WP-1 / 22nd community of expertise

3 February 2023

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Sources of medication data

José Costa Teixeira – UNICOM WP1, IHE Europe
Robert Stegwee – UNICOM WP1, CEN/TC 251 Health Informatics
Ian Green – UNICOM WP1 & 8, SNOMED International
Jane Millar – UNICOM WP1&8, SNOMED International

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SOME RULES FOR THE VIRTUAL MEETINGS

UNICOM

- ✓**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

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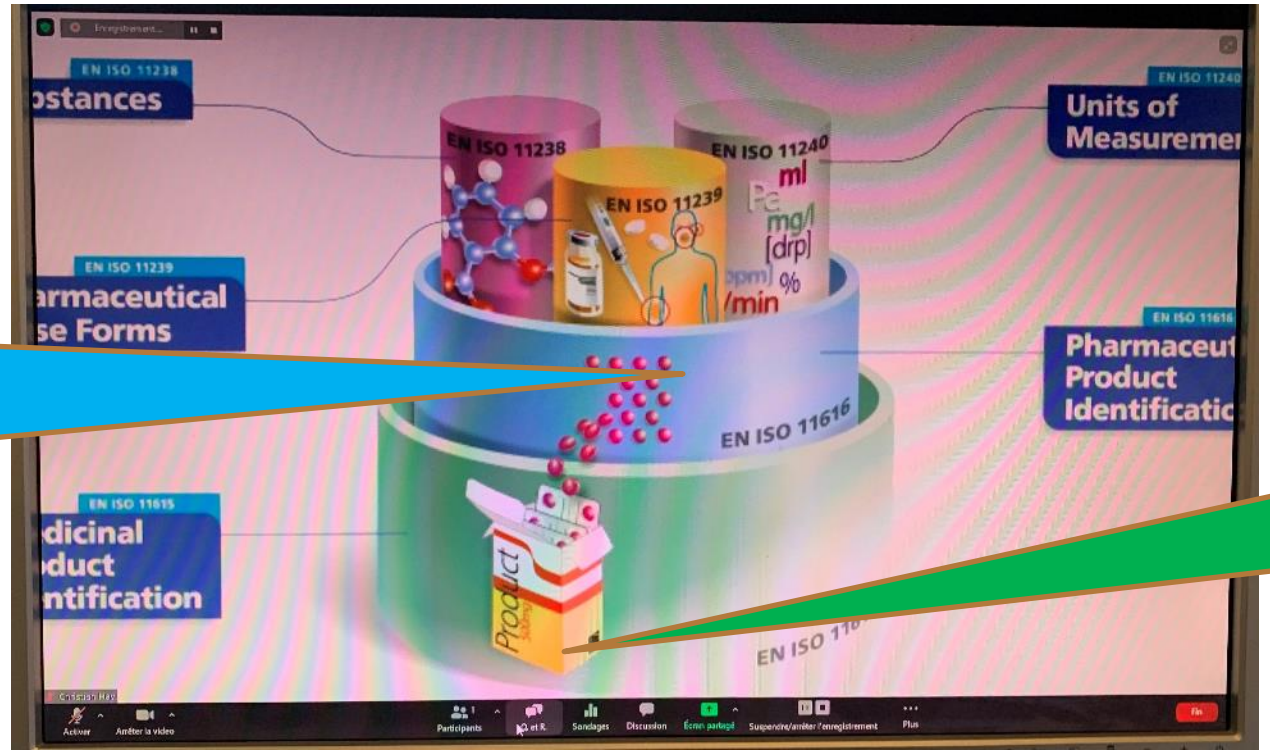
Asking a question or making a comment: please use the Q&A facility

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



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

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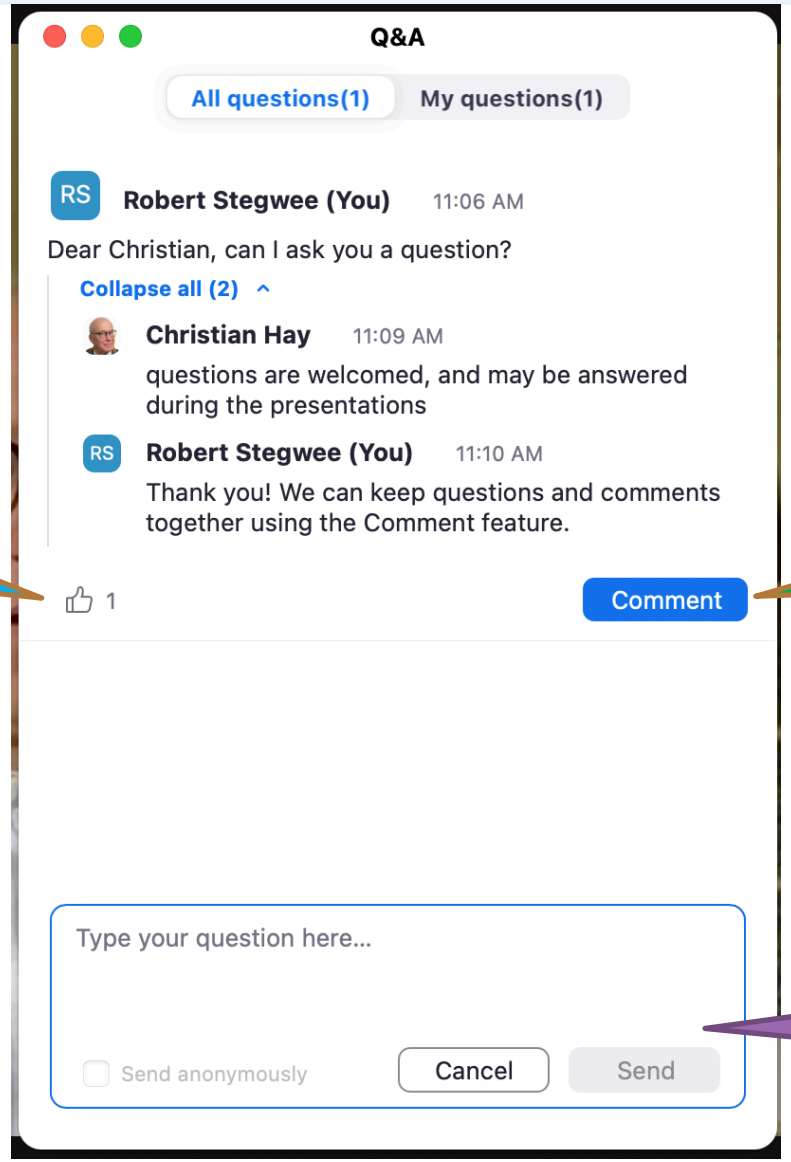
Showing support and providing a comment on a question or answer

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



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

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Security

- Security is our priority
- This session is password protected

Recording of this session is made available on UNICOM's youtube channel
https://https://www.youtube.com/c/UNICOM-IDMP

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

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Introductions to our esteemed colleagues and today's speakers...

Ian Green

Jose Costa Teixeira

Robert Stegwee

...and pannelist

Jane Millar

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Questions in the Q & A facility, please

For feedback, please go to :

https://docs.google.com/forms/d/e/1FAIpQLScww7piDetzy4_dyv5mMxjtfxIXKBnOBl7ajUjP22x1drxLbA/viewform?usp=pp_url

Thanks for your time

SNOMED International

Delivering SNOMED CT

EHRs and prescribing systems as a source of medication data ?

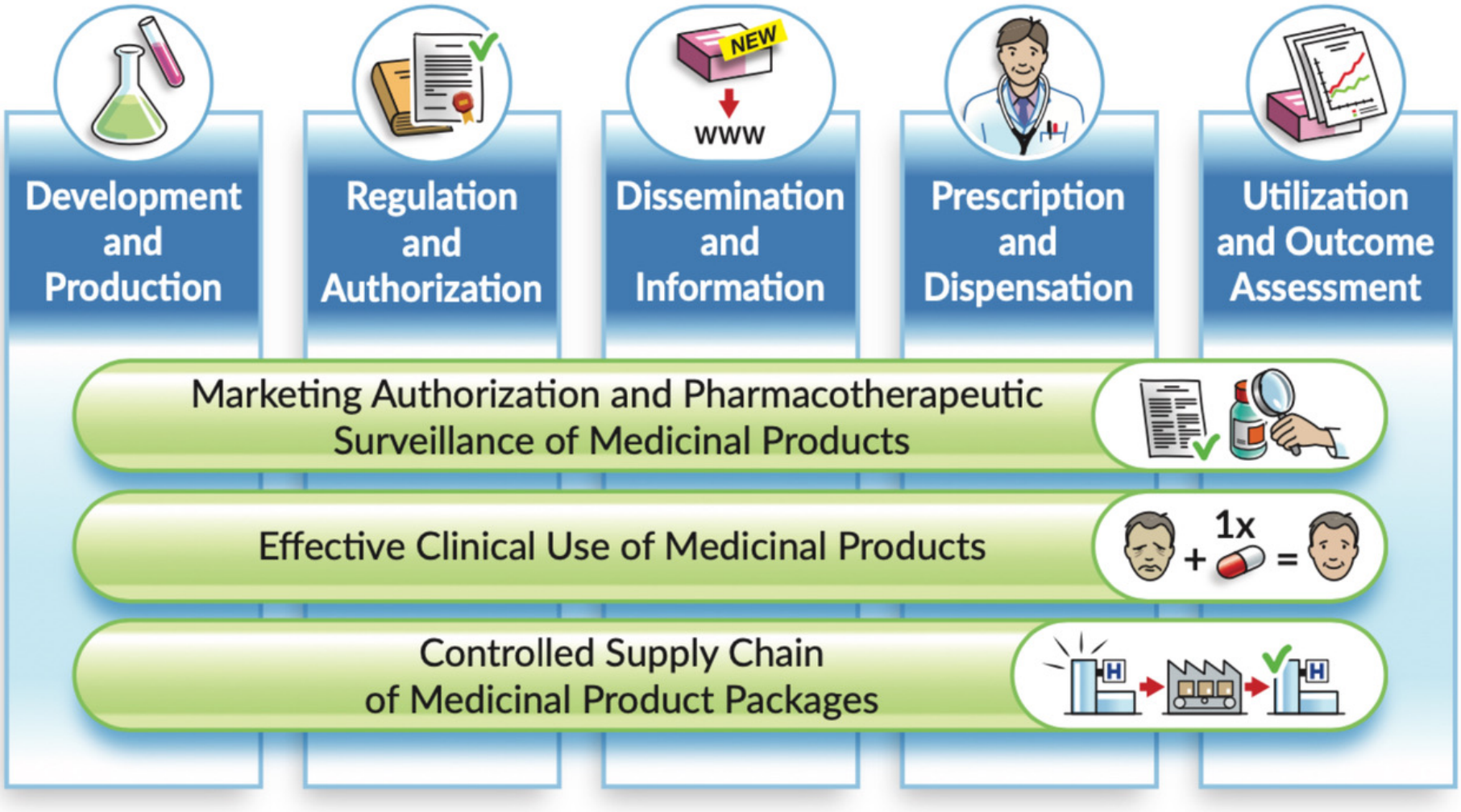
Ian Green

Customer Relation Lead, Europe and Global Clinical Engagement Lead (SNOMED International)

Jane Millar

Collaboration and Clinical Engagement specialist (SNOMED International)

Landscape of IDMP related standards and terminologies



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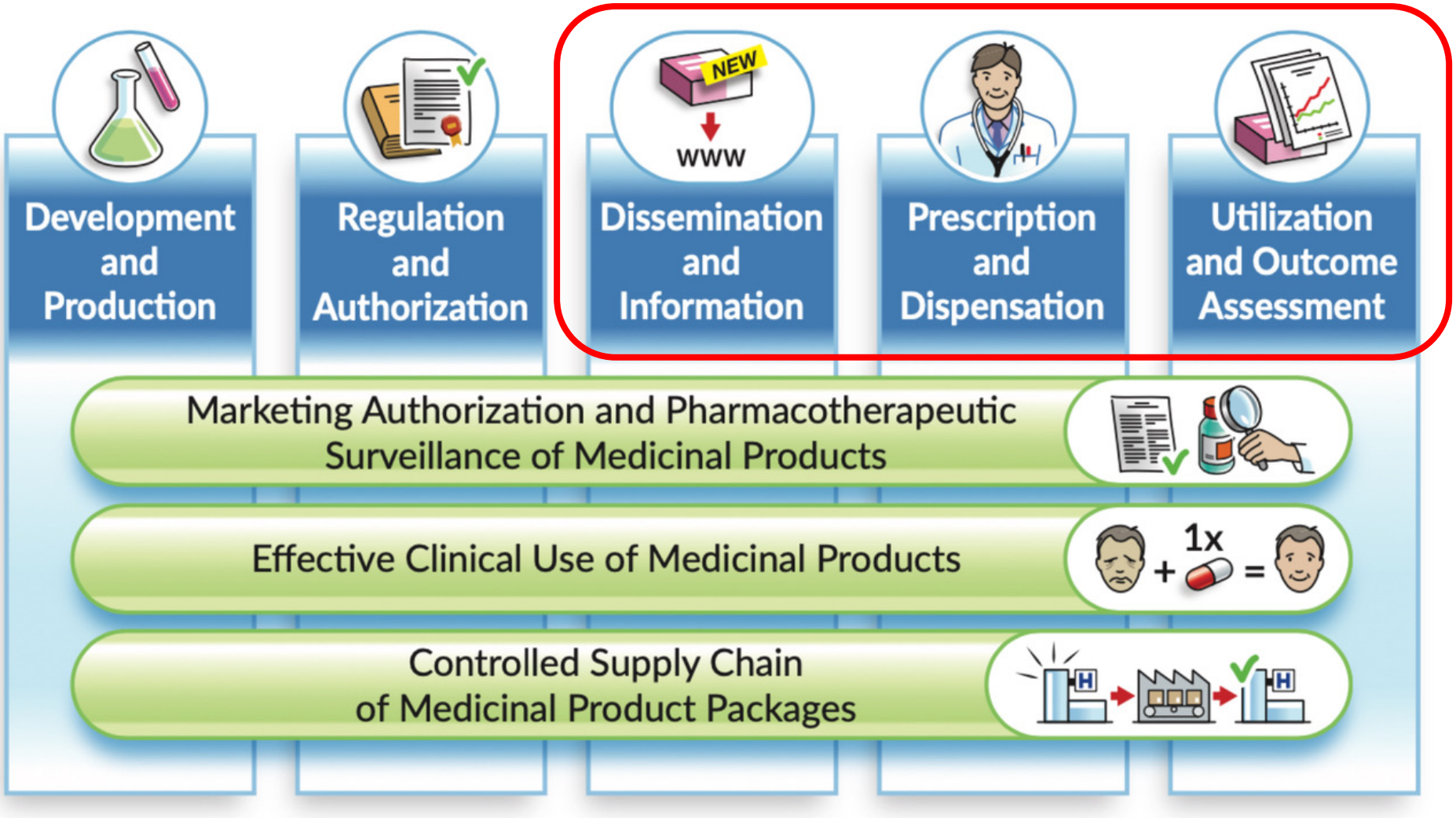
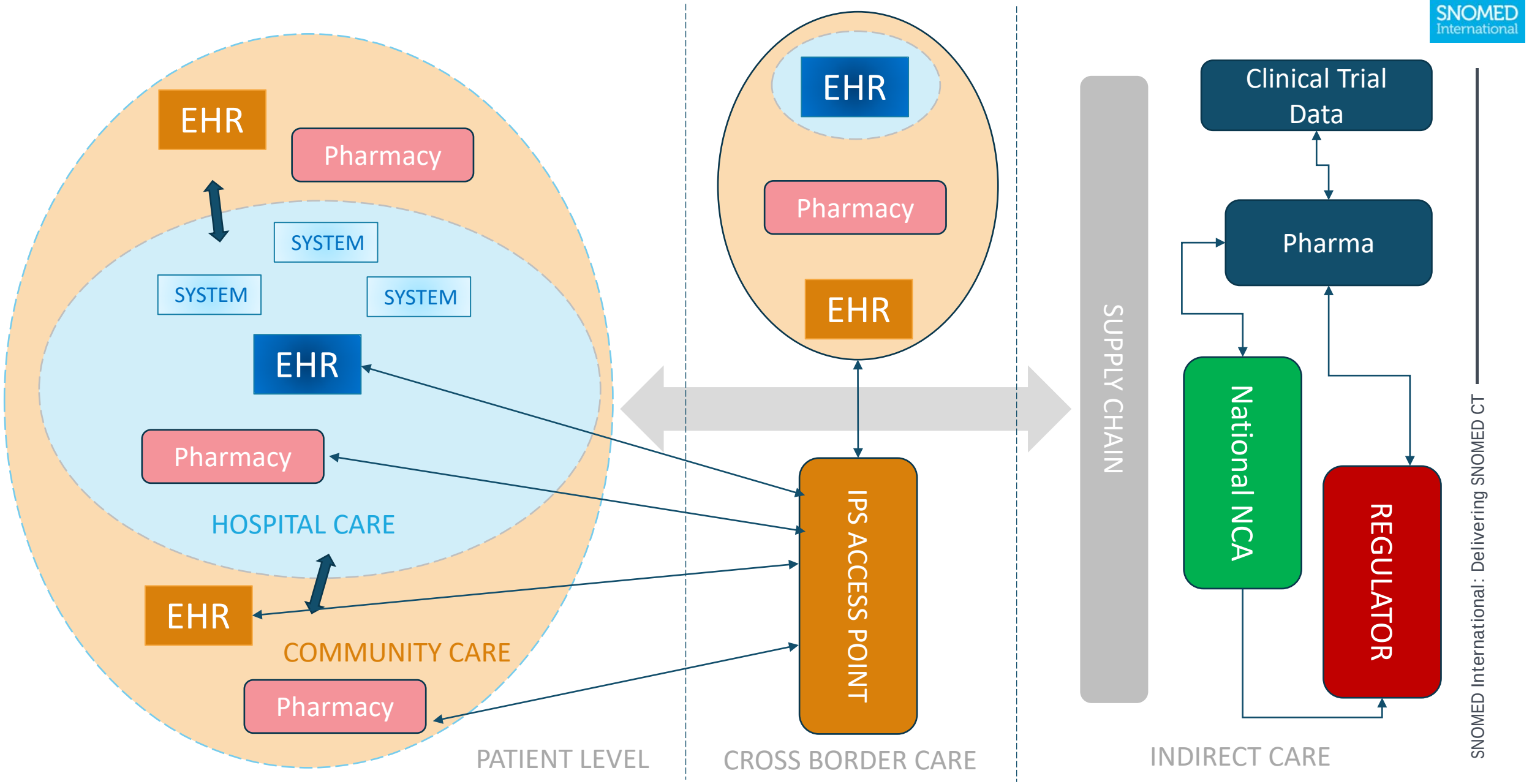


Starting with the patient . . .

- Focusing on the information collected and shared as part of the prescribing processes within the electronic patient record
- Access and utilisation of all the available patient information with the electronic health records (EHRs) and connecting systems
- Connecting systems, including pharmacy systems
- Types of information within the EHR and connected systems – diagnosis, allergies, past medical history (PMH), past prescribing history, patient conformance and responses to medication, vital signs
- Data and communication is key . . .

Pharmaceutical Data Landscape



Sharing medication and prescribing related information

EHR

- Problems and diagnosis
- Allergies
- Past Medical History
- Interventions
- Laboratory results
- Plans and goals
- Medication history
- Personal and social circumstances

(etc . . .)

links to:

- Clinical Decision Support
- Prescribing systems
- Specialist systems

Prescribing system

- Drug dictionary (IDMP based)
- Drug information sources
- Bar coding
- Supply chain information
- Inventory
- Decision support systems

(etc . . .)

Links to:

- EHR's
- NCA's
- Inventory systems
- Ordering and supply chain systems

Sharing medication and prescribing related information standards

EHR

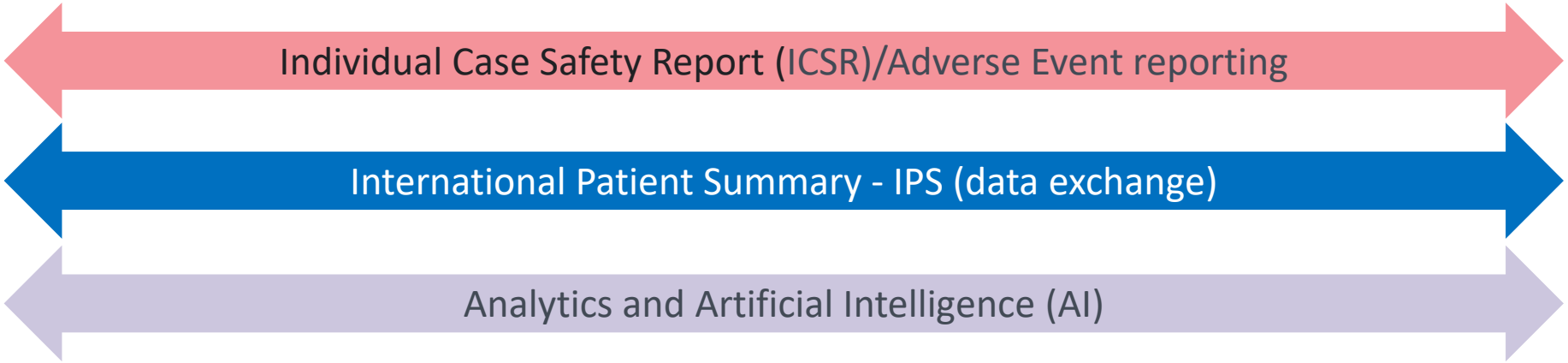
- SNOMED CT
- ICD-10
- Drug information (IDMP based)
- LOINC
- Local coding
- Free text
- Specialist coding sets (e.g. AJCC, NCPT, IDDSI

Prescribing system

- Drug dictionary (IDMP based)
- Supply chain information
- Bar coding (GS1)
- Drug information sources (e.g. BNF, MIMS)
- UNICOM implementation guides

Using information models, messaging and profiles

- HL7 (CDA, FHIR)
- OpenEHR
- IHE profiles
- Propriety data models



Patient care information reuse (related to medication)

Data feeds related to patient care for use in the medication landscape

- Prescribing
  - Access to “right drugs, right time”
  - Drug information
  - Prescribing guidelines
  - Clinical decision support systems
- Adverse event reporting
- Clinical review
- Support for drug recall
- Clinical trials – “providing rich clinical data”
- Reporting to NCAs
- Public health reporting and investigation

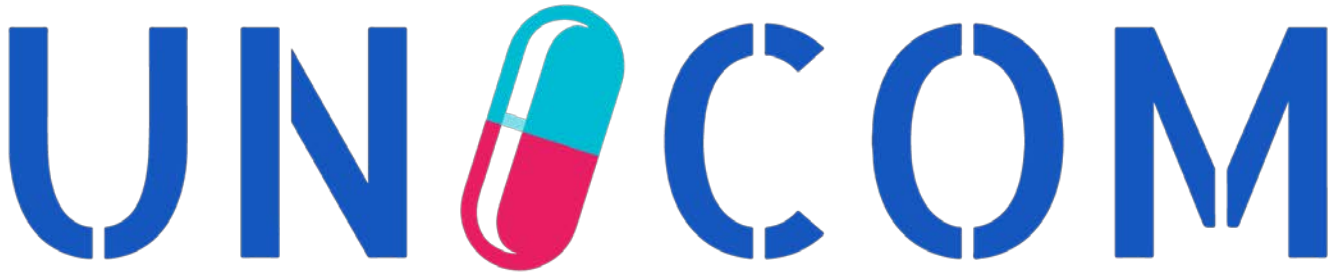
Related Data Standard challenges for data reuse

- Prescribing
  - EDQM Standard Terms are required for route of administration and dose form
  - IDMP identifiers are being mandated for medicinal product identification at regulatory, NCA and Pharma levels
    - Local prescription identifies the medication in the EHRs
    - IDMP for identifying substances – no global database to enable linkage to EHR representation of substances
  - Drug dictionaries – no agreed global standard
- Adverse Event reporting
  - HL7 V3 is used to represent an Individual Case Safety Report (ICSR) – interoperability challenges
  - MedDRA (for Europe) is mandated for adverse event coding
- Recall
  - Requires patient level identification and clinical representation to be read in EHR
- Clinical trials
  - Currently using CDISC, which is not always based on information standards used in EHR
- NCA reporting
  - Involves data transformation

Currently these data requirements need either transformation of existing data in EHRs requiring QA, mappings etc . . . , or are provided by duplicate data collections.

THANK YOU

SNOMED International



Sources of Medication Data in a Cross-border Context

José Costa Teixeira
WP 1, WP 5, WP 6, IHE Europe

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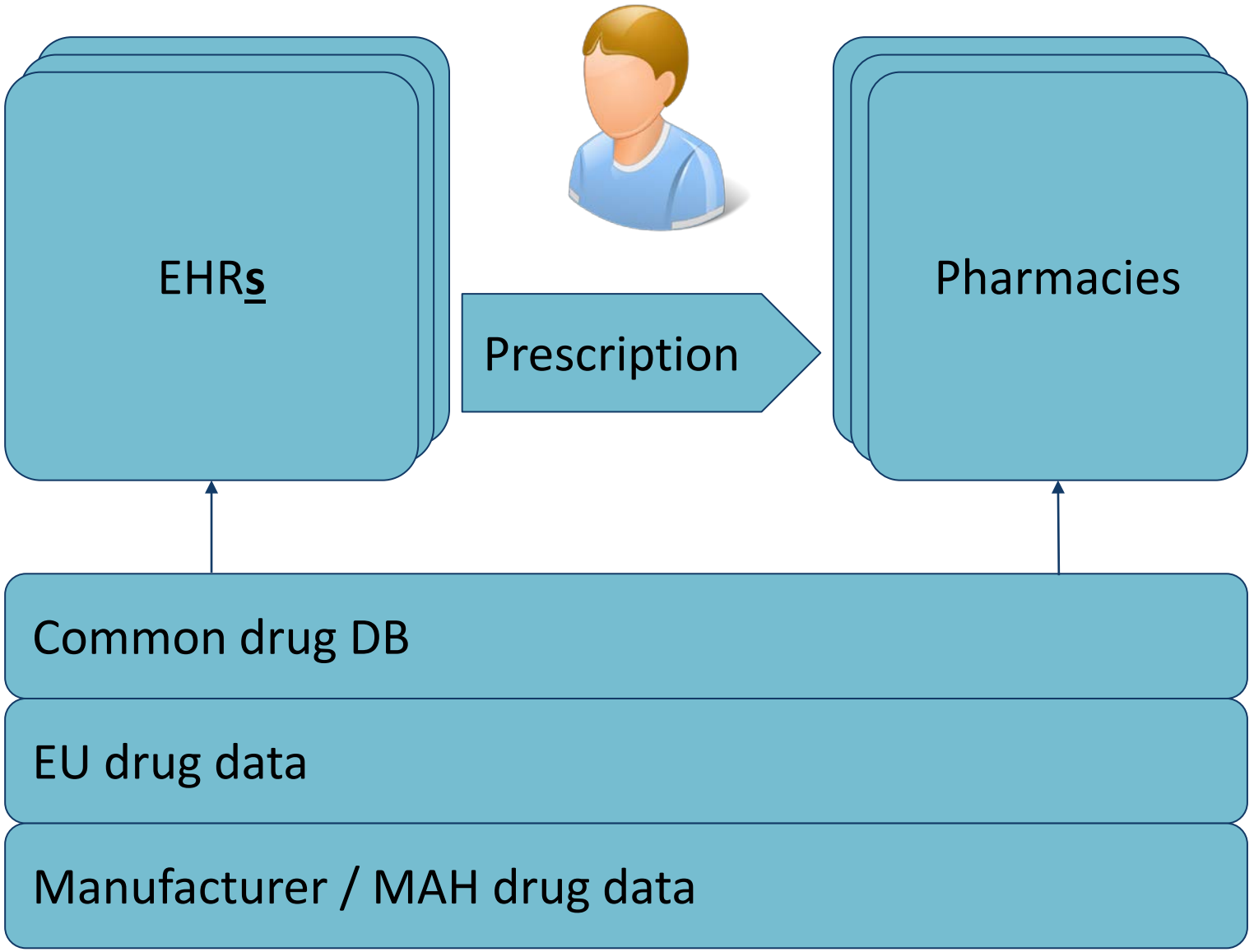

Simple case of patient care: Medication prescribed and dispensed.

Product data comes from MPDs, Manufacturers, other referentials.

Most cases are within the same country:

- In most cases, both systems use the same language (NL, FR…)
- Both systems have the same product data

What if there is a language or jurisdictional border?

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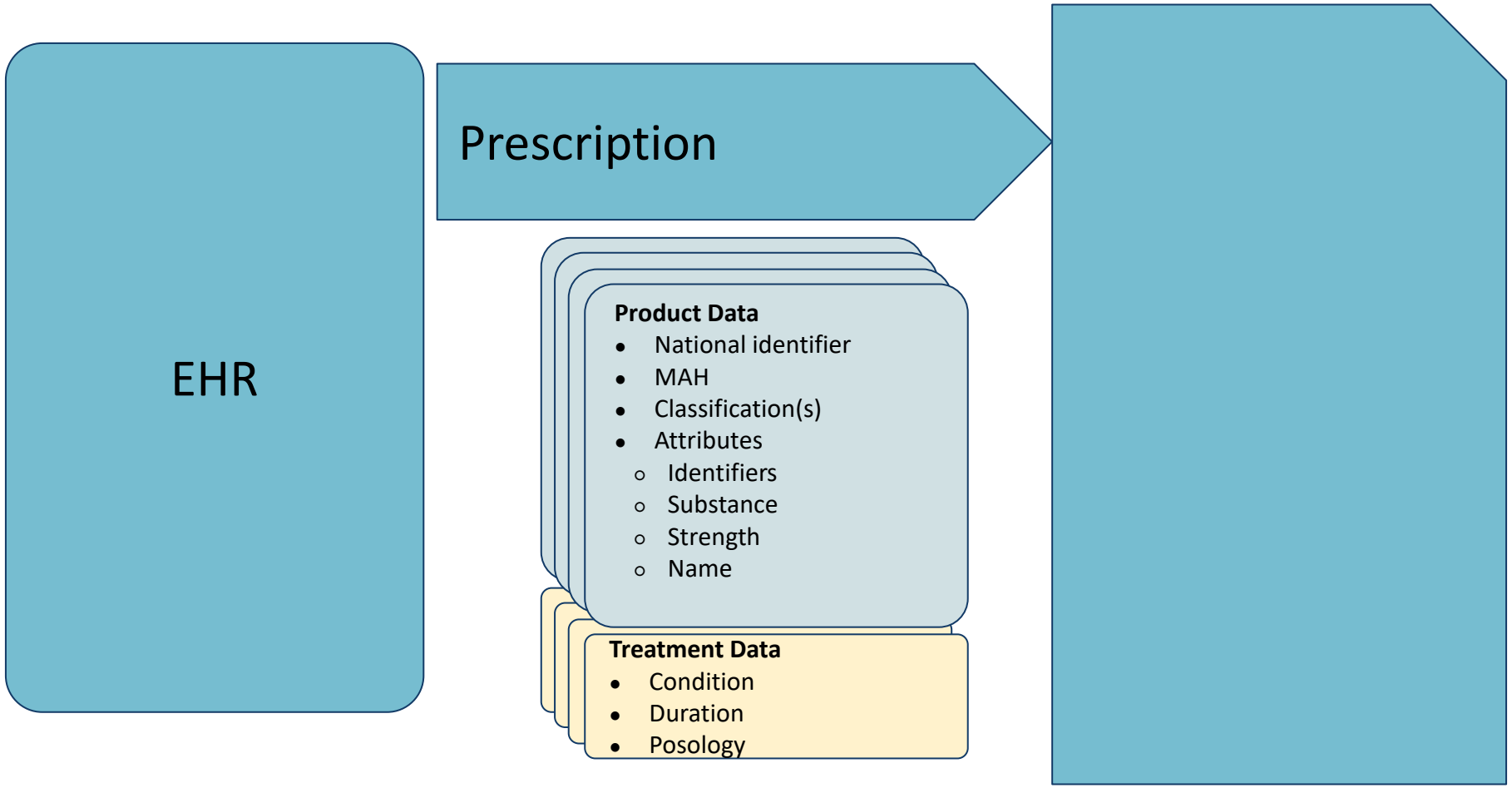
At national level, we know our data.



But different countries, different models….

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Where does all this data come from?

To allow interoperability there needs to be data consistency

- Syntactical
  - Structure
  - Formats of data

- Semantic (meaning)
  - The data elements and models used
  - The contents of coded data

Examples:

- What is the format for posology?
- How to express total amount?
- Which product attributes are in a prescription?

- What can “Product id” mean in a prescription?
- What are the values for dose form, classification…?

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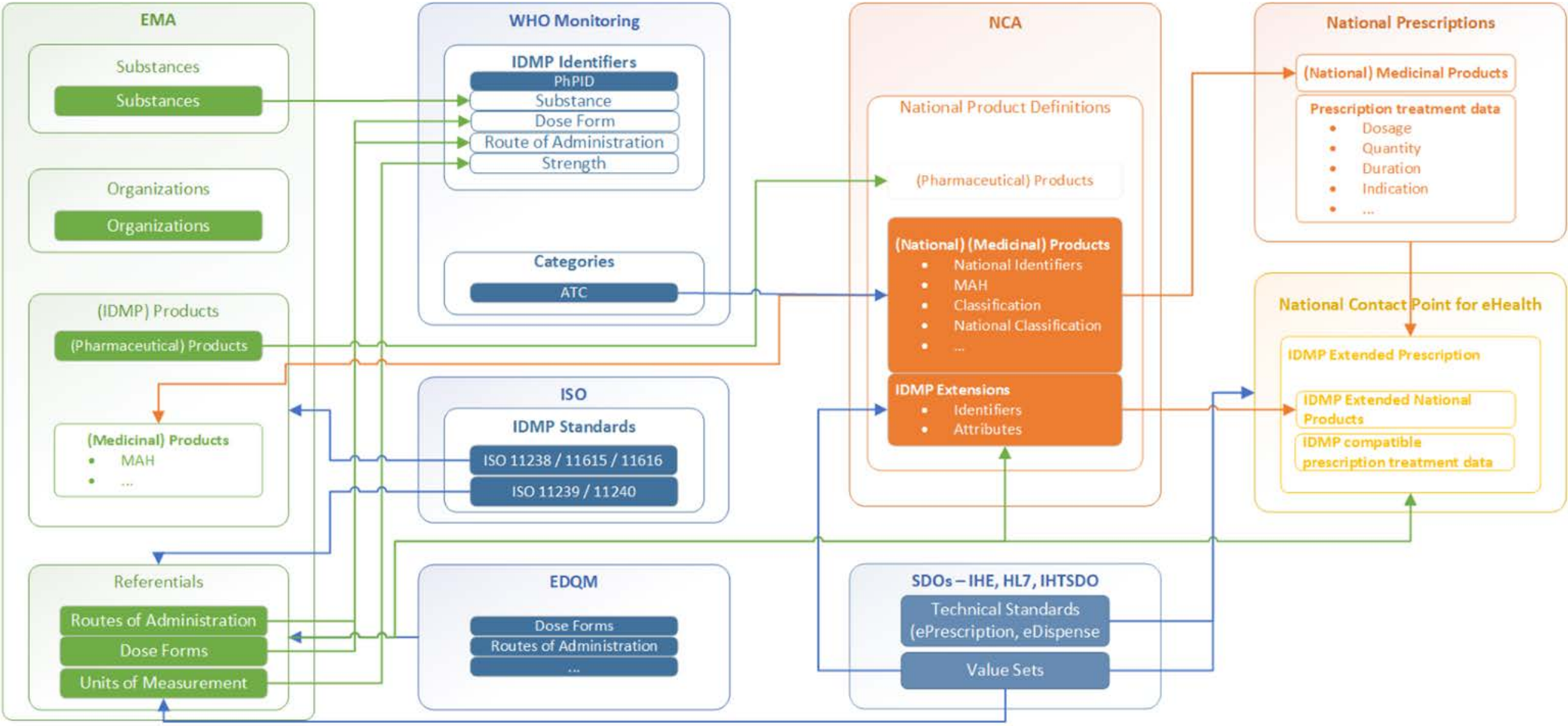

Note: This is a conceptual representation. Some organizations are mentioned here but only to illustrate types of competences. This diagram does not presume or preclude any role assignment, commitment or delegation.

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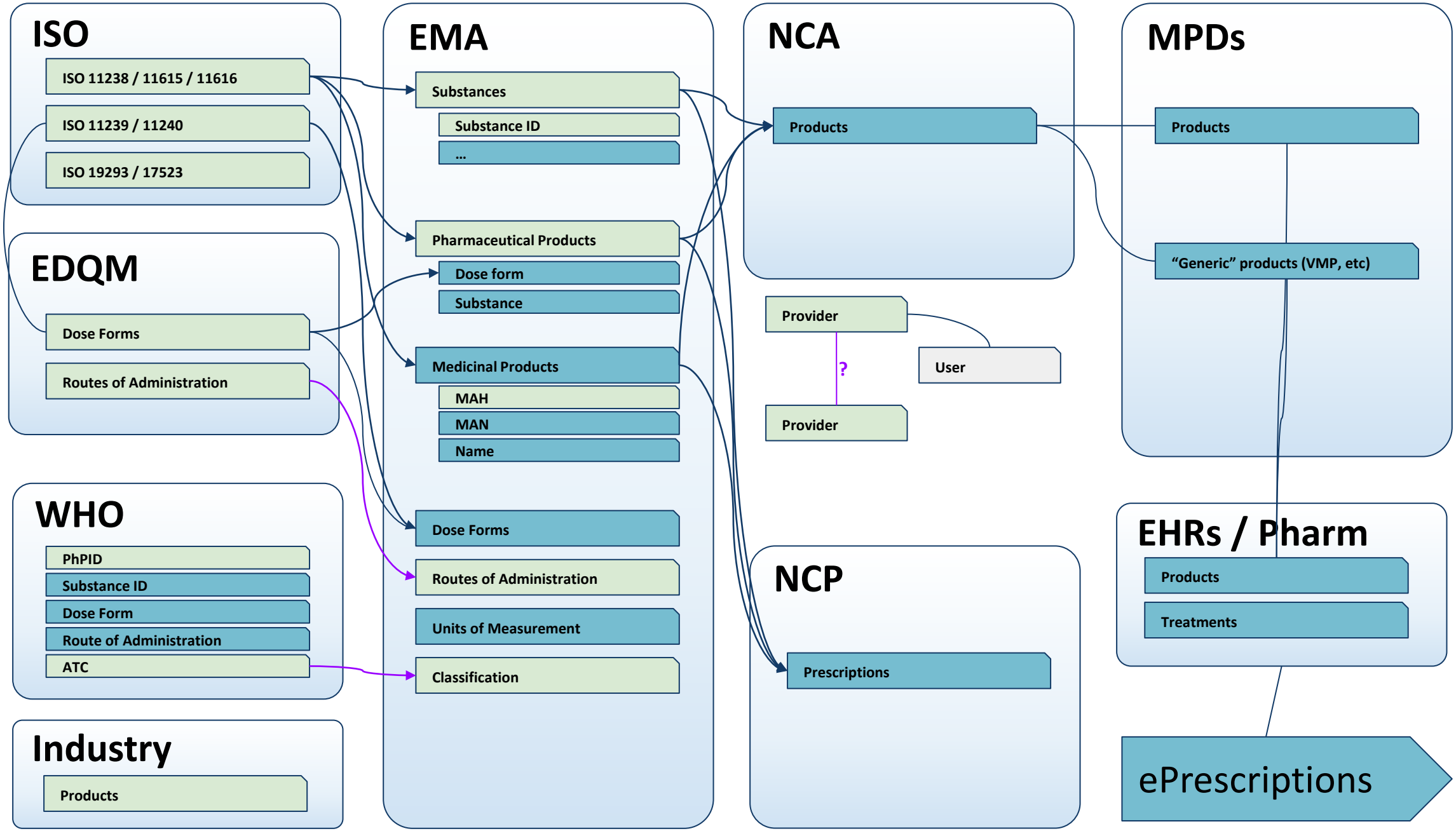

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How to manage this at the scale we need

UNICOM keeps providing examples, validators, guidelines on how the different parts move together. But how will it work at the scale we need?

- Data lineage needs to be known!
  - Sources? Usage? Impact assessment?
  - Version homogeneity or compatibility?
  - Data quality at source - but what is data quality?
  - **Terms of Responsibility?**

- Data governance needs to be established at the source!
  - Versioned,
  - With processes
  - Supported by metadata
  - Example: SNOMED has mature metadata management. Others?

- Master / Reference Data brokerage needs to be standardized
  - Producing and accessing valuesets
  - APIs for accessing data
  - Data enrichment?

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Thank you!

UNICOM

Perspectives on “correct” medication information

Dr Robert A. Stegwee
WP 1 Co-Lead, CEN/TC 251 Health Informatics
Based in The Netherlands

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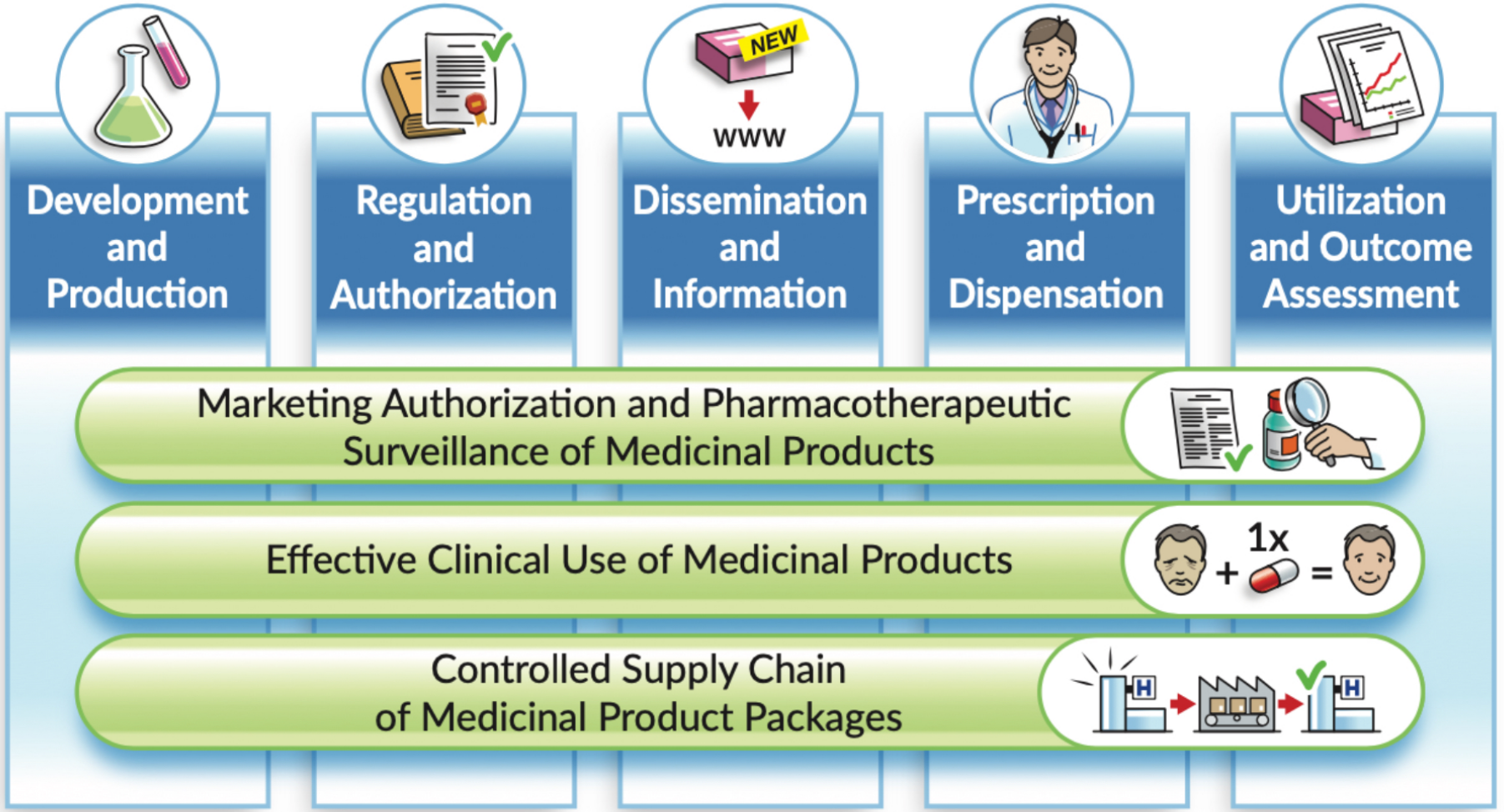
The source of the data may be far away from it's actual use, causing some problems



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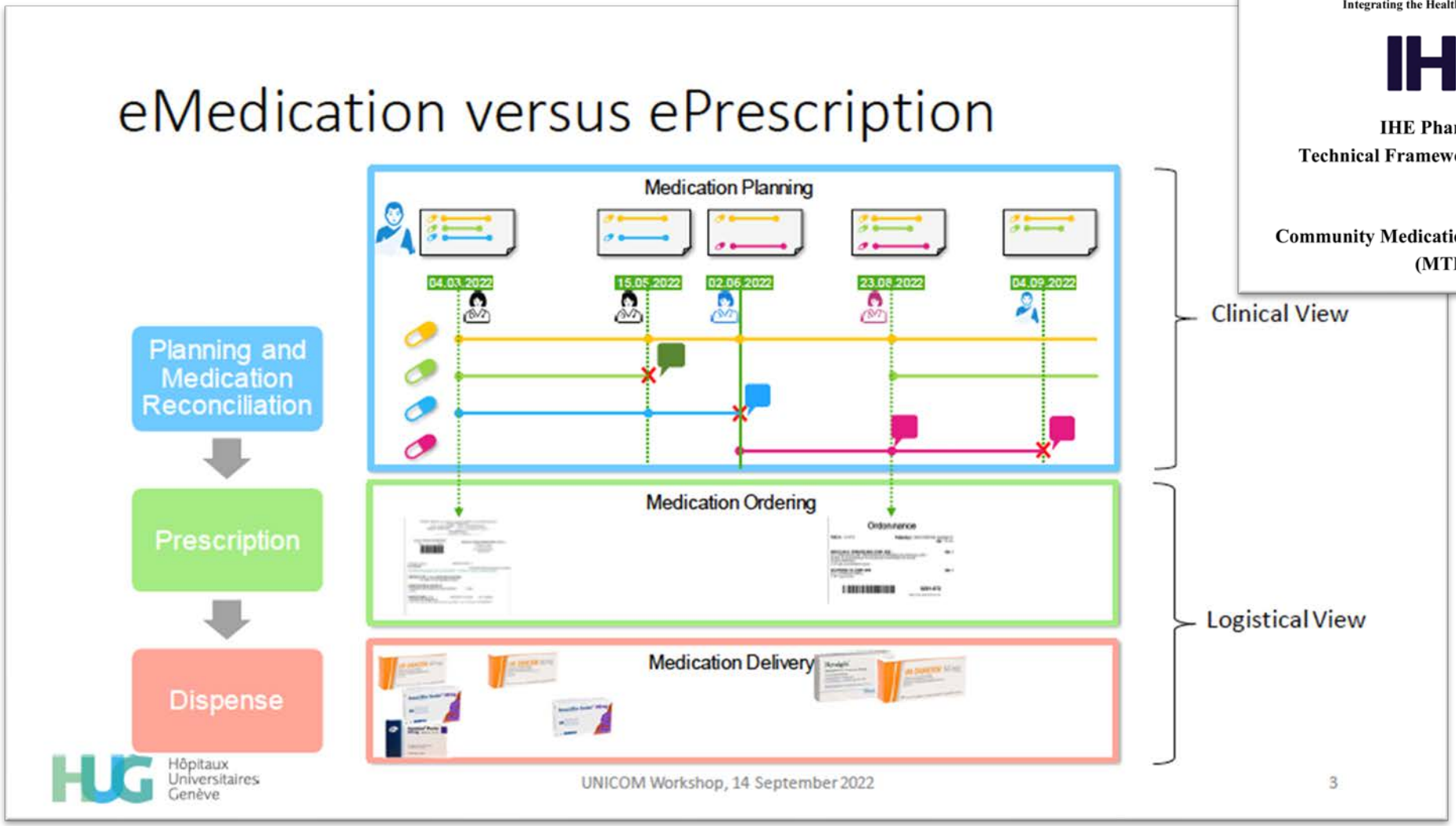
The role of medication data in the Medication Reconciliation process



Integrating the Healthcare Enterprise

IHE

IHE Pharmacy
Technical Framework Supplement

Community Medication Treatment Plan (MTP)

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Why am I using this medication?

Patient Portal

Goorse Apotheek

Medicijn informatie

Klik hier om meer informatie te vinden over dit geneesmiddel.

Naar medicijnen bestellen

Naam medicijn:
HYDROCHLOORTHIAZID T 12,5MG

Voorraad tot:
19-02-2023

Verstrekt door:
Goorse Apotheek

Voorgeschreven door:
Oosterveen, AR (huisarts)

Gebruik:
1 keer per dag 1 tablet

Bestelbaar:

1/2

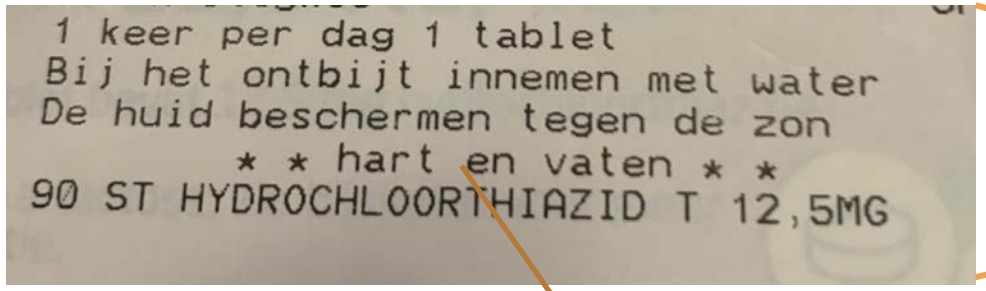
Provision until

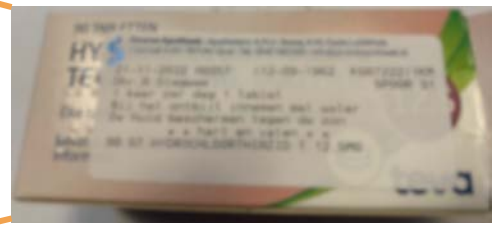
Dispensed by

Prescribed by

Use: 1 tablet per day

Order status





* * heart and arteries * *

Patient Portal

De Goorse huisartsenpraktijk

Nierstenen
Oosterveen
Datum 08-01-2007

Kidney stones

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- What is the indication for which the medication is being prescribed?
  - IHE profile for RSON: “**may** indicate one or more reasons for the use of the medication”
  - IHE profile for RSON: “**must** match the identifier of a concern entry contained elsewhere within the CDA document”
  - IHE profile for Concern: “Each concern is about one or more related problems or allergies"
  - IHE profile for Problem: “the value may be a coded or an uncoded string”
  - IHE profile for Allergy: “the value may be a coded or an uncoded string”

Example Problem Vocabularies
SNOMED Controlled Terminology
International Classification of Diseases, Clinical Modifiers, Version 9
A classification system from MEDICOMP Systems.

- Is it effective in the way it was intended – how is this being recorded?

- Pharmacotherapeutic Review takes place at all levels
  - Face to face meetings with local pharmacies and GPs, supported by local labs
  - National evaluation of guidelines, sometimes initiated by MPD providers
  - Post-marketing surveillance by pharma industry
  - International surveillance and research

- How do we make sure
  - the indication is captured and verified?
  - the effect is captured and verified?

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- Unapproved use of an approved drug is often called “off-label” use. This term can mean that the drug is*:
  - Used for a disease or medical condition that it is not approved to treat, such as when a chemotherapy is approved to treat one type of cancer, but healthcare providers use it to treat a different type of cancer.
  - Given in a different way, such as when a drug is approved as a capsule, but it is given instead in an oral solution.
  - Given in a different dose, such as when a drug is approved at a dose of one tablet every day, but a patient is told by their healthcare provider to take two tablets every day.
- Again: the importance of capturing and verifying the indication
- But also: dose form, route of administration and dosage instruction variations

* *Source: https://www.fda.gov/patients*

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Inconsistencies between dose form, route of administration, intended site, and prescription

UMC Utrecht

Patient Portal

29-9-2016 HYDROCORTISON/OXYTETRACYCL/POLYMYXB OOGZALF 3,5G | Orthopedie | OOG | 1 x per dag aanbrengen op wond linker been

Over dit medicijn

Eye gel

Orthopaedics

RoA: Eye

1 x per day apply to wound on left leg

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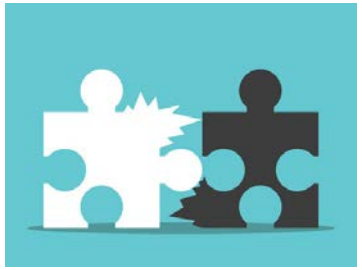
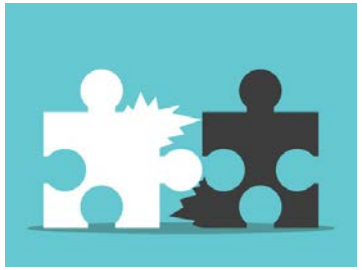
Possible options:

- Ask the prescribing physician to actually mark it as unauthorized use

- Discrepancies between (coded) approved use and the actual indication





- Descrepancies with patient instructions
  - dose form, intended site, administration method, ...

Pharmacotherapeutic surveillance may lead to:

- Guideline revision to include off-label use
- Application for market authorization for this particular use
- Clinical trials or other (global) evidence to support market authorization

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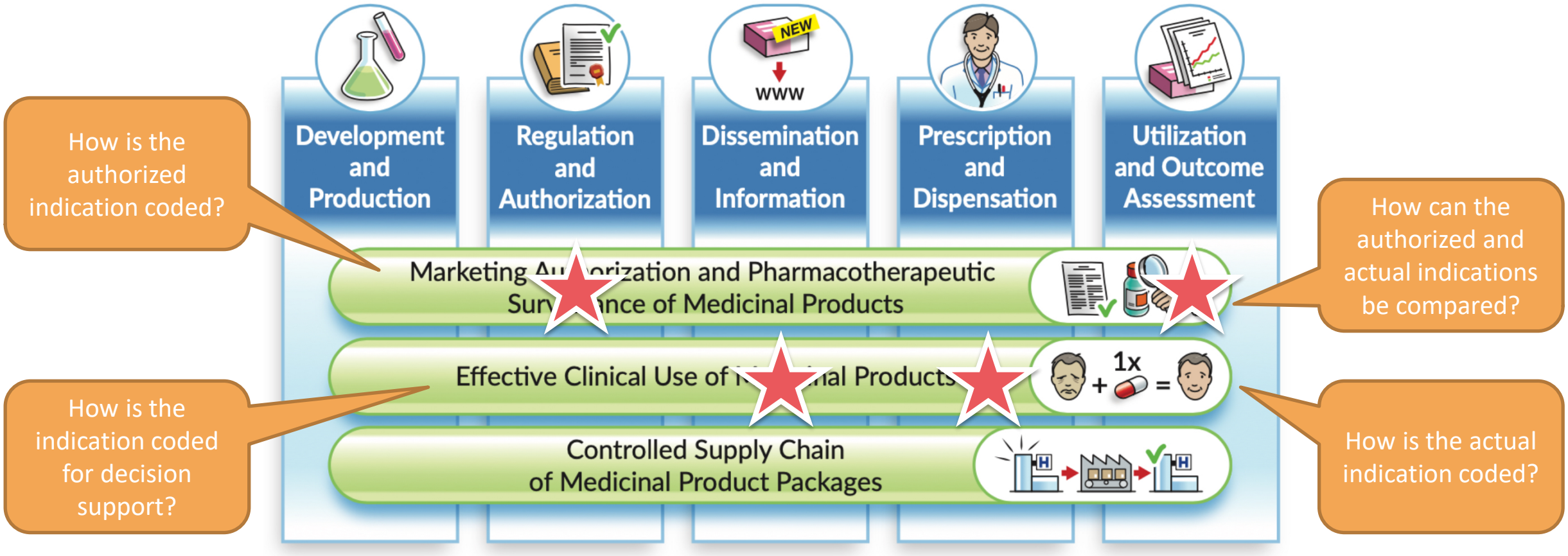
The need for proper and compatible coding across the landscape of medication data



1. Authorized use is defined in the authorization process by the NCA
2. Intended use is defined in the MPD as part of the clinical use process
3. Actual use is recorded in the clinical use process in the prescrption
4. Off-label use is analysed as part of Pharmacotherapeutic Surveillance

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Findings

Dose Form Challenge

- Dose Form expression variations (e.g. Pfizer Covid-19 vaccine)
  - EMA – ***Dispersion*** for Injection
  - FDA – ***Suspension*** for Injection
  - UK – ***Solution*** for Injection

Pharmaceutical Dose Form	Release Characteristics	Intended Site	Administration Method	Basic Admin. Dose Form
Dispersion for Injection	Conventional (0047)	Parenteral (0033)	Injection (0012)	**Dispersion** (0079)
Suspension for injection	Conventional (0047)	Parenteral (0033)	Injection (0012)	**Suspension** (0085)
Solution for injection	Conventional (0047)	Parenteral (0033)	Injection (0012)	**Solution** (0083)

FDA

Uppsala Monitoring Centre 22

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How does this impact the cross-landscape processes?

- No impact for the direct vaccination of patients
- Possible implications for cross-border vaccination certificates
- Direct impact on the calculation of a global PhPID
- Hence direct impact on any use case involving a global PhPID or other search for equivalents based on dose form
  - Global pharmacotherapeutic surveillance and pharmacovigilance
  - Substitution in prescribing/dispensing
  - Substitution in supply chain
- Influence on the pharma industry?

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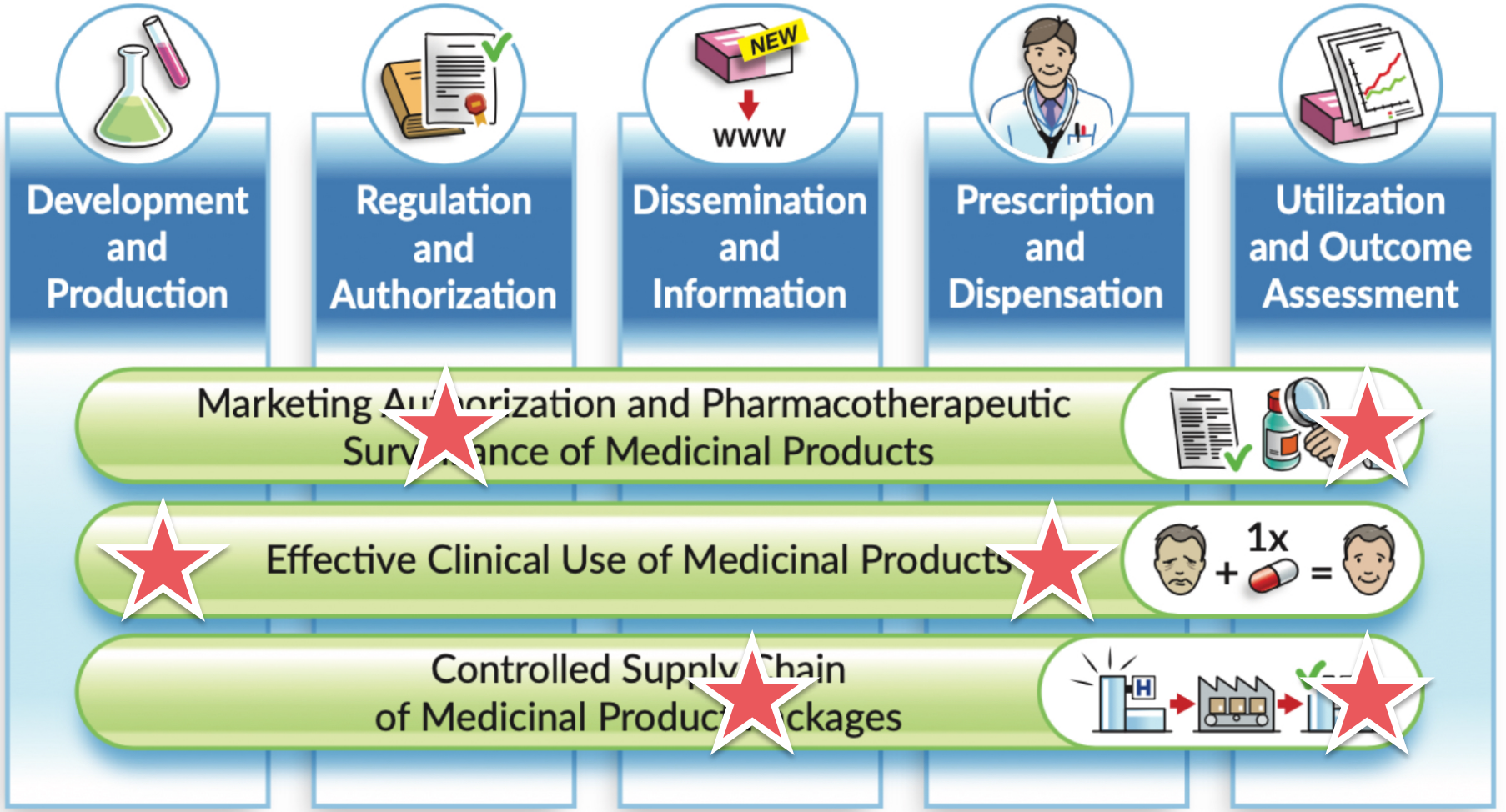
Use case based requirements versus cross use case coordination



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In conclusion

- We want to achieve a trusted flow of information across the domains and processes of the IDMP landscape
  - Identifiers need to be shared
  - Data elements need to be reused
- In order to fulfill the requirements of a “downstream” use case
  - it may be necessary to implement changes in an ”upstream” use case
  - taking into account requirements that are deemed “out-of-scope” for the impacted use case
- What if the available information is not coded or formatted for appropriate reuse?
  - We tend to invest in correcting, recoding, rekeying, etc. – the only way we know how to address an issue
  - We should look “upstream” and confront the source of the data with the issue we have in reusing the data
  - In practice, I hope to see both: fix the issue for the short term, but do engage with the source to find a long term solution
- The IDMP Logical Model should help pinpoint the identifiers and data elements that are reused
  - Work on coordinated requirements across use cases
  - Seek aligned solutions for proper coding that addresses the requirements
  - Implement at the source and take advantage of reuse “downstream”

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Questions, comments

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Thanks for your time