

Global Identification of Medicinal Products Implications for electronic health records, prescribing, medical education, rational drug therapy

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No conflict of interest to declare



- ▶ Our Background
- ▶ Short presentation of 5 CEN/ISO Standards
- ▶ The UNICOM Project
- ▶ Use cases
 - ▷ The medication list in the EHR (in open EHR)
 - ▷ The International Patient SumMary (iPS)
 - ▷ Pharmacovigilance : the Individual Case Safety Report ICSR
 - ▷ Crossborder prescribing
 - ▷ INN prescribing
 - ▷ Decision support
 - ▷ Deprescribing
 - ▷ Pscribe platform for rational pharmacotherapy
 - Standardization
 - Internationalisation



- ▶ Work Package WP8 (IDMP and Clinical Care)

- ▶ GP and Clinical Pharmacologist
 - ▷ Practice and research experience
 - ▷ Training experience in medicine and pharmacy
- ▶ Belgian Independent Drug Information Centre
 - ▷ Web information for health professionals
 - ▷ The Authentic source of medicines (SAM Database)
 - ▷ The Belgian ICT-Implementation of INN Prescribing
- ▶ Drug Utilisation Research
 - ▷ ESAC project (European Surveillance of Antibiotic Consumption)
 - ▷ Guidelines for Cross National Comparison of Drug Exposure
- ▶ Doctoral Thesis on drug information for patients in package inserts



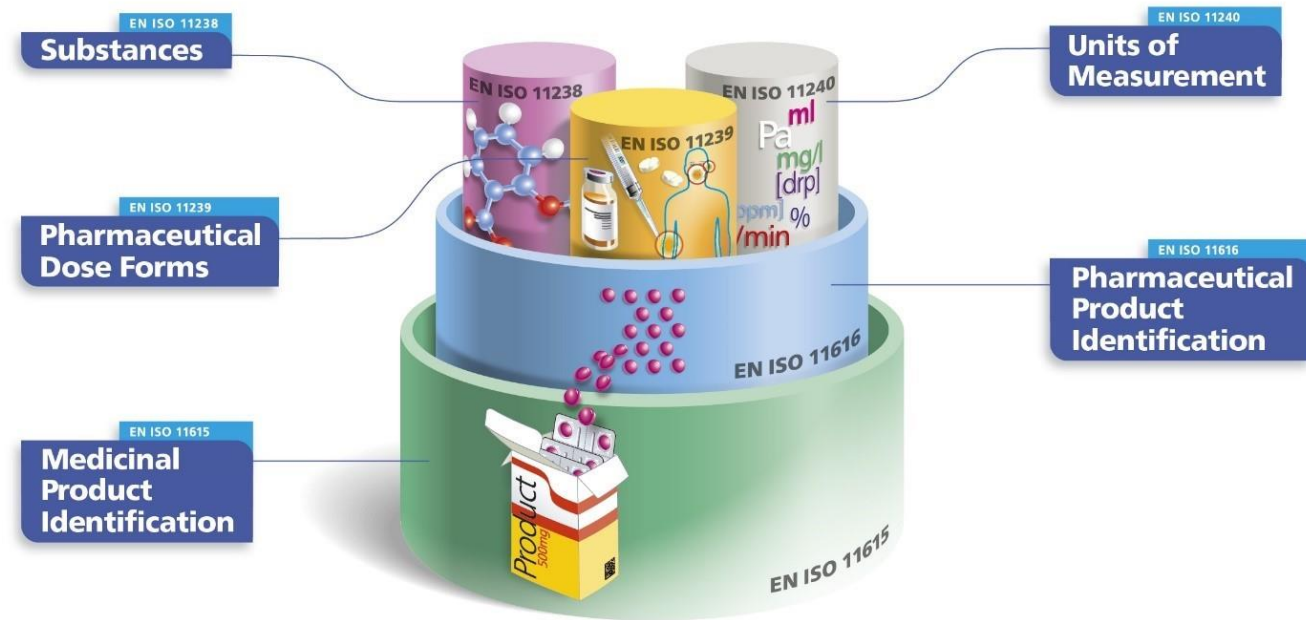
A few words about UNICOM and IDMP

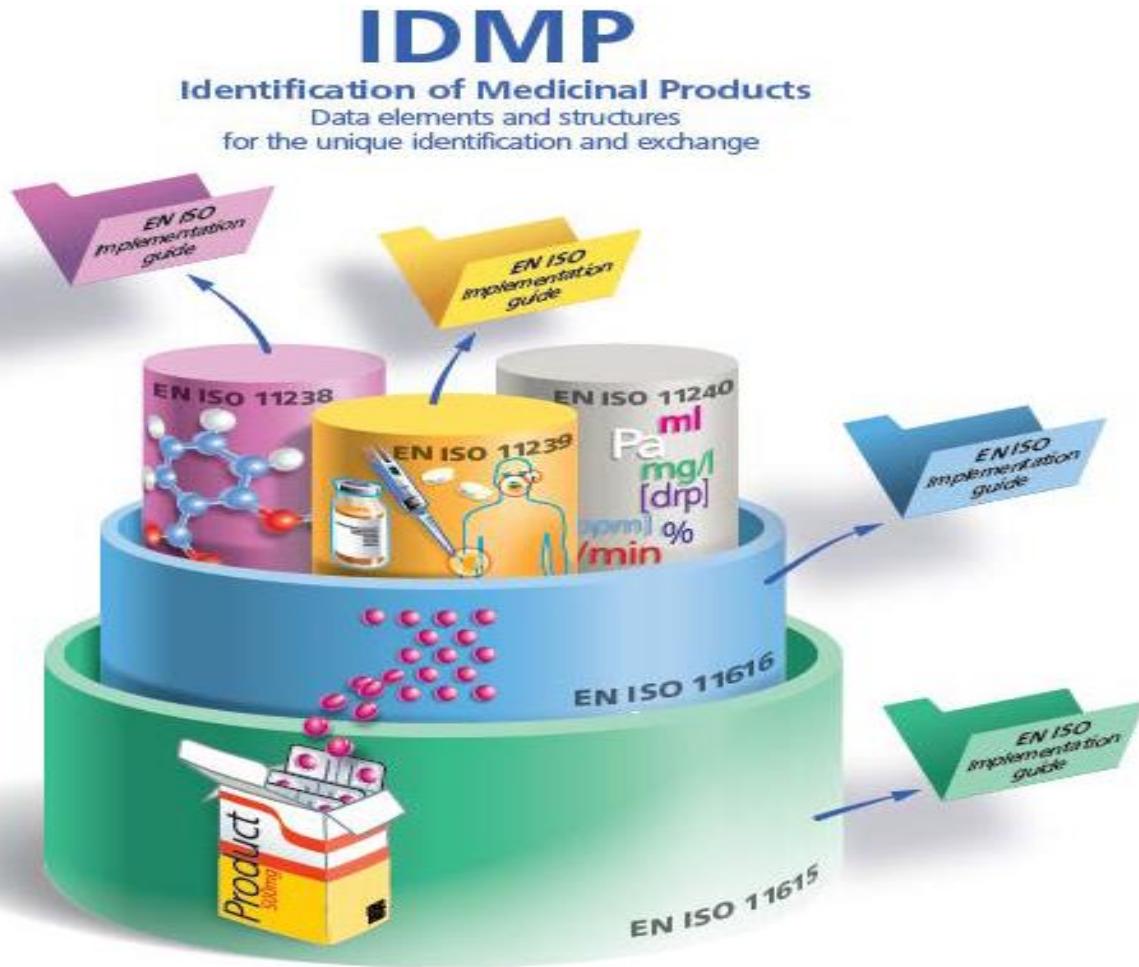
UN  COM

► What if

We would be able to recognise any medicinal product from anywhere in the world anywhere in the world.

That is the ambition of the 5 SO/CEN Standards



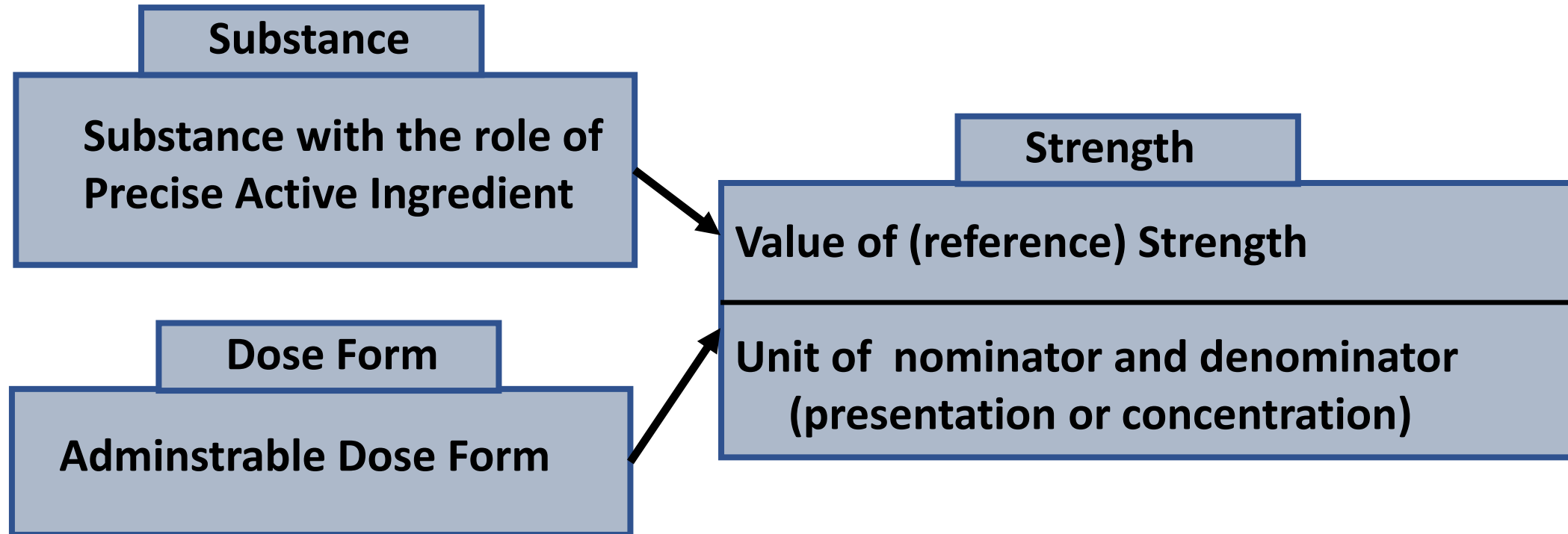


The ISO IDMP standards establish definitions and concepts and describe data elements and their structural relationships that are required for the unique identification of:

- **Medicinal products** (MPID) and **packages** (PCID) - ISO 11615
- **Pharmaceutical products** (PhPID) - ISO 11616
- **Substances** (Substance ID) - ISO 11238
- **Pharmaceutical** dose forms, units of presentation, routes of administration and packaging - ISO 11239
- **Units of measurement** (UCUM) - ISO 11240

ISO IDMP standards apply to both authorised and developmental medicinal products for human use

- ▶ Substance, Dose Form, and strength are key elements that determine the pharmaceutical product.



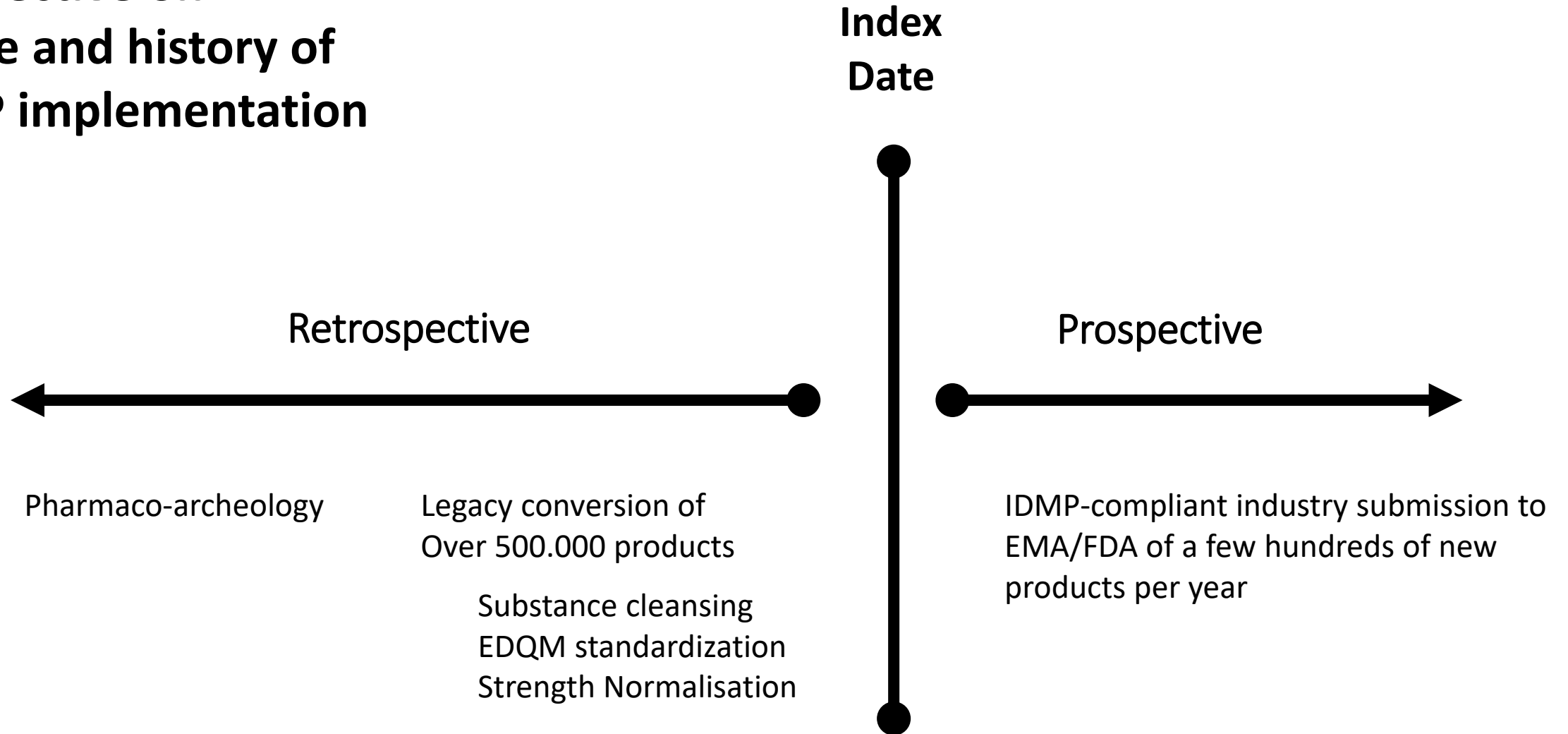
Note: Substance with dose form and strength determine the effect of the medication

- ▶ A large action program, from the EU Horizon programme,
 - ▷ with a 20 MEURO Budget,
 - ▷ 44 participating organisations,
 - ▷ among which 11 National Competent Agency for marketing authorization of Medicinal Products and a number of eHealth Institutions
 - <https://unicom-project.eu>

- ▶ Testimony of large institutional support for IDMP implementation
 - ▷ Supported by ICH (International Council of Harmonisation)
 - ▷ Supported by EMA, FDA
 - ▷ Supported by a global Working Group (bringing together FDA, EMA, WHO_Uppsala Monitoring Centre for Pharmacovigilance)
 - ▷ Supported by Horizon 20/20 through UNICOM



Perspective on future and history of IDMP implementation



PhPID generation for Humalog Mix50 KwikPen

50 mg/ml of Insulin lispro/Insulin lispro protamine suspension, solution for injection

Pharmaceutical Product

Substance ID

Strength

Dose form

Numerical expression

GSID-2ZT4AY1CH-1
GSID-35V9XJV9Z-5

50.00

37

1.00

20

0085

0011

0033

0047

Input string

2ZT4AY1CH1;;;;;;;;;50.00;37;1;20;;;;;;;;;;;;;|35V9XJV9Z5;;;;;;;;;50.00;37;1;20;;;;;;;;;;;;;0085;0011;0033;0047

MD5
digestion

PhPID

0x073AF2E5B92AE19E8B67635AFFB3D6CA

Work on substance

- A meticulous cleaning effort of all types of substances
 - by Bfarm (Germany)
 - the EU substance Register System (EU-SRS) from the European Medicines Agency (EMA)
 - the Food and Drug Administration (FDA)
Resulting in a european ID for substances
(available for regulatory agencies (NCAs) through the SPOR terminology server
And soon as a Global Substance Identifier (GSID)
- Providing a final list of modifiers for the active moieties (if any)
 - Checked against pharmacovigilance records for current use in the world
 - Following International Non-proprietary Nomenclature (INN), where possible
 - Providing detailed, often confidential information for regulatory purposes
 - Preparing a public export of relevant substance details
 - (links to different library systems, molecular mass)

Work on dose form

- World agreement to adopt the EDQM Standardised Terms of the European Directorate for Quality in Medicines

For pharmaceutical dose form, administrable dose form, unit of presentation, route of administration

- Well supported by a publicly available knowledge base

with definitions of terms

with provision of new tools to identify the administrable dose form (basis for PhPID construction).

dealing with transformation from manufactured to administrable dose form

forming the basis for the European SPOR terminology service

- Assuring a more granular identification of medicines than the US RxNorm System

Work on Strength Expression

- Standardizing the expression of strength is a tricky issue
- Global discussions and coordination in the Global IDMP Working Group (GIDWG), bringing EMA, FDA, WHO UMC, and others together
- Resulting in detailed business rules for presentation/concentration strength of different types of medicines

Solid oral forms, Solid liquid forms, topical products, transdermal products, inhalers, injections (uni-dose and multidose), etc



resulting in consensus business rules, soon to be published

Summary of the description of the effort to implement IDMP

Massive international collaboration to standardize the creation of a global Pharmaceutical Product Identifier based on

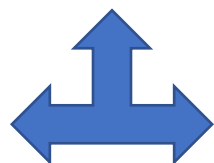
1. Substance with the role of precise active ingredient
2. Administrable dose form
3. Normalised Strength

A harmonization of detailed description of national medicinal products

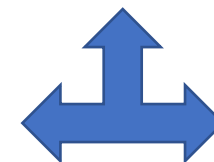
including complex products : Biologicals, Vaccines, Triphasic oral anticonceptives,
Combination products, Medicines combined with devices

And from there semantic interoperability to all other clinical drug classifications

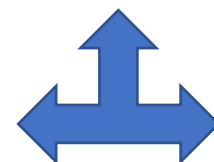
Drug Ontology



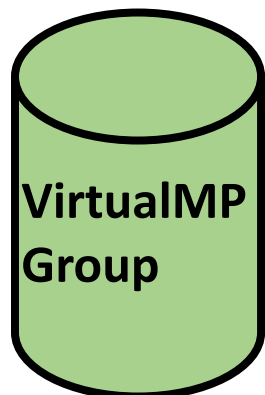
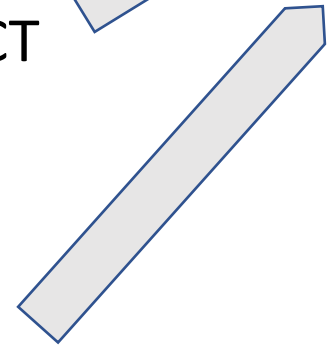
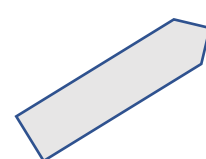
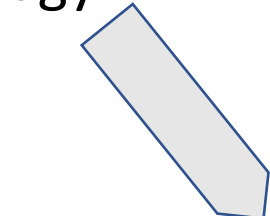
RX-NORM



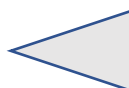
SNOMED-CT



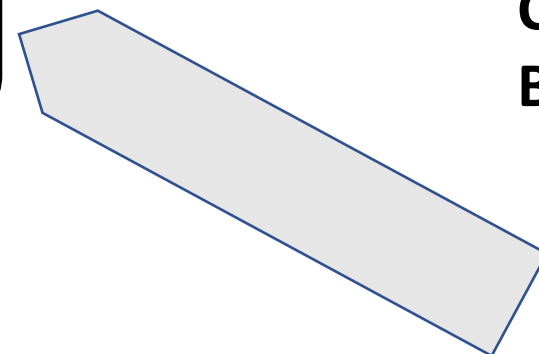
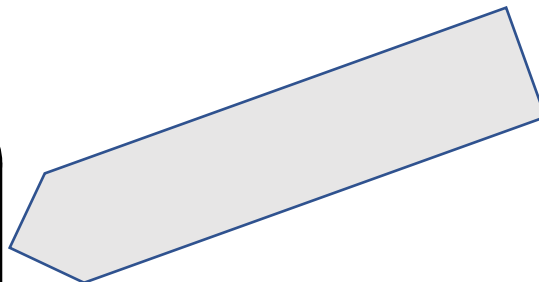
ATC+ROA



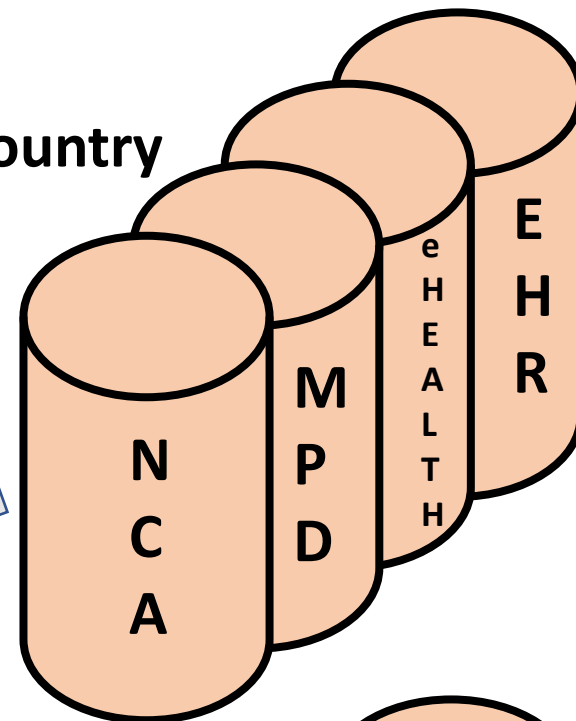
VirtualMP Group



Pharmaceutical product



Country A



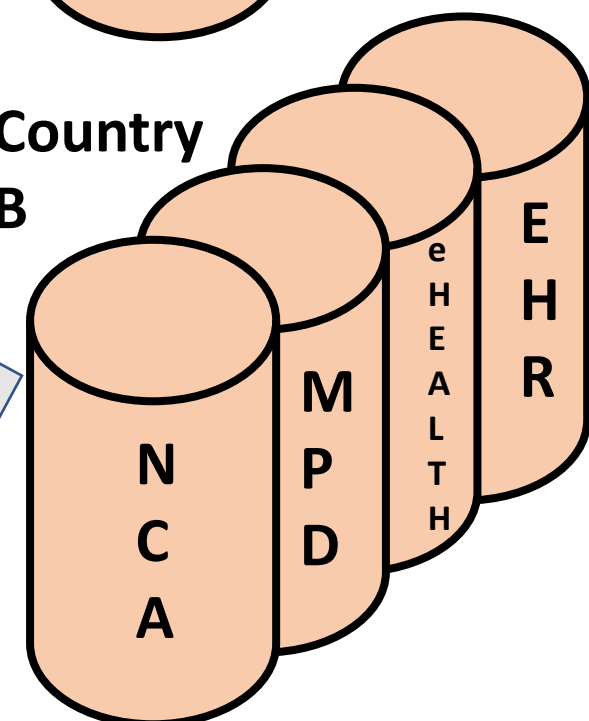
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Country B



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Building a chain from international classification to national identification of medicinal products

WHO CC DMS
Oslo



ATC
Classification



amlodipine
C08CA01

WHO Collaborating Centrum
Upsalla Monitoring Centre



Repository of
Pharmaceutical Product IDs



amlodipine besilate,
capsule, hard, 10mg

National NCA for
Marketing Authorization



IDMP-compliant
Medicinal Product
Dictionaries



Amlor 10 mg,
Pfizer Belgium

Building a chain from international classification to national identification of medicinal products

WHO CC DMS
Oslo



ATC
Classification



amlodipine
C08CA01



International
Consortium



creating
INN prescribing
grouping



amlodipine
oral 10mg



WHO Collaborating Centrum
Upsalla Monitoring Centre



Repository of
Pharmaceutical Product IDs



amlodipine besilate,
capsule, hard, 10mg



National NCA for
Marketing Authorization

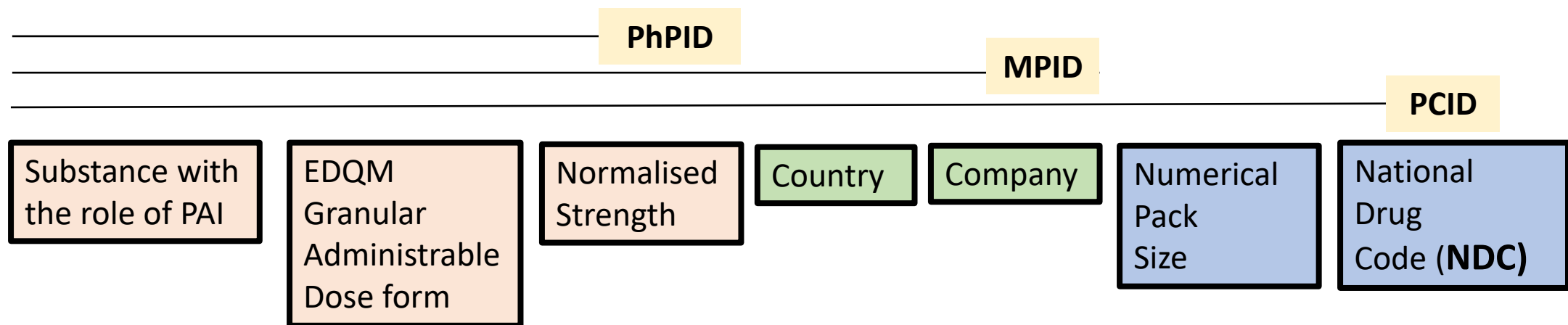


IDMP-compliant
Medicinal Product
Dictionaries



Amlor 10 mg,
Pfizer Belgium

Portfolio of Identifiers for Global Univocal Identification of Medicinal Products: UNICOM



Global identification

National identification

Link to

- INN Prescribing Concept: Virtual Medicinal Product Group
- ATC-Level V code
- International Pharmacotherapeutic Classes

Link to :

- Batch Number
- FMD Serialisation
- GTIN
- GS1 DataMatrix
- ATC/DDD/DPP
- URL to Labeling
- Local MPD
- OMOP/Conception

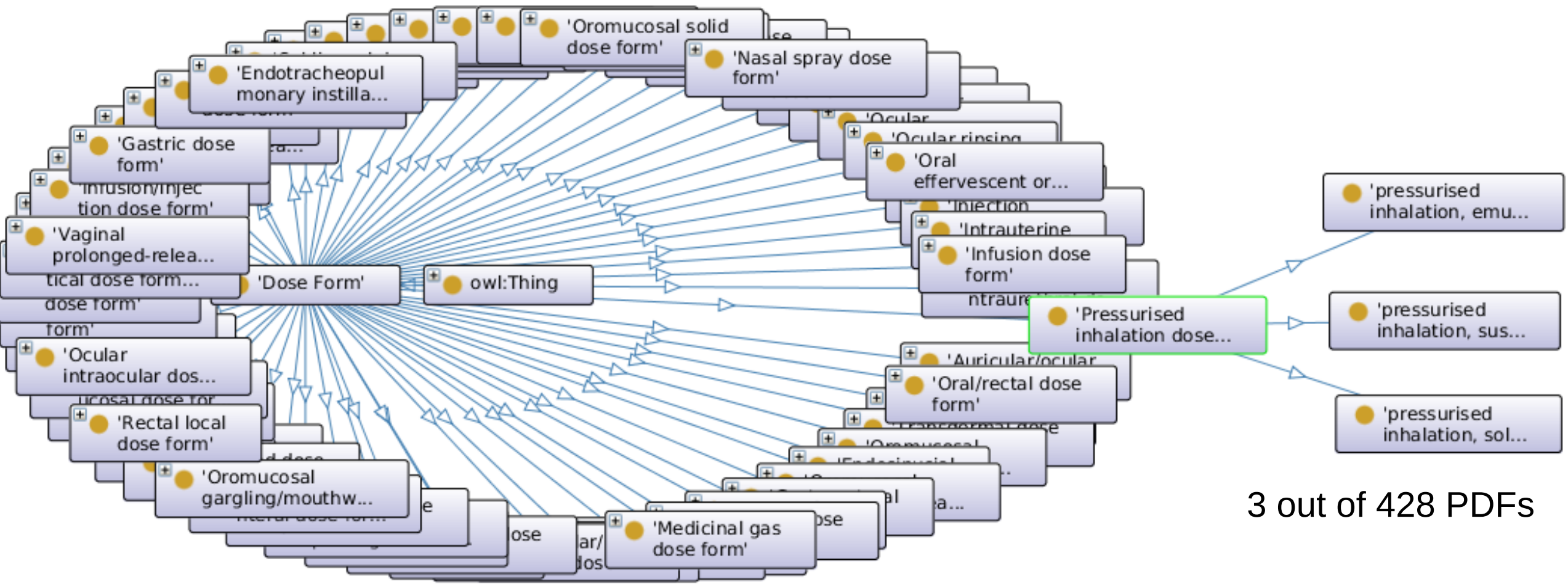
Hierarchy of substance

Hierarchy of Substance				
moiety	modifier	moiety+modifier	Substance with the role of PAI	Group of substances with same moiety
amlodipine				amlodipine
	besilate	amlodipine besilate	amlodipine besilate	
	mesilate	amlodipine mesilate	amlodipine mesilate	
	maleate	amlodipine maleate	amlodipine maleate	
carbamazepine			carbamazepine	carbamazepine
ibuprofen			ibuprofen	ibuprofen
	sodium	ibuprofen sodium	ibuprofen sodium	
	potassium	ibuprofen potassium	ibuprofen potassium	
	arginine	ibuprofen arginine	ibuprofen arginine	
	lysine	ibuprofen lysine	ibuprofen lysine	
simvastatine			simvastatine	simvastatine
amlodipine has 3 possible modifiers, which must be specified				
carbamazepine has no modifier				
ibuprofen has 4 possible modifiers but can also be an active substance without modifier				
simvastatin has no modifier				
Concepts covered by the coding systems SMS, WHODrug, UNII, CAS, SNOMED-CT				

► Proposal for small ontology of dose form terminology

AURICULAR Auricular dose form Auricular/nasal dose form Auricular/nasal/ocular dose form Auricular/ocular dose form	ORAL, CONVENTIONAL-RELEASE Oral solid dose form Oral semi-solid dose form Oral drops dose form Oral liquid dose form Oral effervescent or dispersible dose form Oral/rectal dose form
CUTANEOUS Cutaneous dose form Cutaneous/transdermal dose form Cutaneous/nasal dose form Cutaneous/oromucosal dose form Cutaneous/parenteral dose form	ORAL, MODIFIED-RELEASE Oral gastro-resistant dose form Oral prolonged-release dose form Other oral modified-release dose form
DENTAL Dental dose form	OROMUCOSAL Oromucosal spray dose form Oromucosal solid dose form Oromucosal prolonged-release dose form Oromucosal liquid dose form Oromucosal gargling/mouthwash dose form
ENDOCERVICAL Endocervical dose form	form Sublingual dose form
EXTRACORPOREAL Extracorporeal dose form	PARENTERAL Implantation prolonged-release dose form Injection prolonged-release dose form Injection dose form Infusion dose form Infusion/injection dose form
EXTRACORPOREAL/PARENTERAL Dialysis dose form	PULMONARY Vapour dose form Nebuliser dose form Pressurised inhalation dose form Inhalation dose form Medicinal gas dose form Endotracheopulmonary instillation dose form
GASTRIC Gastric dose form	RECTAL Rectal systemic dose form Rectal local dose form
GASTROENTERAL Gastroenteral dose form	TRANSDERMAL Transdermal prolonged-release dose form Transdermal dose form
INTRAPERITONEAL Intraperitoneal dose form	VAGINAL Vaginal prolonged-release dose form Vaginal dose form Vaginal device
INTRAUTERINE Intrauterine dose form Intrauterine device	MISCELLANEOUS Radiopharmaceutical dose form Wound dressings prolonged-release dose form
INTRAVESICAL Intravesical/intraurethral dose form	form Ungrouped dose form
OCULAR Ocular semi-solid dose form Ocular drops dose form Ocular rinsing dose form Ocular intraocular dose form Ocular prolonged-release dose form	
NASAL Nasal spray dose form Nasal solid or semi-solid dose form Nasal drops dose form Endosinusal dose form Nasal/ocular/pulmonary dose form	





3 out of 428 PDFs

65 intermediary level dose form groupers

Visualising the ontology with WebProtégé

The screenshot displays the WebProtégé interface for the 'dose form ontology +EDQM +ADF'. The top navigation bar includes 'Classes', 'Properties', 'Individuals', 'Comments', 'Changes by Entity', and 'History'. The main interface is divided into two panes.

Class Hierarchy Pane (Left):

- owl:Thing
 - Dose Form (Lvl 2)
 - Auricular local dose form** (Lvl 3)
 - ear cream
 - ear drops, emulsion
 - ear drops, powder for suspension
 - ear drops, solution
 - ear drops, suspension
 - ear gel
 - ear ointment
 - ear powder
 - ear spray, emulsion
 - ear spray, solution
 - ear spray, suspension
 - ear stick
 - ear tampon
 - ear wash, emulsion
 - ear wash, solution
 - Auricular/nasal dose form
 - Auricular/nasal/ocular dose form
 - Auricular/ocular dose form
 - Cutaneous dose form
 - Cutaneous/transdermal dose form

Class: Auricular local dose form Pane (Right):

IRI: [http://unicom-project.eu/doseforms.owl#Auricular local dose form](http://unicom-project.eu/doseforms.owl#Auricular%20local%20dose%20form)

Annotations:

Property	Value	Language	Action
rdfs:label	Auricular local dose form	en	✕
hasComment	1 dispersion, not relevant	lang	✕
hasComment	Installation, spraying, application, rinsing/washing, application/insertion : not relevand distinctions	lang	✕
hasDFId	# 2	lang	✕
hasISI	AURICULAR	lang	✕
Enter property	Enter value	lang	

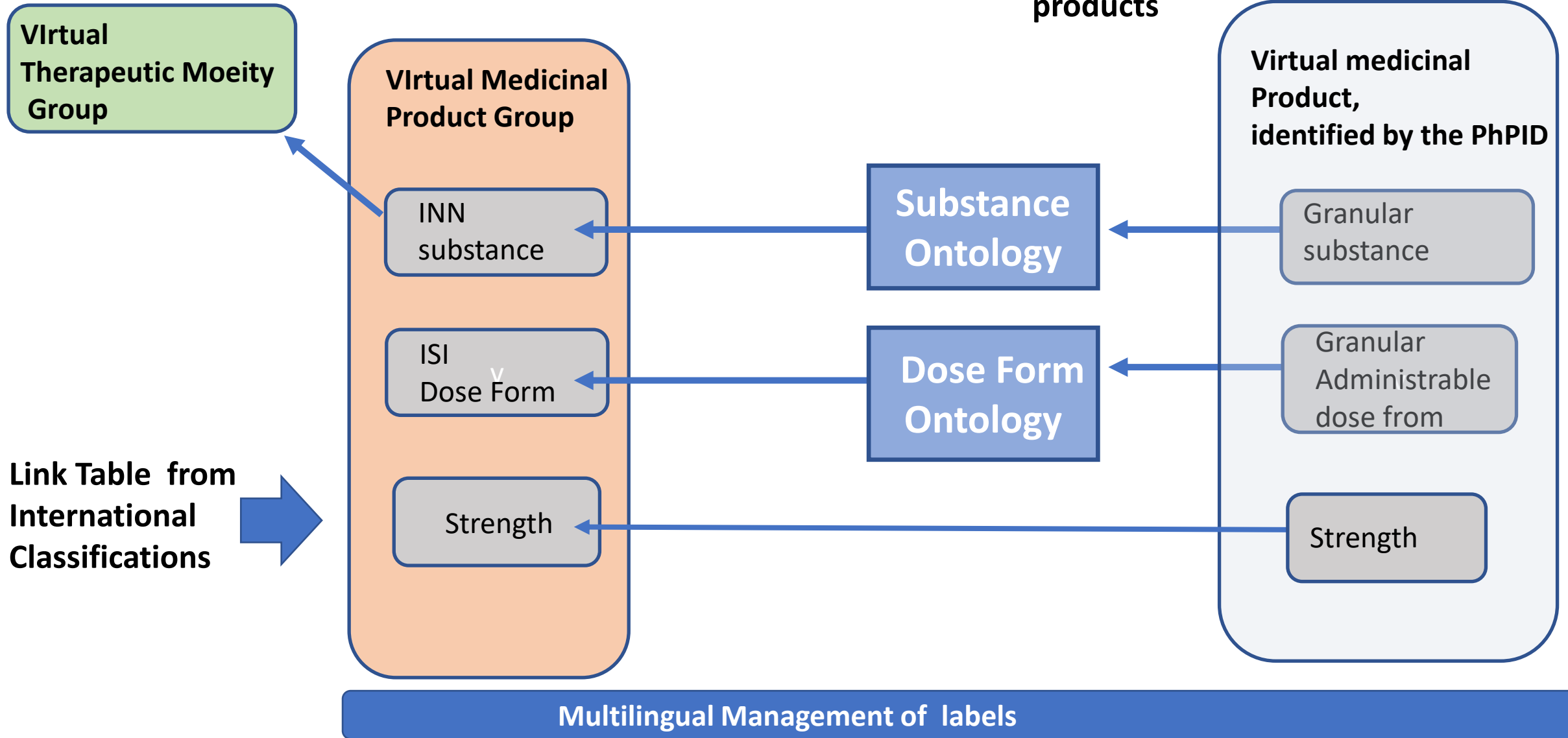
Parents:

- Dose Form ✕
- Enter a class name

Relationships:

Property	Value	Language
Enter property	Enter value	lang

Basis of INN Prescribing and Smart Substitution



The minimal data sets in UNICOM and quality control by multinational pharmaceutical companies

4 substances

Amlodipine

Carbamazepine

Ibuprofen

Simvastatin

5 countries

Belgium, Greece, Italy, Norway, USA

Companies present in several countries

Novartis, Pfizer, Sandoz, Upjohn, Teva, Mylan

The minimal data sets in UNICOM and quality control by multinational pharmaceutical companies

Minimal Data Set for 4 substances and 5 countries

	Source	MPs	MPPs	Status
Belgium	SAM	81	141	Complete
Greece	IDIKA	197	238	Complete
Norway	NOMA	43	89	In progress
Italy	ARIA	165	220	Complete
US	NLM	1003	5167	In progress
Finland	KELA			Initiated

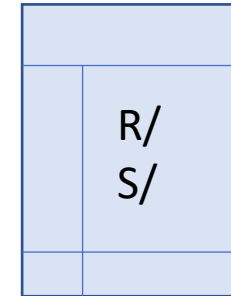
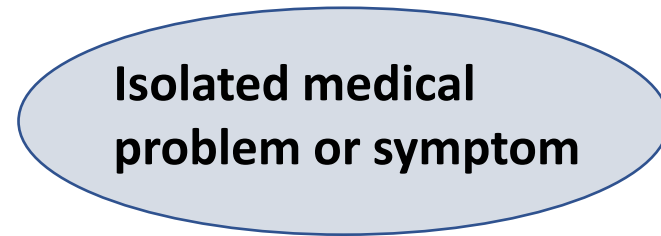
USE CASES

UN  COM

Use Case The Electronic Medical Record and paradigm shift in prescribing

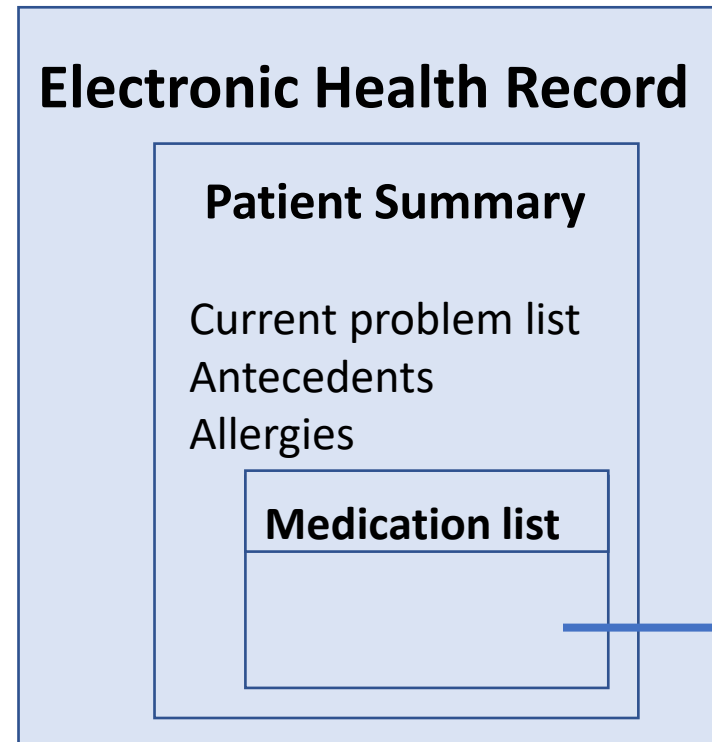
From paper prescription to e-Prescription

Previously



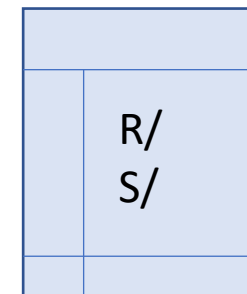
Paper prescription

Now

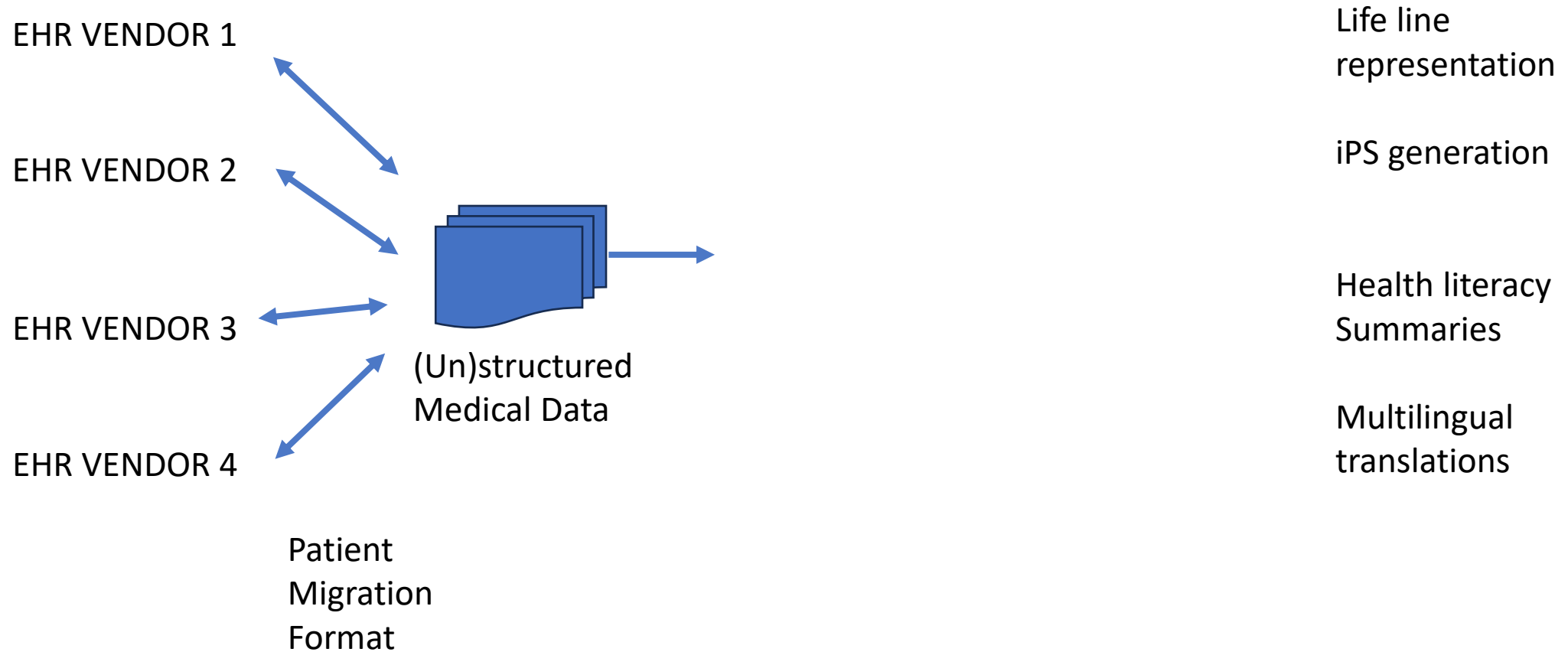


Generated by a change

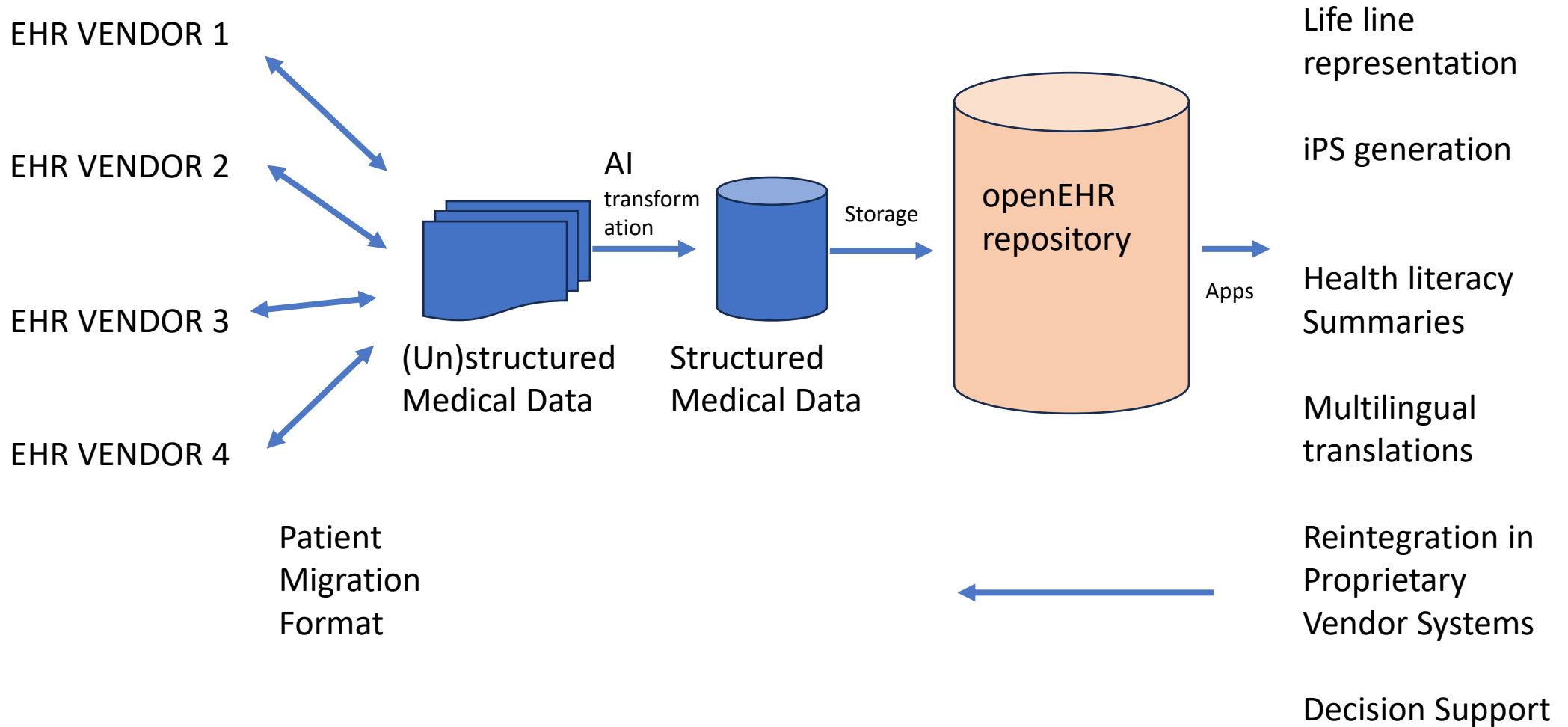
in the medication list



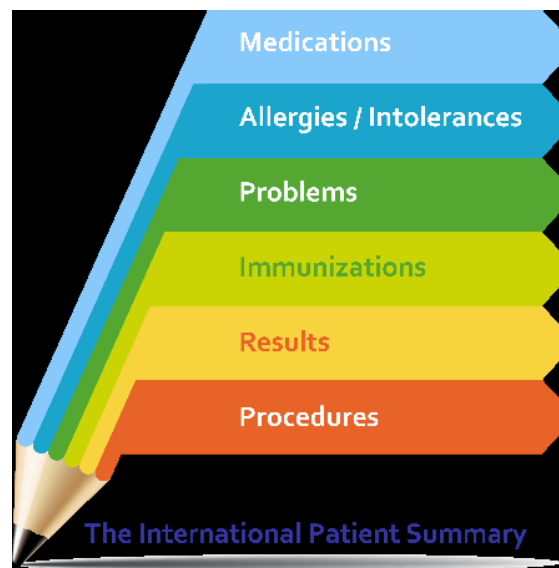
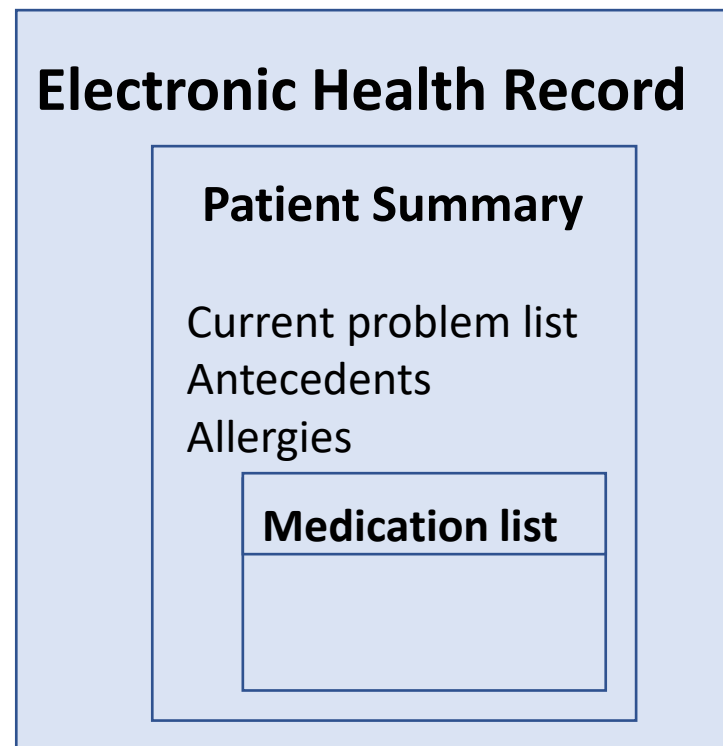
Use Case The medication list in the EHR (in openEHR)



Use Case The medication list in the EHR (in openEHR)



Use Case The International Patient Summary (iPS)



International Patient Summary
For unplanned acute care

First step to
Integrated care

Corner Stone for
eHealth
Cross Border
Exchange
projects

and

European
Health Data
Space EHDS

Use Case Crossborder prescribing and dispensing

What if

a Greek patient shows up on in a Belgian Pharmacy and requests a prescription for

αμλοδιπίνη

By identifying the IDMP data on the box, the pharmacist realizes that this about

amlodipine,

and more specifically

amlodipine oral 10 mg,

and even more specifically :

amlodipine besilate capsule, hard 10mg

In Belgium available as : Amlor 10 mg (Upjohn), and in generics by a number of companies but as tablets

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Example of aggregated representation of medicinal products at work

Group of Medicinal Products with the same active moiety of substance

C08CA01 amlodipine

Virtual Medicinal Product Group

amlodipine oral 10 mg

amlodipine oral 5 mg

Pharmaceutical Product

amlodipine besilate capsule, hard 10 mg

amlodipine besilate tablet 10 mg

(note : amlodipine maleate film-coated tablet 10 mg recently disappeared from the Belgian market)

amlodipine besilate capsule, hard 5 mg

amlodipine besilate tablet 5 mg

Medicinal Product (Belgium)

amlodipine besilate capsule, hard 10 mg

Amlor harde caps. 10 mg Upjohn

amlodipine besilate tablet 10 mg

Amlodipine EG (PIP) tabl. (deelb.) Besilate 10 mg PI-Pharma

Amlodipine EG tabl. (deelb.) Besilate 10 mg EG

Amlodipine Mylan tabl. (deelb.) Besilate 10 mg Mylan

Amlodipine Teva tabl. (deelb.) 10 mg Teva

Amlodipin Sandoz (Impexeco) tabl. (deelb.) Besilaat 10 mg Impexeco

Amlodipin Sandoz tabl. (deelb.) Besilaat 10 mg Sandoz

Amlobemed tabl. (deelb.) 10 mg 3DDD

Amlodipin AB tabl. 10 mg Aurobindo

Amlodipin Sandoz tabl. (deelb.) Besilaat 10 mg Sandoz



1.Exact Cross Border Equivalents, using the granular PhPID (or PhPID Label “amlodipine besylate tablet 10 mg”)

4516	AMLIBON TAB 10MG/TAB BTx30 (BLISTER)					GRC amlodipine besylate SANDOZ GMBH, KUNDL, AUSTRIA tablet 30 x 10mg/		
4320	NORMODIN TAB 10MG/TAB BTx14					GRC amlodipine besylate GENEPHARM AE tablet 14 x 10mg/		
6180	AMLIBON BES TAB 10MG/TAB BT x 30 σε BLISTERS					GRC amlodipine besylate SANDOZ GMBH, KUNDL, AUSTRIA tablet 30 x 10mg/		
7813	NORDEX/MEDICAL PHARMAQUALITY TAB 10MG/TAB BTx14 (1 BL,x 14)					GRC amlodipine besylate MEDICAL PHARMAQUALITY AE tablet 14 x 10mg/		
7732	AMLODIPINE BESILATE/TEVA TAB 10MG/TAB BT x 30 (3x10)					GRC amlodipine besylate TEVA PHARMA B.V., Haarlem, THE NETHERLANDS tablet 30 x 10mg/		
8817	AMLODIPINE/MYLAN GENERICS TAB 10MG/TAB BTx30					GRC amlodipine besylate GENERICS PHARMA HELLAS ΕΠΕ tablet 30 x 10mg/		
5976	NORVAGEN TAB 10MG/TAB BT x 30 (σε BLIST)					GRC amlodipine besylate STARGEN Ε.Π.Ε. tablet 30 x 10mg/		
9063	NORMODIN TAB 10MG/TAB BTx28					GRC amlodipine besylate GENEPHARM AE tablet 28 x 10mg/		

In the first 2 collums the information on available Italian equivalents is given (national identifier and national medicinal product pack label).

In the other 2 collums the Global identifying (possible basis for PhPID production) is given with indication of the country, the company and the IDMP compliant labels of substance with precise active ingredient, granular EDQM administrable dose form and normalized strength

2.INN cross border equivalents, using the Aggregated label of the INN prescription “amlodipine oral 10mg”

5150	NORVALET CAPS 10MG/CAP BTx30 (BLIST 3x10)		GRC amlodipine besylate INNOVIS HEALTH A.E. capsule, hard 30 x 10mg/
4358	FLODIL CAPS 10MG/CAP BTx30 (BLIST 2x15)		GRC amlodipine besylate MINEPBA ΦΑΡΜΑΚΕΥΤΙΚΗ A.E. capsule, hard 30 x 10mg/
2720	AMLODIN CAPS 10MG/CAP BT x 30(BLIST 3x 10)		GRC amlodipine besylate BENNETT ΦΑΡΜΑΚΕΥΤΙΚΗ A.E. capsule, hard 30 x 10mg/
4516	AMLIBON TAB 10MG/TAB BTx30 (BLISTER)		GRC amlodipine besylate SANDOZ GMBH, KUNDL, AUSTRIA tablet 30 x 10mg/
4303	AMODIPAN CAPS 10MG/CAP BTx30(BLISTER 3x10)		GRC amlodipine besylate SANTA PHARMA A,E, capsule, hard 30 x 10mg/
6237	PIDOLEN (ΓΕΝΟΣΗΜΟ) CAPS 10MG/CAP BTx30 (BLIST 2x15)		GRC amlodipine besylate ΦΑΡΜΕΞ A.E. capsule, hard 30 x 10mg/
4306	AGGOVASK CAPS 10MG/CAP BTx14(BLIST 2x7)		GRC amlodipine besylate PROTON PHARMA ANQNMYMH ΦΑΡΜΑΚΕΥΤΙΚΗ ΕΤΑΙΡΕΙΑ capsule, ha
4308	LODIPIN CAPS 10MG/CAP BTx14 (BLIST 1x14)		GRC amlodipine besylate IASIS PHARMA capsule, hard 14 x 10mg/
4309	LODIPIN CAPS 10MG/CAP BTx30 (BLIST 3x10)		GRC amlodipine besylate IASIS PHARMA capsule, hard 30 x 10mg/
4320	NORMODIN TAB 10MG/TAB BTx14		GRC amlodipine besylate GENEPHARM AE tablet 14 x 10mg/
6180	AMLIBON BES TAB 10MG/TAB BT x 30 σε BLISTERS		GRC amlodipine besylate SANDOZ GMBH, KUNDL, AUSTRIA tablet 30 x 10mg/
4269	BARUDEN CAPS 10MG/CAP BTx14 (BLIST 1x14)		GRC amlodipine besylate ANΦΑΡΜ ΕΛΛΑΣ A.E. capsule, hard 14 x 10mg/
4270	BARUDEN CAPS 10MG/CAP BTx28 (BLIST 2x14)		GRC amlodipine besylate ANΦΑΡΜ ΕΛΛΑΣ A.E. capsule, hard 28 x 10mg/
7813	NORDEX/MEDICAL PHARMAQUALITY TAB 10MG/TAB BTx14 (1 BL,x 14)		GRC amlodipine besylate MEDICAL PHARMAQUALITY AE tablet 14 x 10mg/
8145	AMLORETIN CAPS 10MG/CAP BTx28(BLISTER 2x14)		GRC amlodipine besylate NATURALIA A.E. capsule, hard 28 x 10mg/
1913	NORVASC CAPS 10MG/CAP BTX14(BLIST1X14)		GRC amlodipine besylate UPJOHN HELLAS E.Π.Ε. capsule, hard 14 x 10mg/
5843	ALDOSION CAPS 10MG/CAP BTx30 (BLIST 3x10)		GRC amlodipine besylate ALAPIS ABEE capsule, hard 30 x 10mg/
4576	amlodipine maleate/GENERICS TAB 10MG/TAB BTx14		GRC amlodipine maleate GENERICS PHARMA HELLAS ΕΠΕ tablet 14 x 10mg/
4577	amlodipine maleate/GENERICS TAB 10MG/TAB BTx28		GRC amlodipine maleate GENERICS PHARMA HELLAS ΕΠΕ tablet 28 x 10mg/
4230	AMLOPRESS CAPS 10 MG/CAP BTx 30 (BLIST 3x10)		GRC amlodipine besylate FOS ΦΑΡΜΑΚΕΥΤΙΚΗ IKE capsule, hard 30 x 10mg/
4233	AMLODIL CAPS 10MG/CAP BTX14(2BLIST,X7)		GRC amlodipine besylate GAP A.E. capsule, hard 14 x 10mg/
5394	NORFAN CAPS 10MG/CAP BTx28 (BLIST 2x14)		GRC amlodipine besylate VOCATE ΦΑΡΜΑΚΕΥΤΙΚΗ A.E. capsule, hard 28 x 10mg/
5398	AXYPLOT CAPS 10MG/CAP BTx28 (BLIST 4x7)		GRC amlodipine besylate IAMATICA MON. ΕΠΕ capsule, hard 28 x 10mg/
5049	AMLOSILAT CAPS 10 MG/CAP BTx2 BLISTx 14 CAP		GRC amlodipine besylate ALPHA GENERICS THERAPY AEBEΦ capsule, hard 28 x 10mg/
4464	DAFOR CAPS 10MG/CAP BTx14 (BLIST 1x14)		GRC amlodipine besylate ΠΙΝΓ ΓΕΡΟΥΜΑΤΟΣ ΜΕΝΤΙΚΑΛ A.E. capsule, hard 14 x 10mg/
4465	DAFOR CAPS 10MG/CAP BTx28 (BLIST 2 x 14)		GRC amlodipine besylate ΠΙΝΓ ΓΕΡΟΥΜΑΤΟΣ ΜΕΝΤΙΚΑΛ A.E. capsule, hard 28 x 10mg/
4472	VASCODIN CAPS 10MG/CAP BT x 14 (BLIST 2x7)		GRC amlodipine besylate HELP ABEE capsule, hard 14 x 10mg/
4473	VASCODIN CAPS 10MG/CAP BT x 30 (BLIST 3x10)		GRC amlodipine besylate HELP ABEE capsule, hard 30 x 10mg/
4477	AMLODIPINE BESILATE/NORMA CAPS 10MG/CAP BTx30 (BLIST 3x10)		GRC amlodipine besylate NOPMA ΕΛΛΑΣ A.E. capsule, hard 30 x 10mg/
4751	EVANGIO CAPS 10MG BTx14 (BLIST 1x14)		GRC amlodipine besylate RAFARM A.E.B.E. capsule, hard 14 x 10mg/
4752	EVANGIO CAPS 10MG BTx30 (BLIST 2x15)		GRC amlodipine besylate RAFARM A.E.B.E. capsule, hard 30 x 10mg/
7732	AMLODIPINE BESILATE/TEVA TAB 10MG/TAB BT x 30 (3x10)		GRC amlodipine besylate TEVA PHARMA B.V., Haarlem, THE NETHERLANDS tablet 30 x 10mg/
4715	NOLVAC TAB 10MG/TAB BTx28 σε BLISTERS		GRC amlodipine maleate ΦΑΡΜΑΤΕΝ ΕΛΛΑΣ AEBE tablet 28 x 10mg/
4716	NOLVAC TAB 10MG/TAB BTx30 σε BLISTERS		GRC amlodipine maleate INNOVIS PHARMA A.E.B.E tablet 30 x 10mg/
5434	ABESYL CAPS 10MG/CAP BTx 30(BLIST 3 x 10)		GRC amlodipine besylate MEDOCHEMIE HELLAS AE capsule, hard 30 x 10mg/
5479	ANGIORETIC CAPS 10MG/CAP BTx 30(BLIST 2x15)		GRC amlodipine besylate MEDARTE ΦΑΡΜΑΚΕΥΤΙΚΗ ABEE capsule, hard 30 x 10mg/
4618	PRECARDIN CAPS 10MG/CAP BTX14(BLIST1X14)		GRC amlodipine besylate FARMEDIA AE capsule, hard 14 x 10mg/
4619	PRECARDIN CAPS 10MG/CAP BTX28(BLIST2X14)		GRC amlodipine besylate FARMEDIA AE capsule, hard 28 x 10mg/
8817	AMLODIPINE/MYLAN GENERICS TAB 10MG/TAB BTx30		GRC amlodipine besylate GENERICS PHARMA HELLAS ΕΠΕ tablet 30 x 10mg/
4824	ROVOXID CAPS 10MG/CAP BTx30 (BLIST 3x10)		GRC amlodipine besylate BIAN A.E. capsule, hard 30 x 10mg/
4690	RAMLET CAPS 10MG/CAP BTx14 (BLIST 1x14)		GRC amlodipine besylate RAFARM A.E.B.E. capsule, hard 14 x 10mg/
4691	RAMLET CAPS 10MG/CAP BTx28 (BLIST 2x14)		GRC amlodipine besylate RAFARM A.E.B.E. capsule, hard 28 x 10mg/
4636	AMLOTENS TAB 10MG/TAB BTx30 (BLISTER 3x10)		GRC amlodipine mesylate monohydrate INNOVIS HEALTH A.E. tablet 30 x 10mg/
5976	NORVAGEN TAB 10MG/TAB BT x 30 (σε BLIST)		GRC amlodipine besylate STARGEN E.Π.Ε. tablet 30 x 10mg/
5468	AMILOPID CAPS 10MG/CAP BT x 30(BLIST 3x10)		GRC amlodipine besylate BIANEΞ A.E. capsule, hard 30 x 10mg/
9063	NORMODIN TAB 10MG/TAB BTx28		GRC amlodipine besylate GENEPHARM AE tablet 28 x 10mg/

Use Case Pharmacovigilance

Teaching pharmacists, physicians, nurses, and patients

How to report previously unknown suspected adverse drug reactions

Integrating

Individual Safety Case Report (ISCR)

IDMP : Global Identification of Medicinal Products

Case => Lareb => CBG => WHO Uppsala Monitoring Center

Use Case INN prescribing

(INN = International Non-Proprietary Nomenclature)

Traditional Prescription

R/ Amlor 100 x 5mg

S/ One per day

INN Prescription

R/ Amlodpine oral 5 mg

S/ One per day

during 3 months

Use Case Decision support

Example of a rule in a decision support system for medication management

Decision Rule in Human Language

IF the patient is on an agent acting on the angiotensine system treatment AND on a diuretics,
THEN

He/She should not make use of NON-steroidal antiinflammatory drugs
(especially when the kidney function is already compromised)

BECAUSE

There is a serious risk of renal failure, leading to heart failure, hospitalisation, and possibly death

Decision Rule operational in code

IF the medication list has C09 AND C03; C01AA ;C02L ;C07B ;C07D; C08G
AND

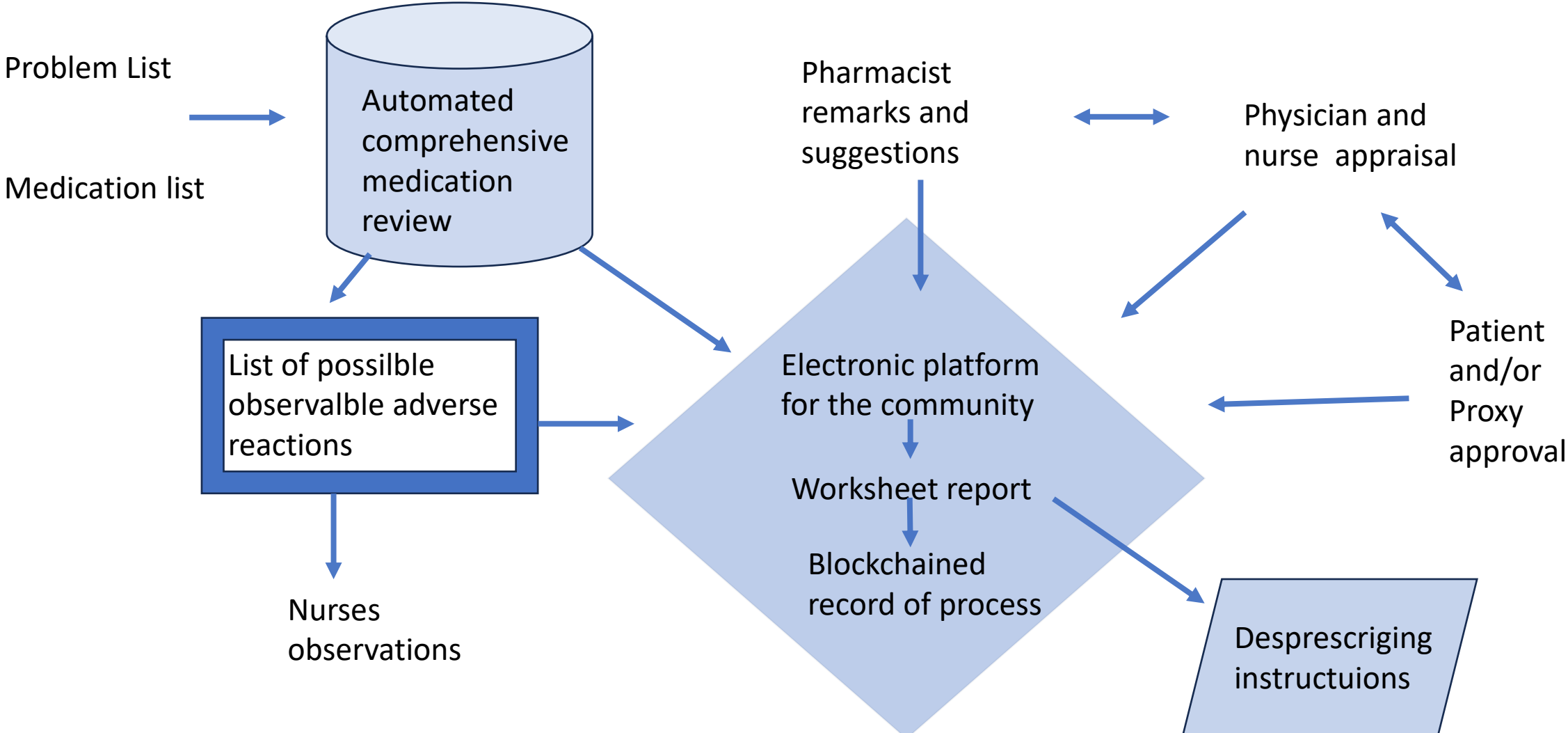
new prescription is requested :

M01A; M01B; N02AJ02 (dihydrocodeine and acetylsalicylic acid); N02AJ07 (codeine
and acetylsalicylic acid); N02AJ08 (codeine and ibuprofen); N02AJ09 (codeine and other non-opioid
analgesics) ; N02AJ16 (tramadol and celecoxib); N02AJ18 (oxycodone and acetylsalicylic acid);
N02AJ19 (oxycodone and ibuprofen)

THEN LAUNCH ALERT 567

Do not add an NSAID to the medication list of this patient. He/She is in serious danger of renal failure, which might lead to hospitalization and possibly death. Consider using a non-inflammatory pain killer

Use Case Deprescribing in polymedicated home-dwelling older adults and residents of nursing homes



Use Case 2Prescribe platform for teaching rational pharmacotherapy

Clinical Case

Step 3

Generate list of possible pharmacotherapeutic classes and active substances to be chosen from according to rational pharmacotherapy

Step 4

Apply to this patient with comorbidities, allergies, contraindications and other medications on his/her list

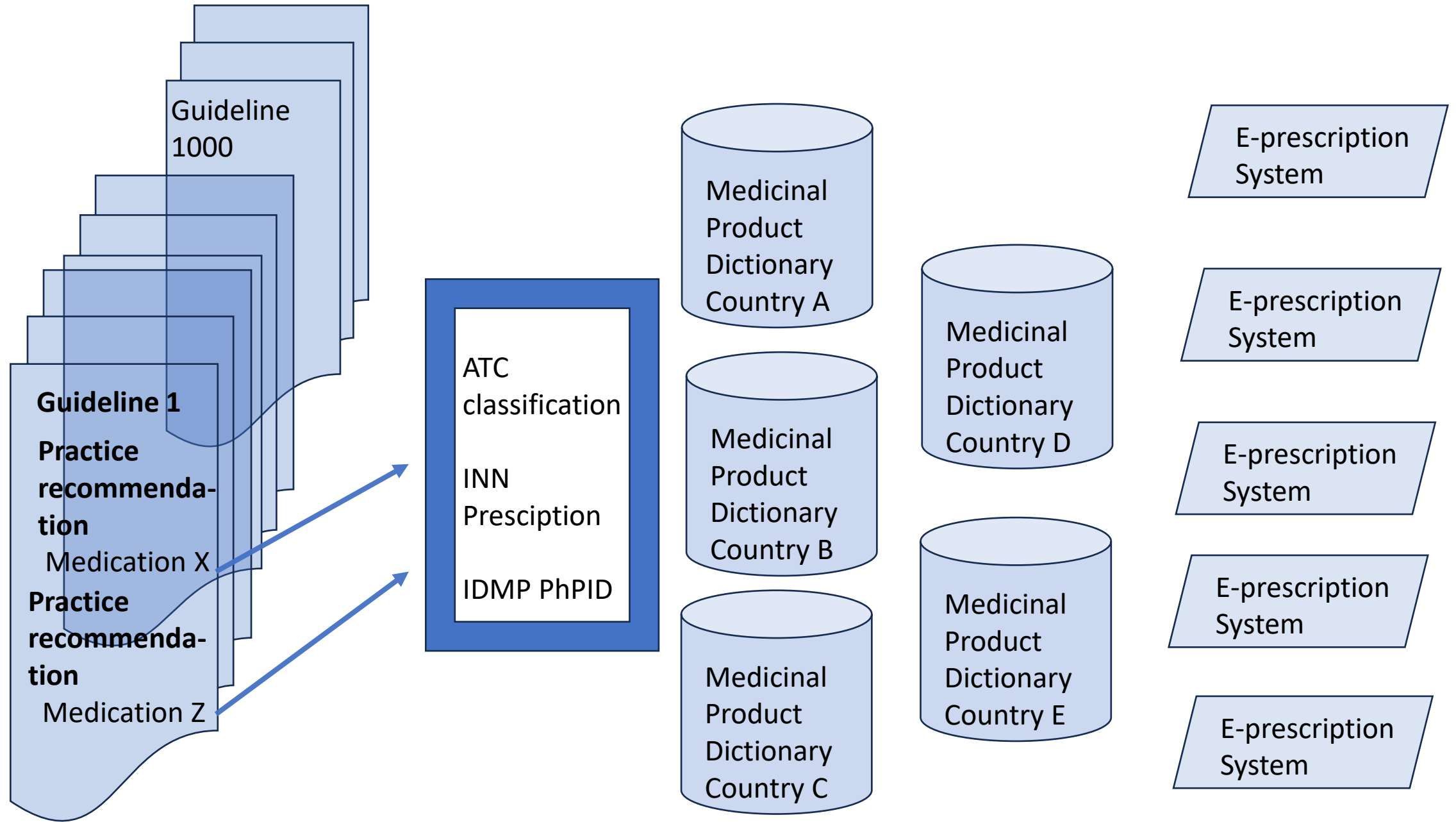
Step 5

Generate a prescription

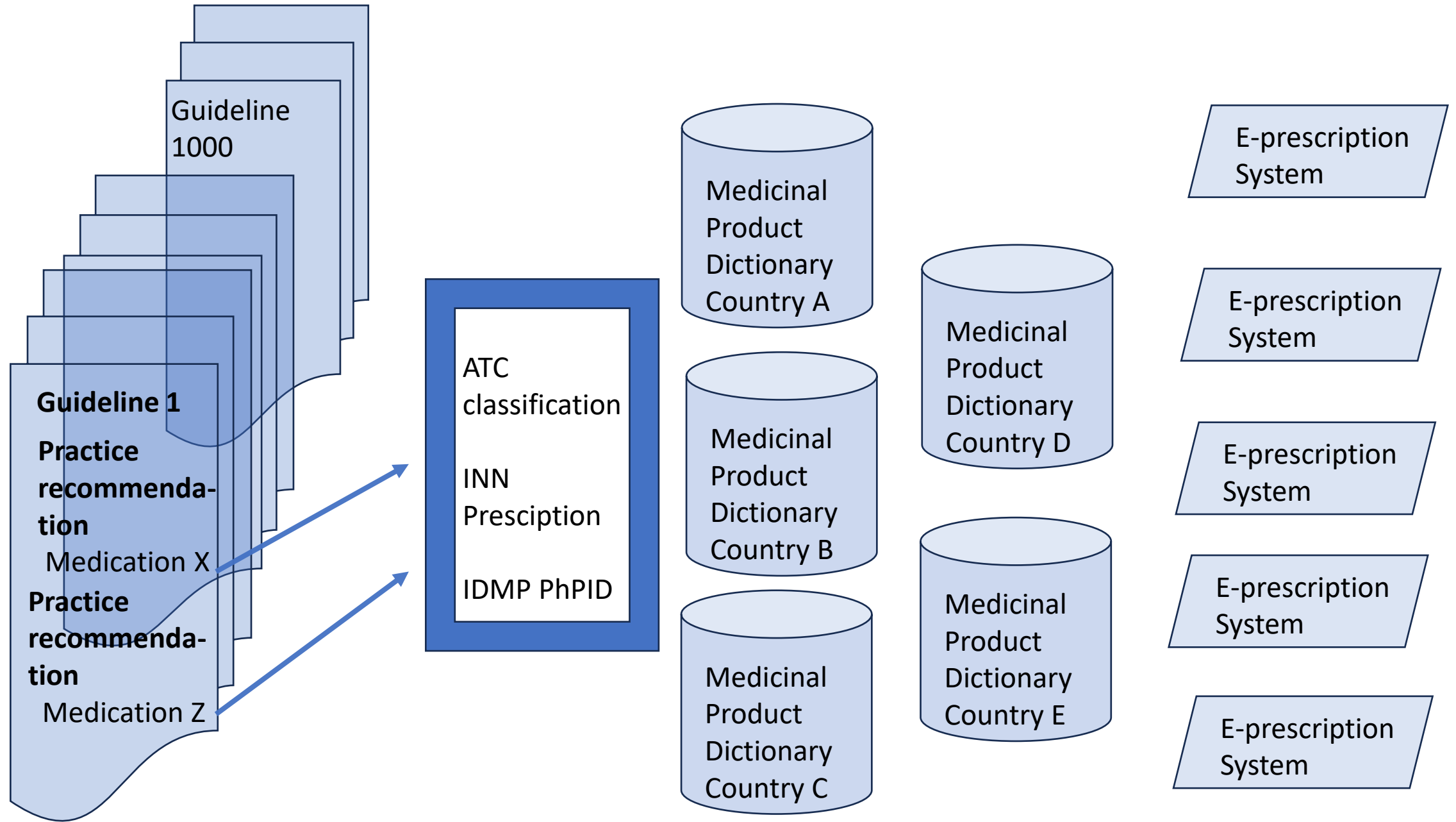
IDMP means support for

Standardization
Internationalisation

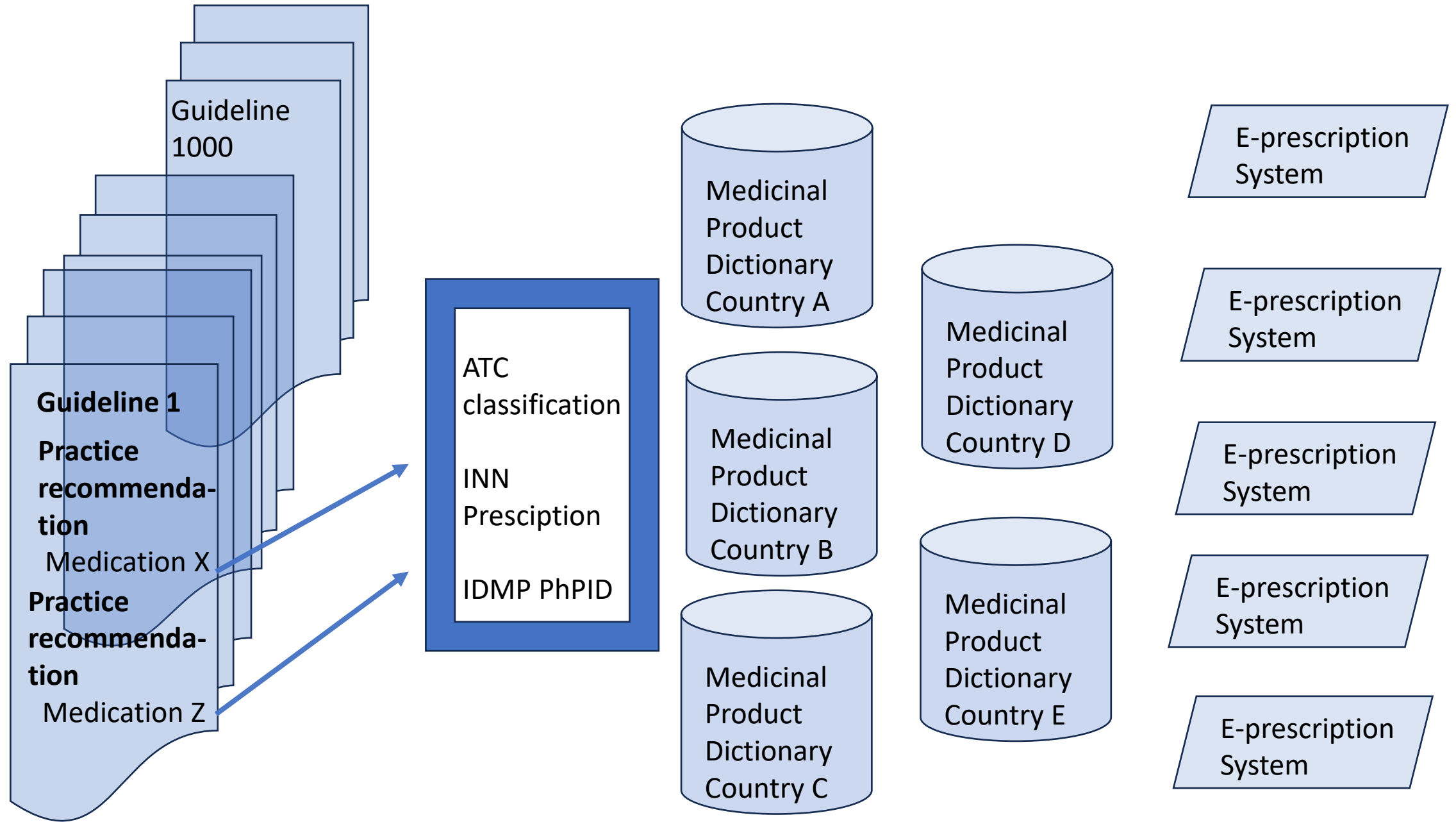
Use Case Internationalisation of Duodecim EBM-Guidelines in Europe



Use Case Internationalisation of Duodecim EBM-Guidelines in Europe



Use Case Internationalisation of Duodecim EBM-Guidelines in Europe



Use Case Alignment IDMP/SNOMED-CT/RxNorm/Virtual Drug Models

Concepts in drug identification at the national level for concrete products

IDMP	SNOMED-CT	Dm+d/SAM	RxNorm
	Real Medicinal Product	Actual Therapeutic Moiety	Brand name
Medicinal Product	Real Clinical Drug	Actual Medicinal Product	Semantic Branded Drug
Packaged Medicinal Product	Real Packaged Clinical Drug	Actual Medicinal Product Package	Brand Name Pack

Medicinal Products

Concepts in drug identification for abstract but granular representation of medicinal products

IDMP	SNOMED-CT	Dm+d/SAM	RxNorm
PhPID Level 1 <small>(precise active ingredient Group)</small>	Medicinal Drug Precisely	Virtual Therapeutic Moiety	
PhPID Level 4 <small>(Pharmaceutical Product Group)</small>	Clinical Drug Precisely	Virtual Medicinal Product	Semantic Clinical Drug <small>(not precise ingredient)</small>
	Packaged Clinical Drug Precisely	Virtual Medicinal Product Package	Generic Pack

“Exact” abstract representation

Concepts in drug identification for higher levels of abstraction in representation of medicinal products

IDMP	SNOMED-CT	Dm+d/SAM	RxNorm	UNICOM-PPL
	Medical Product Only			Virtual Therapeutic Moiety Group
	Medicinal Product Form Only + Strength	Virtual Medicinal Product Group	Semantic Clinical Drug <small>(Not high level dose form)</small>	Virtual Medicinal Product Group
	Real Packaged Clinical Drug			

Higher level aggregation

Prerequisites for the use cases

**Implementation
of IDMP
by the
National
Competent
Authorities**



**Implementation
of IDMP
by the
Medicinal
Product
Dictionaries**



**Implementation
of IDMP
by the
Health
Software
Vendors**

The Netherlands

Commissie Beoordeling
Geneesmiddelen (CBG)

KNMP Z-INDEX
HealthBase

Belgium

Federaal Agentschap
Geneesmiddelen en
Gezondheidsproducten (FAGG)

Source Authentique
Médicaments
BCFI

Conclusion

CONCLUSIONS

The CEN/ISO standards for Identification of Medicinal Products are now 12 years old.

UNICOM project has given a major boost to
implementation in Europe in National Competent Authorities
Global Collaboration between EMA, FDA, WHO, Pharma Industry

ISO/CEN is finishing the revision cycle of these 5 standards in a coordinated way

Another UNICOM NEXT project of 4 years will be needed to complete the implementation in National and Regional Systems

But IDMP is here to stay.

Major developments such as PSCRIBE should take these standards into account, especially if the aim is internationalisation.

There are many interesting use cases for the 2Prescribe Application

INTERESTING LINKS FOR FURTHER READING ON UNICOM

UNICOM WEBSITE

<https://unicom-project.eu/>

UNICOM in a Capsule

https://unicom-project.eu/wp-content/uploads/2021/10/UNICOM-handboek_A4_04.pdf

Public Deliverables

Workpackage 8 : IDMP and Clinical Care, Research and Patient Empowerment

Workpakage 9 : IDMP and IT systems of Physicians and Pharmacists

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2. Vander Stichele R, Kalra D. Aggregations of Substance in Virtual Drug Models Based on ISO/CEN Standards for Identification of Medicinal Products (IDMP). *Stud Health Technol Inform*. 2022 May 25;294:377-381. doi: 10.3233/SHTI220478.
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Gateway to the 21 webinars of the UNICOM Committee of Expertise

<https://unicom-project.eu/all-community-of-expertise-webinars-in-a-nutshell/>

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Haiku on what binds and separates almost similar things



*Cherry blossoms are cherry blossoms and not hedge bindweeds
They are pink, delicate and blossom in the spring
Yet, every cherry blossom is unique*