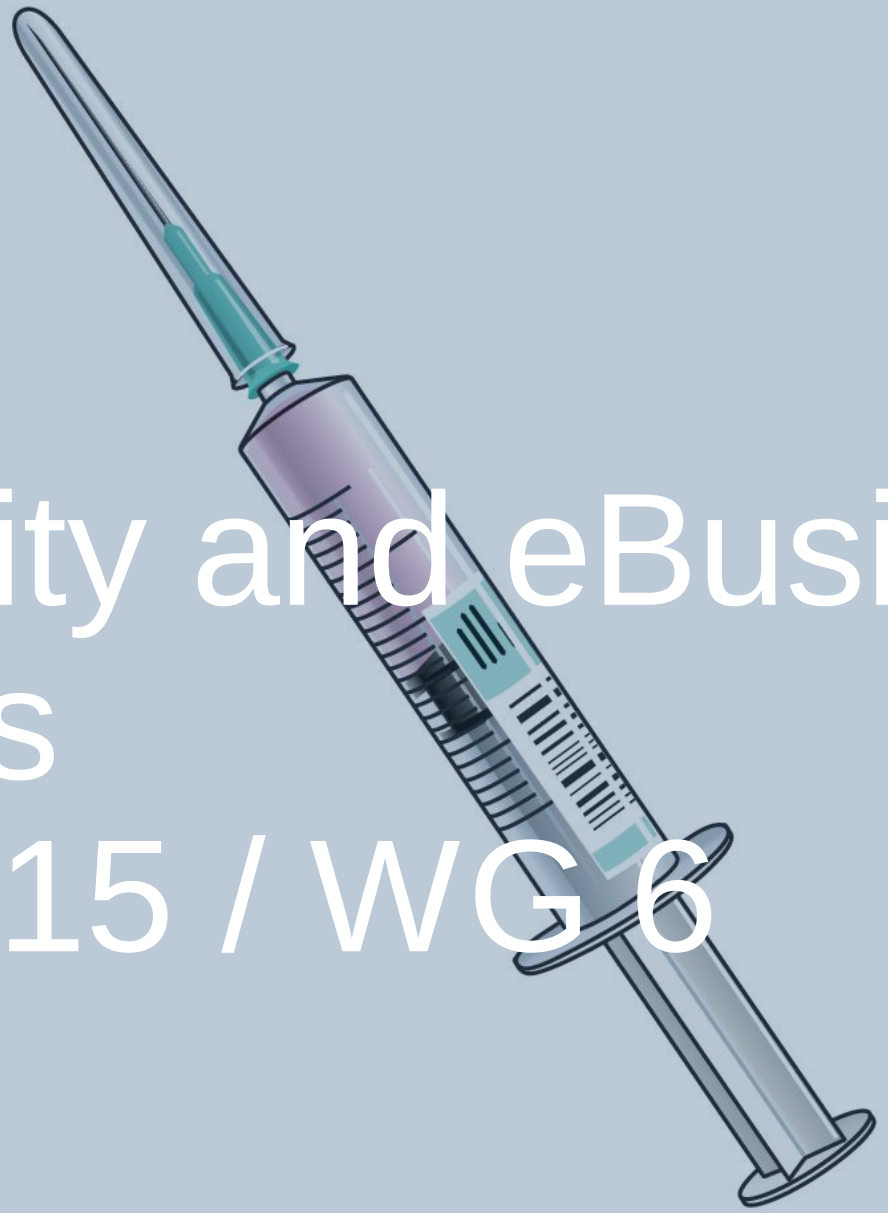
Traceability and eBusiness Standards
ISO TC 215 / WG 6



About traceability

Traceability is the ability to trace the history, application or location of an object [ISO 9001:2015]. When considering a product or a service, traceability can relate to:

- origin of materials and parts;
- processing history;
- distribution and location of the product or service after delivery

(source: GS1 Global Traceability Standard, 2017)

Traceability in the pharma regulatory space

- Pharmacovigilance

  *Any untoward medical occurrence in a patient or clinical investigation subject who is administered a pharmaceutical product and who does not necessarily have to have a causal relationship with this treatment**

- Fight against falsification

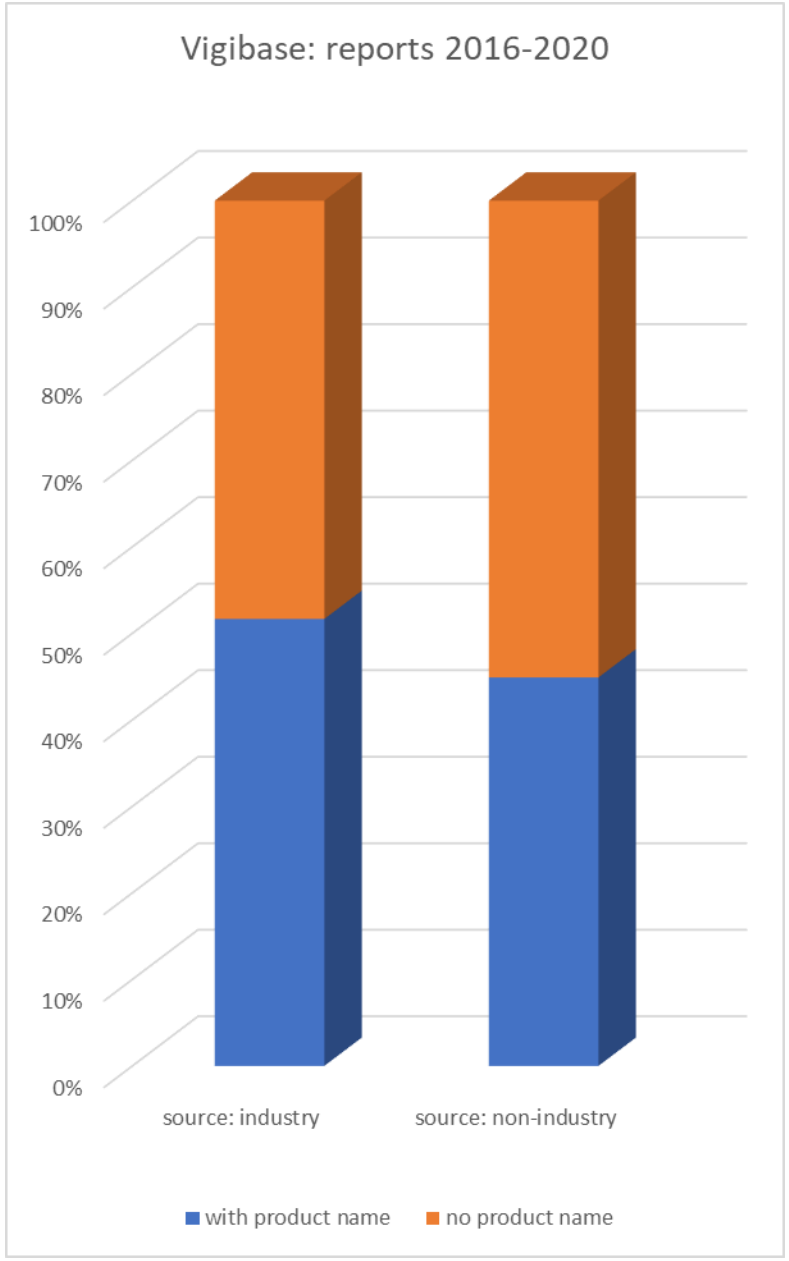
  *A falsified medicine is one which is deliberately and fraudulently mislabelled with respect to identity and/or source***.*

*EU Good Clinical Practice Guideline
** ISO/TS 16791: 2020, § 5.3.1.1

General principles for traceability

- Know what you trace (the object)
  - Master data
  - Item identification
- Know why you trace
  - Business process
- Know locations
  - Know the journey of what you trace

Addressing traceability requirements



Triggers for standards development

With mass-production and acceleration in global trade, adverse events with medicinal products have become a growing risk over several decades

Market fragmentation is a risk factor

Quality of adverse event announcements needs to be improved

Falsification of medicinal products is aggravating this problem

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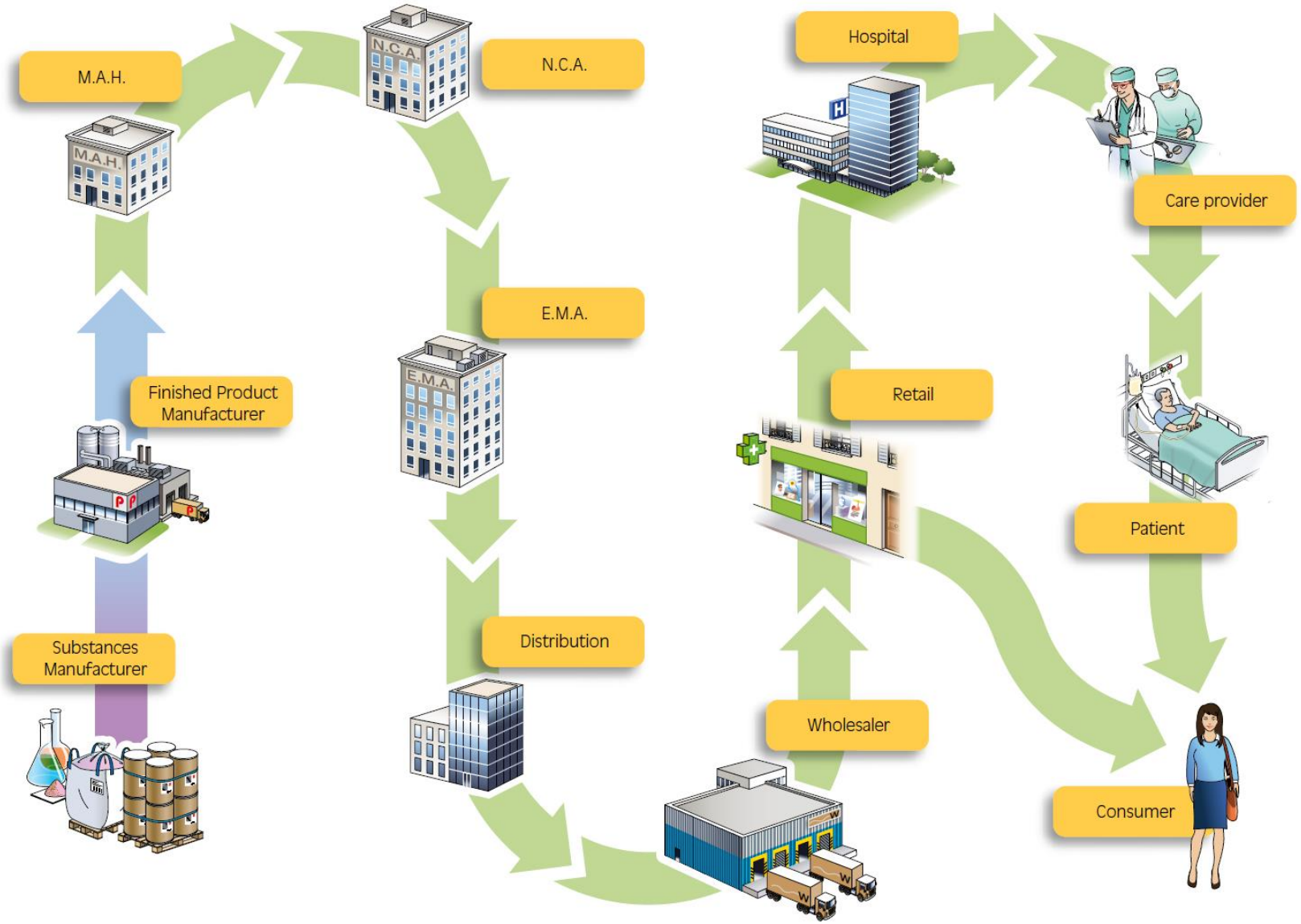


Identifications

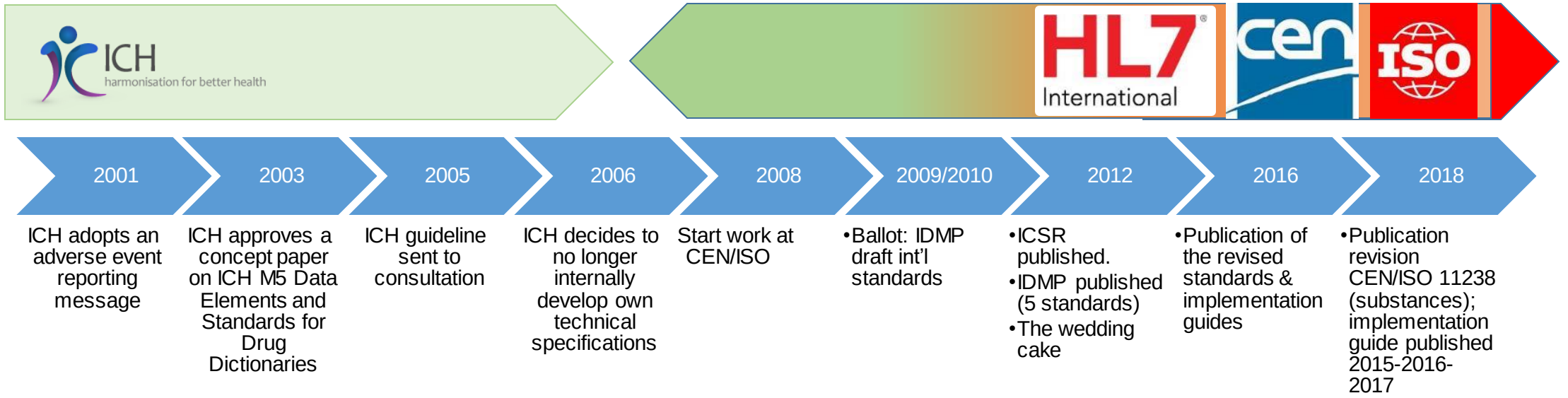
- PhPID
- MPID
- PCID
- DCID/GTIN

Functions

- Submission
- Market information
- Procurement
- Adverse Event
- Recall
- Shortage
- Counterfeit
- Traceability

IDMP – the origin

Recognise the need to improve adverse event management.



Traceability of medicinal products: standards in place*

*And in improvement

IDMP

Identification of Medicinal Products

Substances

ISO 11238

Data elements and structures for the unique identification and exchange of regulated information on substances

This norm distinguishes Substances (defined based on its main, general characteristics ; can have different roles e.g. active, adjuvant, basis of strength, excipient) and Specified Substances (More granular, specific description of a substance e.g. including manufacturing information, purity, grade ; allows for the specification of multiple substances ("Intermediate Products" e.g. AS03 - adjuvant composed of squalene (10.69 milligrams), DL-α-tocopherol (11.86 milligrams) and polysorbate 80 (4.86 milligrams)

Dose forms, etc.

ISO 11239

Data elements and structures for the unique identification and exchange of regulated information on pharmaceutical dose forms, units of presentation, routes of administration and packaging

Identifies for example injection solution, Injection suspension, Infusion solution (or a less granular regional term linked to these)

MPID

ISO 11615

Data elements and structures for the unique identification and exchange of regulated Medicinal Product information

Defines, characterizes and uniquely identifies regulated medicinal products for human use during their entire life cycle (Development, authorization, post-marketing and renewal or withdrawal from the market) ; Establishes definitions and concepts ; Describes data elements and their structural relationships required for the detailed description and unique identification of medicinal products

Units of mesurement

ISO 11240

Data elements and structures for the unique identification and exchange of units of measurement

Specify rules for the usage of units of measurement for IDMP ; Define requirements for traceability to metrological standards ; Establish reference code system for units ; Provide structures and rules for mapping between different unit vocabularies and language translations, linking to existing systems, dictionaries and repositories

PhPID

ISO 11616

Data elements and structures for the unique identification and exchange of regulated Medicinal Product information

Pharmaceutical Product Identification (PhPID) based on the following subset of elements that describe the pharmaceutical product:

- Substance(s)/Specified Substance(s)
- Strength(s) - Strength units (units of measurement and/or unit of presentation)
- Reference Strengths
- Administrable Dose Form

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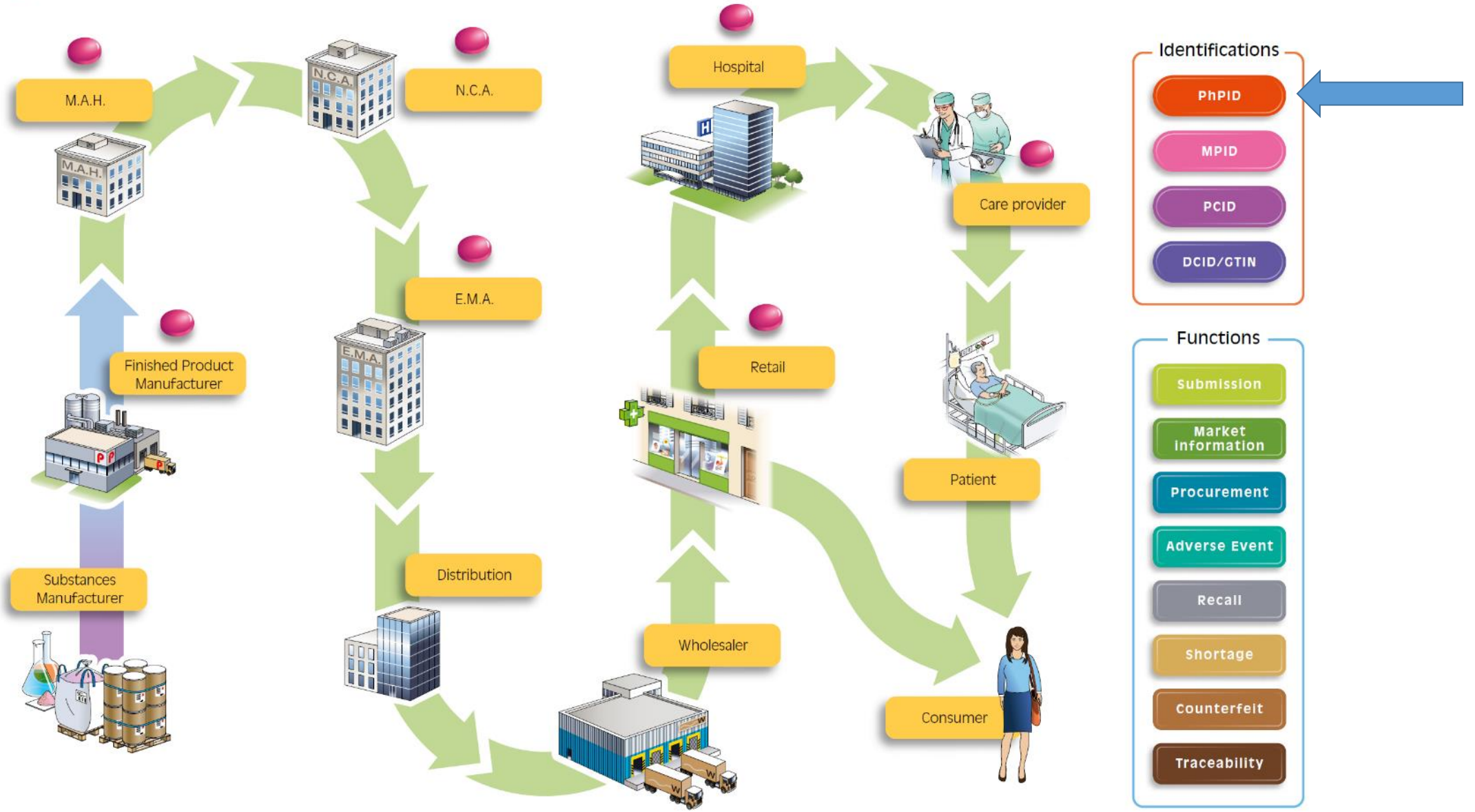

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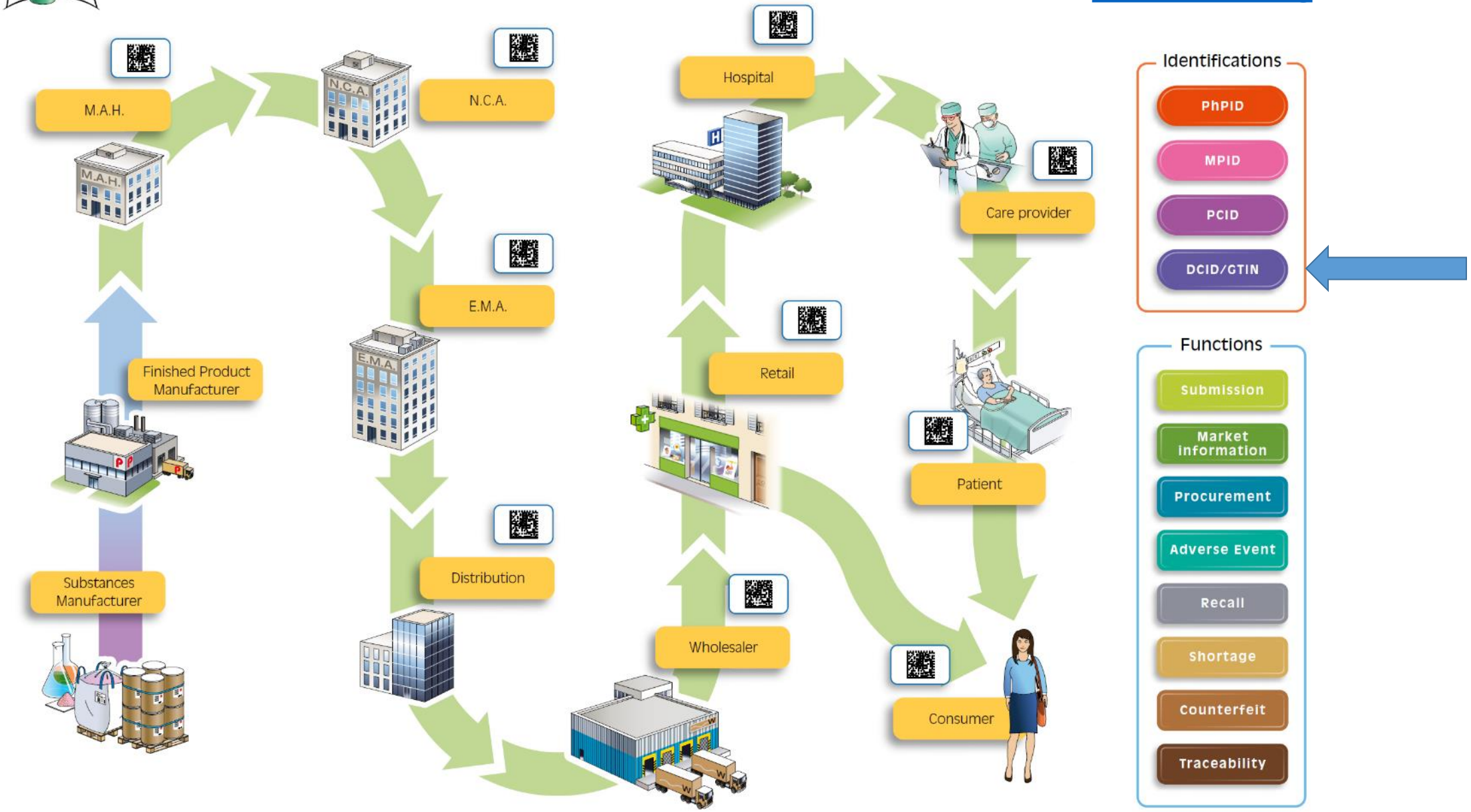
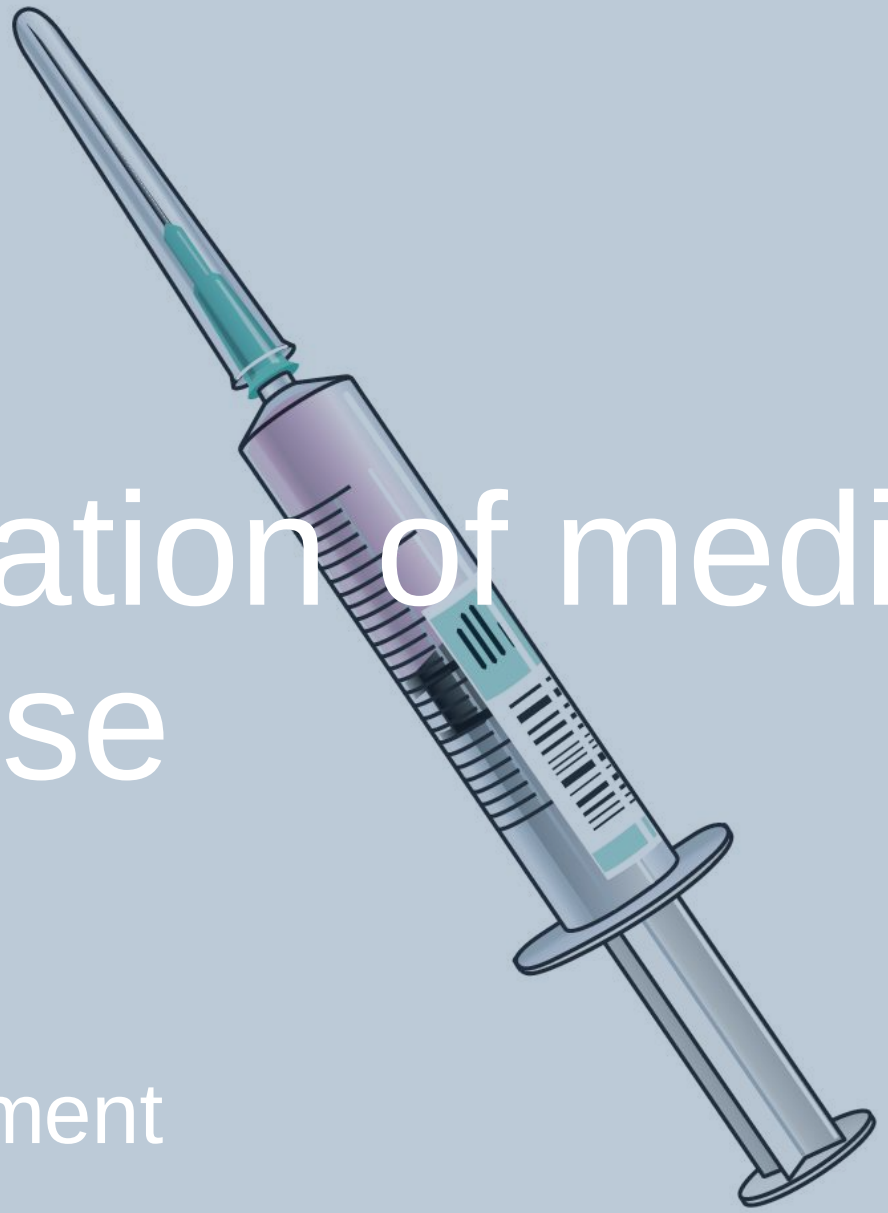


Reconciliation of medicinal product use



*And in improvement

Do these two vials contain the same vaccine?

Market: country A

Market: country B

Do these two vials contain the same vaccine?

Data carrier:
GTIN 1234

IDMP Substance Identifier ? IDMP Substance Identifier

IDMP Pharmaceutical Product identifier ? IDMP Pharmaceutical Product identifier

IDMP Medicinal Product Identifier ? IDMP Medicinal Product Identifier

IDMP Package Identifier ? IDMP Package Identifier

Data carrier:
GTIN 9876

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