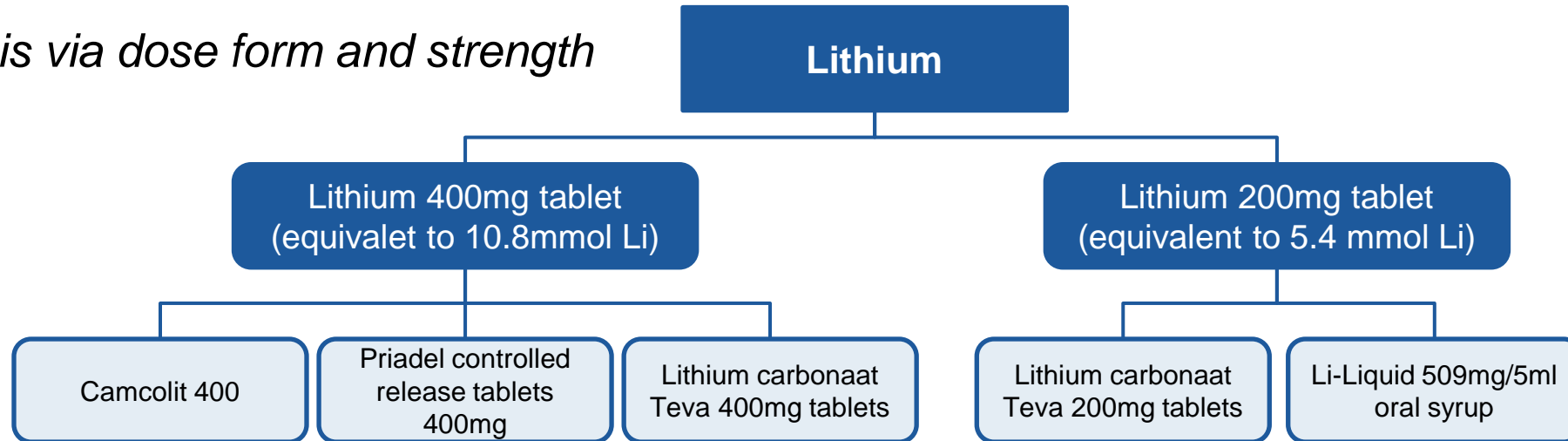




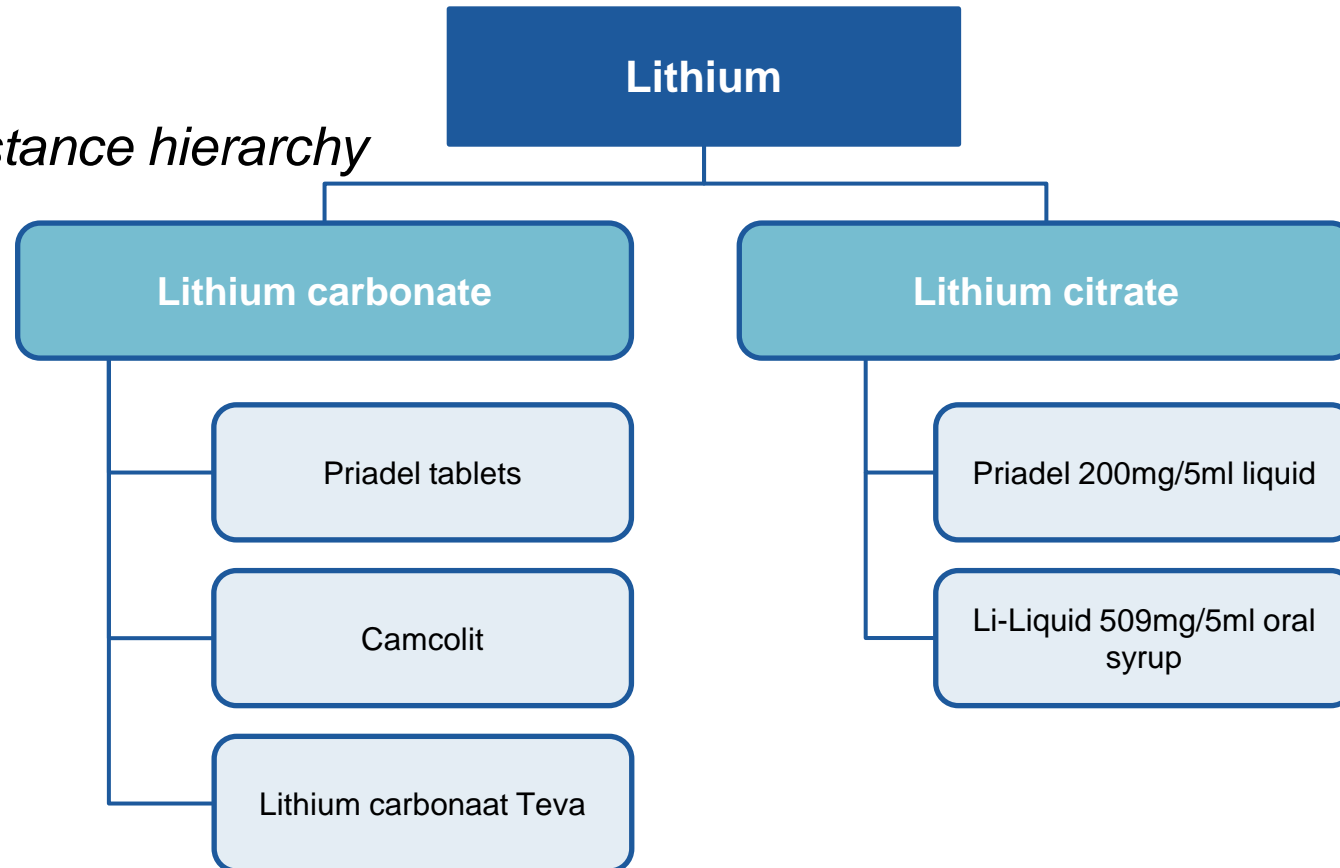
- ▶ After first screening of ICSR data at active substance base level, there are several options to use IDMP levels for further analysis as shown in these simplified examples starting with lithium (PhPID L1):

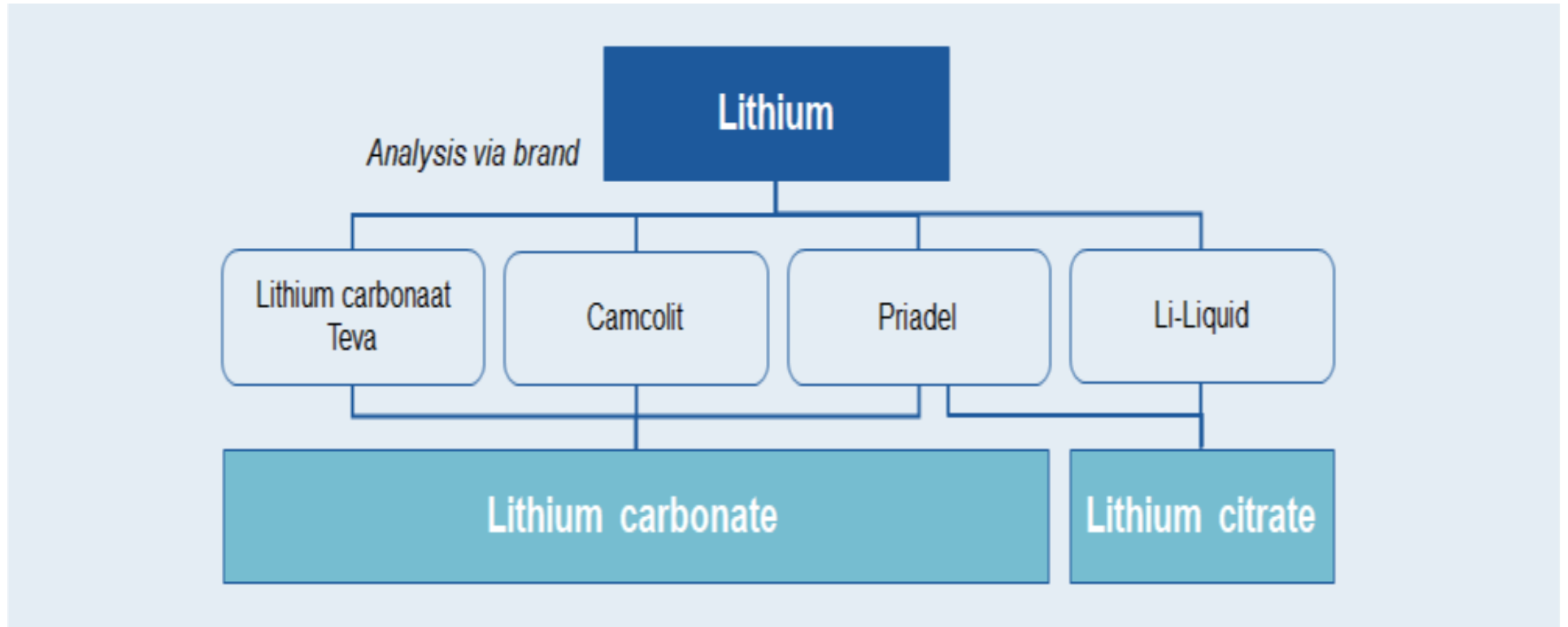


*Analysis via dose form and strength*

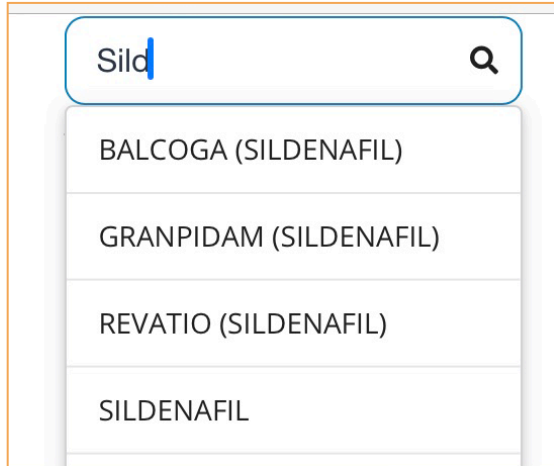


*Analysis via substance hierarchy*





Drop downs and auto fill features are implemented in the ADR reporting webform used by the Dutch Pharmacovigilance Centre Lareb.



Sild

- BALCOGA (SILDENAFIL)
- GRANPIDAM (SILDENAFIL)
- REVATIO (SILDENAFIL)
- SILDENAFIL



Drank, 1 mg/ml (milligram per milliliter)

- Tablet, 20 mg (milligram)
- Tablet, 25 mg (milligram)
- Tablet, 50 mg (milligram)

### Step 1:

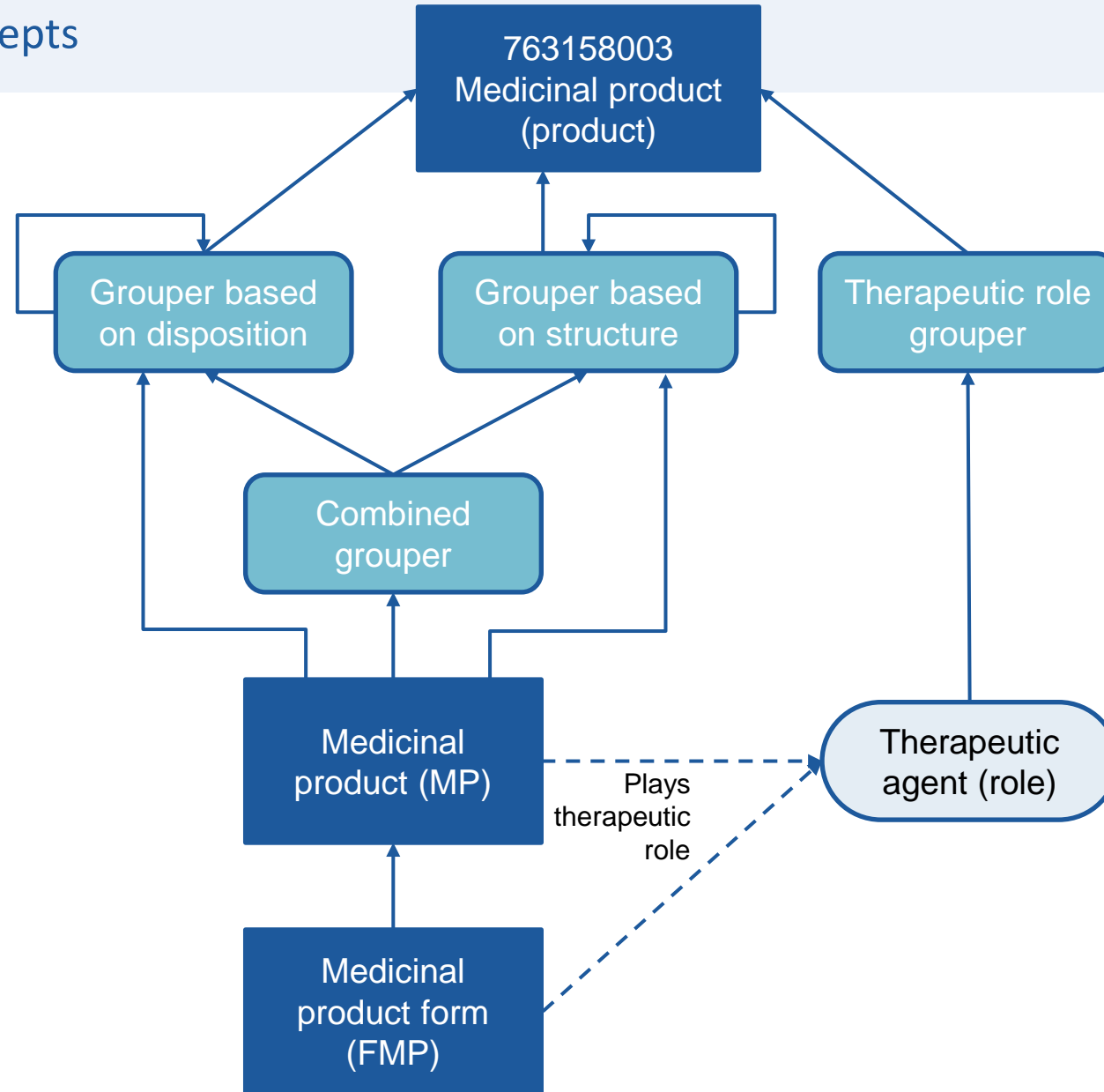
Drug search starts after typing first 4 characters; both substance and brands are available for selection.

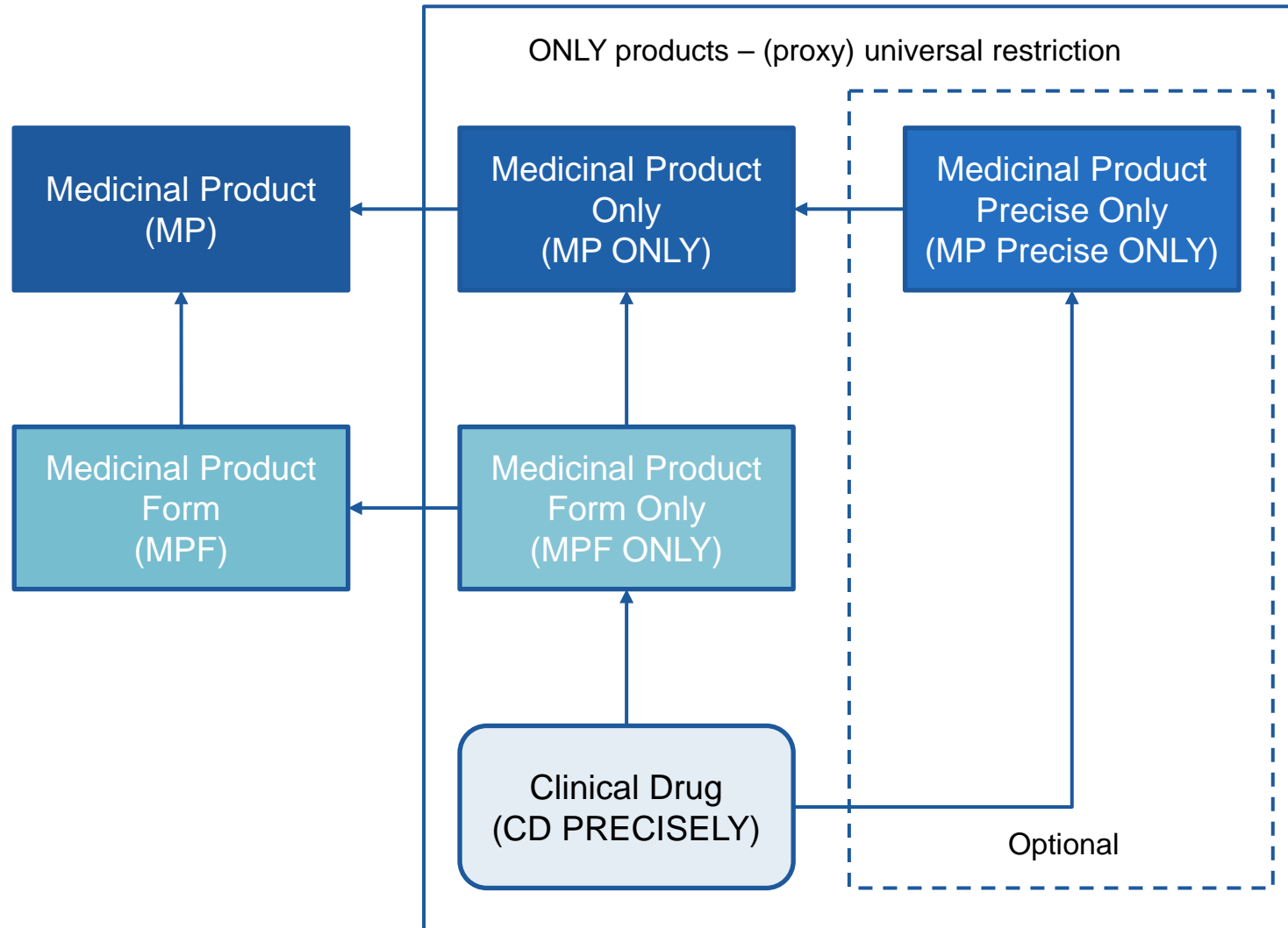
- The search will become more specific when typing is continued
- Free text is captured if reporter continues typing and doesn't make a selection

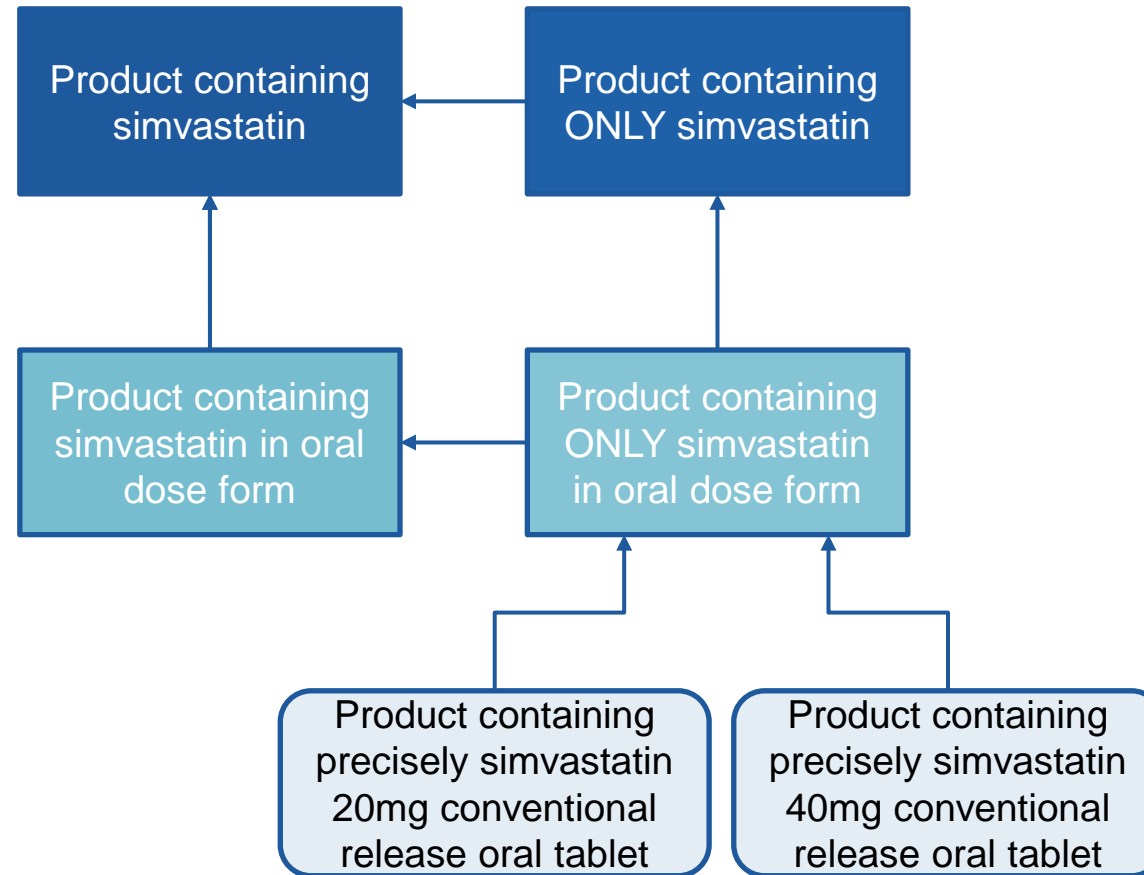
### Step 2:

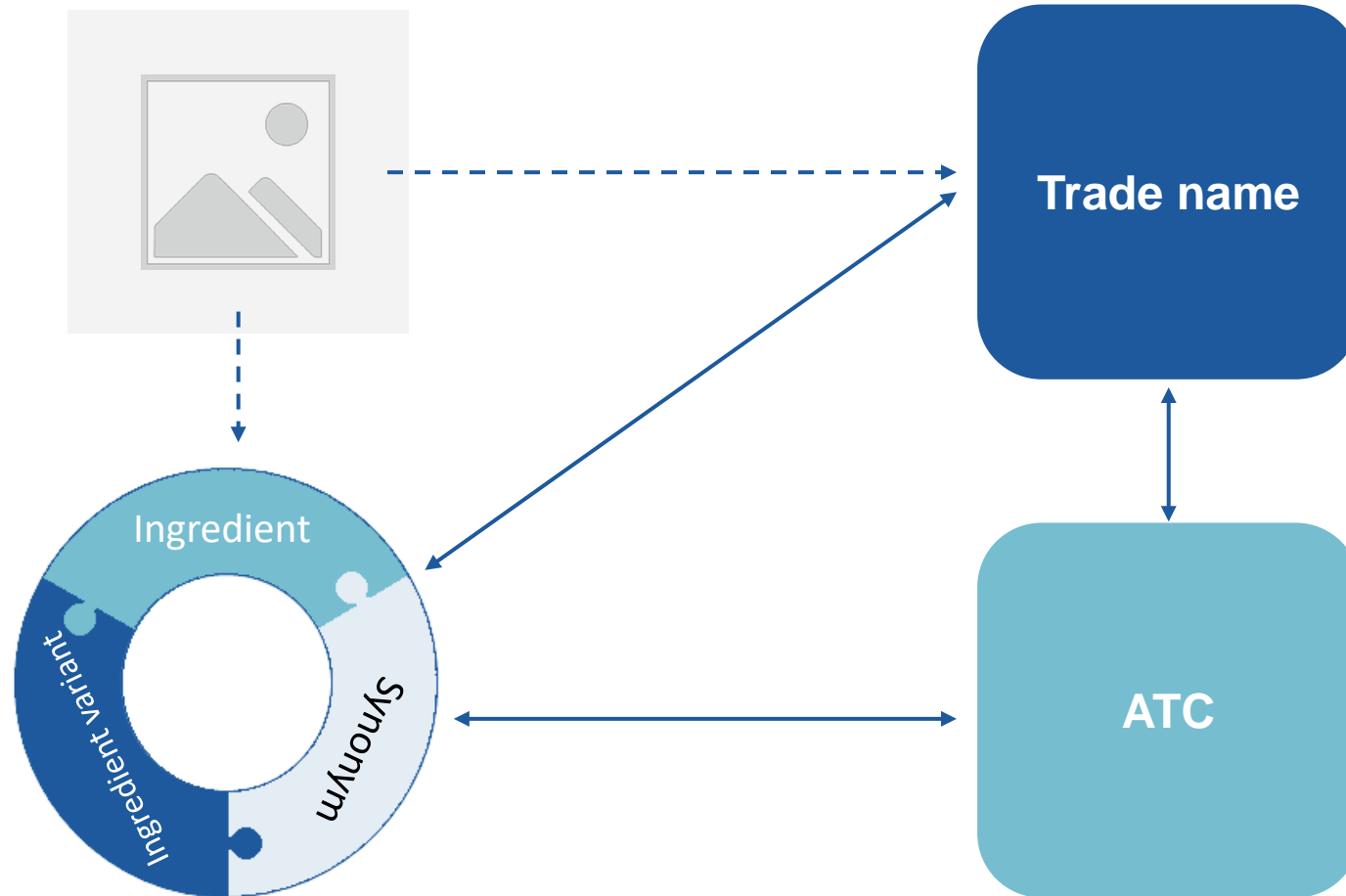
If a selection has been made for step 1, a list with relevant pharmaceutical form/strengths will appear

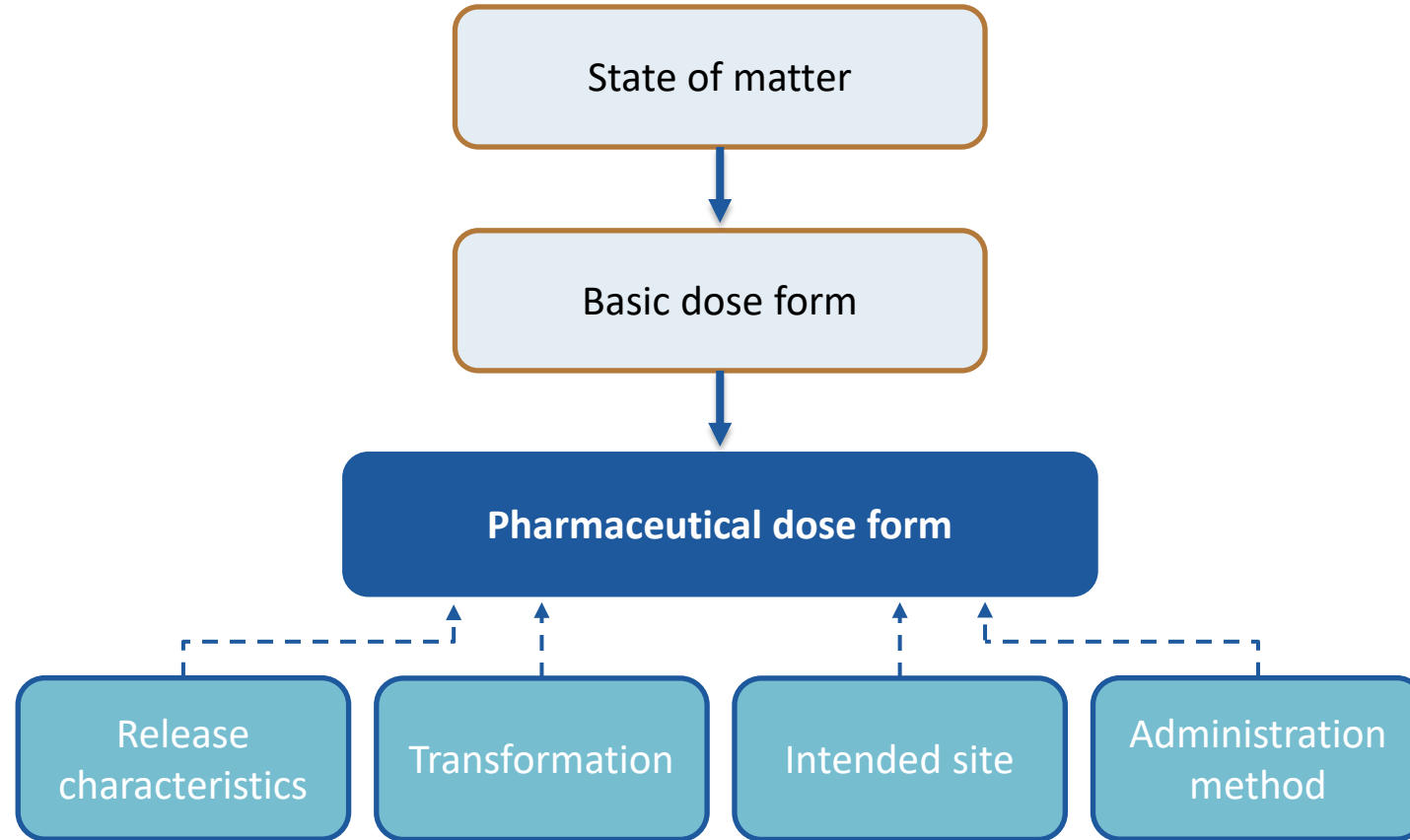
When both step 1 and 2 result in a selection, the drug verbatim will be coded against the most precise match available in the drug dictionary.











Hierarchy of the pharmaceutical dose form, arranged according to the state of matter and basic dose form, and further characterised by release characteristics, transformation, intended site, and administration method (EDQM, 2018)

Questions in the Q & A facility, please

For feedback, please go to : <https://forms.gle/g7reYNcGJ75QdndN9>

*Thanks for your time*

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