Federal Institute
for Drugs
and Medical Devices

BADI Drug Regulatory Affairs e-Congress

The UNICOM Project – benefits from ISO IDMP/SPOR for health care professionals and patients

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10 YEARS

There is one central question

If I have a prescription for medicine ‘Bonn‘ and

- there is a shortage of this specific brand
- I‘m travelling in the EU/EEA (or the world)
- …

how could someone

- identify my medicine ‘Bonn‘
- subsitute my medicine ‘Bonn‘ with the equivalent medicine ‘Sofia‘

and make my happy?

How to identify a medicinal product in a unic way ?

How to identify a medicinal product?

- name of the medicinal product
- the active substance/moiety (valsartan / валсартан)
- the strength
- the pharmaceutical form

- or by a unic number

… and what is comparable

- 5 mg tablet / 10 mg tablet
  5 mg tablet / 10 mg tablet with a breakline
  (strength of the product vs. administrable strength)
- tablet /capsule / sacchet / oral solution / …
- …

What do we need?

Standards and Masterdata

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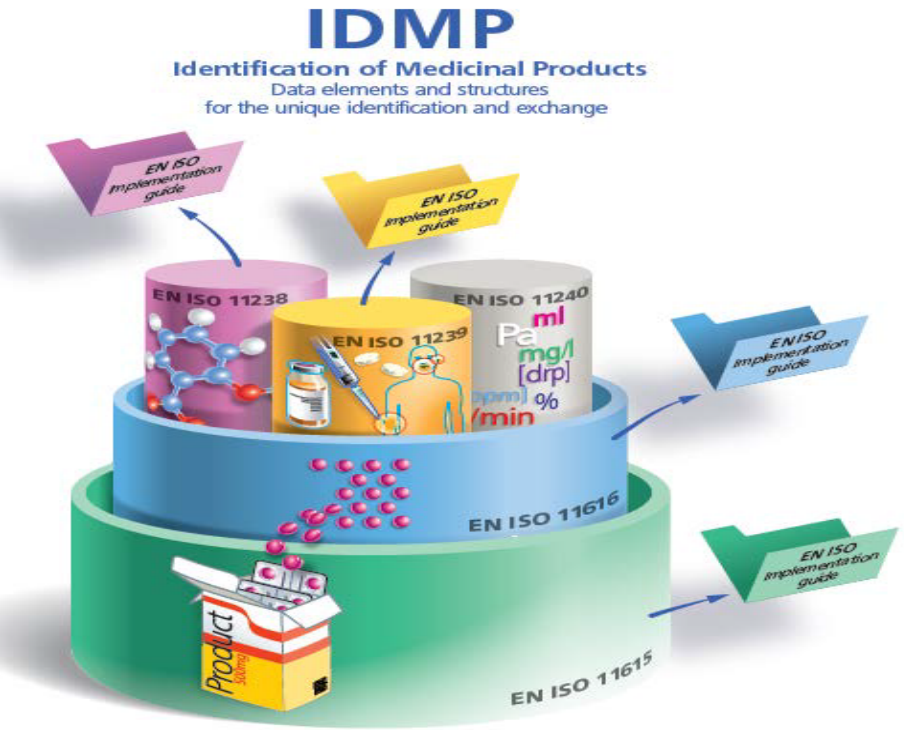
ISO IDMP Suite of Standards



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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

Response to Regulatory Requirements

Implementing Regulation (EU) No 520/2012 on "the performance of pharmacovigilance activities"

- **states that "*terminology* set out in the ISO IDMP suite of standards" is binding for "Member States, marketing authorisation holders and the [European Medicines] Agency."**
- **specifies this as "internationally agreed terminology" applied "for … electronic exchange and communication of pharmacovigilance and *medicinal product information*."**

Implementing ISO IDMP through SPOR

- Four projects have been established to implement services that centralise management of each of the domains of master data

Substance Management Services (SMS)

Organisations Management Services (OMS)

Product Management Services (PMS)

Referentials Management Services (RMS)

- The implementation of the four SPOR projects will be phased
- All proposals relating to the implementation of SPOR have been and will continue to be consulted on widely with regulators and industry representatives
- SPOR applies to both domains, Human and Veterinary

Some facts and questions

- the authorisation of medicinal products delivers the basic set of informations about a medicinal product (active substance, composition, indication, contraindication, populations, …) to be used in a health care system
- structured data about a medicinal product from (clinical trial) application to the deletion of the MA is crucial

- How to provide the (end)user with this information?
- How to keep the quality of the data at a high level during the life cycle?
- Is a name of a substance (= SMS) sufficient to characterise a substance?
- …

European Innovation Action – Goals, Context, Challenges

UNICOM

Vision & Mission

Vision

- Improving patient safety
- Facilitating better healthcare for all

Mission

- Enabling the univocal identification of medicinal products by supporting and accelerating the
  - further development,
  - implementation, and
  - diffusion of ISO IDMP standards (IDentification of Medicinal and pharmaceutical Products)
- across European health systems, to
- facilitate the free flow of semantically coded interoperable medicinal product information

This project has received funding from the European Union's
Horizon 2020 research and innovation programme under grant agreement No 875299

UNICOM - Overview

- This **HORIZON2020** innovation action will give a powerful impulse to the implementation of ISO IDMP standards in EU Member States drug databases, supporting safe cross-border ePrescription/eDispensation and effective pharmacovigilance.

- Once EU-interoperable data on medicines taken by patients become available, further benefits will accrue through better health data for improved clinical decision support, patient empowerment, public health and clinical research. New opportunities will arise for pharma industry, software developers, SMEs providing smart apps and others, thereby fostering their innovation capacity and competitiveness.

- Project ambition centres on **conversion of key regulatory and clinical processes to use IDMP**. These information value chains must be converted over their full length from data input to data repositories to data usage. Project work spans all three areas, focussing on the most challenging, the implementation of **EU and national SPOR compatible** (substances, products, organisations, referentials) **data bases**, including establishing an **EU Substance Reference System (EU-SRS).** Such information is fundamental to cross-border ePrescription where safe dispensation may require reliable identification of substances in available products.
  - **19 countries are represented**
  - **26 national Drug and eHealth Agencies**
  - **Stakeholders are involved through their associations**
  - **duration is 4 years (Dec. 2019 – Nov. 2023)**
  - **budget € 21 m, with requested funding € 19 m.**

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Application Domains and Objectives

UNICOM

By accelerating the diffusion of ISO IDMP standards UNICOM supports

- **regulatory processes** of National Medicines Authorities (NMAs) & the European Medicines Agency (EMA)
- **cross-border digital health services** (ePrescription, Patient Summary**)**
- **global pharmacovigilance**
- **better healthcare, public health, medical research** (e.g. Big Data Analytics, Artificial Intelligence applications)

Core objectives focus on:

- Adaptation and **implementation of IDMP at NMA/EU levels**
- Adaptation of Member States **cross-border digital health services** (ePrescription; Patient Summary…) to IDMP
- Exploration and implementation of IDMP for **pharmacovigilance** reporting, Medicinal Product Dictionaries (MPDs), **digital health** support services, patient empowerment

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UNICOM Action Lines

To achieve the objectives envisaged and reach the outcomes foreseen, UNICOM is organised along three closely interrelated vertical action lines:

I. **Implementation of IDMP at national and EU level (WPs 2 – 4)**

II. **Adaptation of cross-border digital health services (WPs 5 – 7)**

III. **Exploration for pharmacovigilance services, Medicinal Product Dictionaries [MPDs], healthcare services, patient empowerment, Big Data etc. (WPs 8 – 9)**

These three action lines are supported by two horizontal activity clusters:

a) **Further development of IDMP standards and implementation support (WP 1)**

b) **Socio-economic impact assessment and sustainability strategies, scientific coordination, project management, awareness raising/dissemination, ethics (WPs 10 – 13)**

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Core UNICOM activities by National Medicines Authorities (NMAs)

Action Line I: Implementation of IDMP at national and EU level

WP2: EU Substance Registration System (EU-SRS)

- **Implementation of EU-SRS**
  - EU regulatory-network-wide accessible, structured database
  - unambiguous identification of substances in medicinal products based on their scientific properties
  - in accordance with ISO IDMP standard 11238 (Substance IDs) and ISO standard 19844 (Implementation guidelines for ISO 11238 for data elements and structures)
- **Heads of Medicines Agencies (HMA) endorsed implementation plan (first phase ready by 2021/22)**
- **Will be linked with EMA SPOR (substances, products, organisations, referentials) IDMP-compatible databank system, particularly SMS [Substance Management System])**

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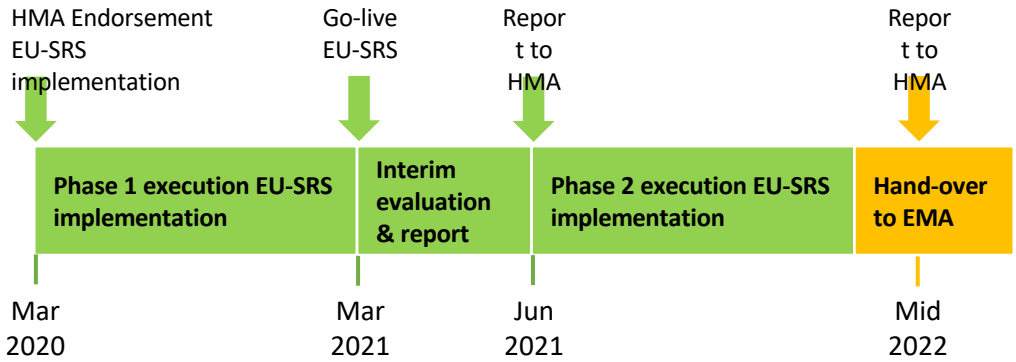
Roadmap EU-SRS Implementation



Phase 1:

- Continue data cleansing (chemicals, proteins, vaccines, polymers (H+V))
- Q2/2020: Installation EU-SRS (GSRS version 2.5.1) – used for cleansing of e.g. vaccines
- Q4/2020: Installation & validation EU-SRS (GSRS version 3.0)
- Q1/2021: Load cleansed data into EU-SRS
- Q1/2021: Go live EU-SRS for use by EU Regulatory Network
- Training, Substance Management Process & Governance, discuss veterinary substance management

Onboarding Team: Substance Validation Group (SVG)

Organization	#SVG members	Country
NoMA	1	Norway
EMA	2	Europe
MPA	1	Sweden
AEMPS	2	Spain
MEB	Chair, 3H, 1V	Netherlands
SUKL	1	Czech Republic
BfArM	2	Germany
Ages	2	Austria
JAZMP	1	Slovenia
WHO-UMC	1	World
ANSES	1V	France

WP 3: IDMP compliant ‘Application Forms’ (CESP)

UNICOM

- Applying for authorisation of medicinal products & managing their life cycles
- Electronic tools and forms compliant with IDMP
- IDMP compliant electronic tools supporting
  - Initial application
  - Variation
  - Renewal activities
- Replace the legacy PDF-technology based application forms with the web-based CESP Dataset Module
- Integration with EMA’s SPOR services
- Ensure well-structured IDMP compliant interoperable drug information for all further processes and actors

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UNICOM WP 3 in short

- Applying for authorisations for medicinal products and managing their life cycles is a regulated process supported by **electronic application forms** and **supporting electronic tools**.
- At the moment neither application forms nor the tools for initial authorisations, variations and renewals are **compliant** to the IDMP standards.
- Thus it is currently not possible to start, automate and feed regulatory processes with IDMP compliant/structured data and easily re-use the data in EU-wide eHealth services.

- Providing application forms based on IDMP-standards enables harmonised structured data for all following consumers and processes.

- 7 National competent authorities work together in this WP to refactor the application forms plus tools towards IDMP
  - Austria, Spain, Netherlands, Germany, Ireland, Sweden, Norway
- This WP will be aligned with a planned EMA/HMA telematics project called “CESP Phase 2” which will utilize the results and implement the outcomes in the regulatory network.

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WP 4: IDMP Implementation at National Medicines Authorities

- **11 national implementation projects**
- **Austria, Belgium, Croatia, Estonia, Finland, Germany, Ireland, Norway, Portugal, Spain, Sweden, (The Netherlands)**
- **Development of guidelines, training and knowledge about IDMP**
- **Adaptation of the European Communication and Tracking System (CTS)**
  - Used for tracking and co-ordinating pre- and post-licensing regulatory processes
  - for human and veterinary medicinal products
  - authorised via mutual recognition and decentralised procedures

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IDMP and European crossBorder digital health services (ePrescription; Patient Summary)

Action Line II: Adaptation of cross-border digital health services

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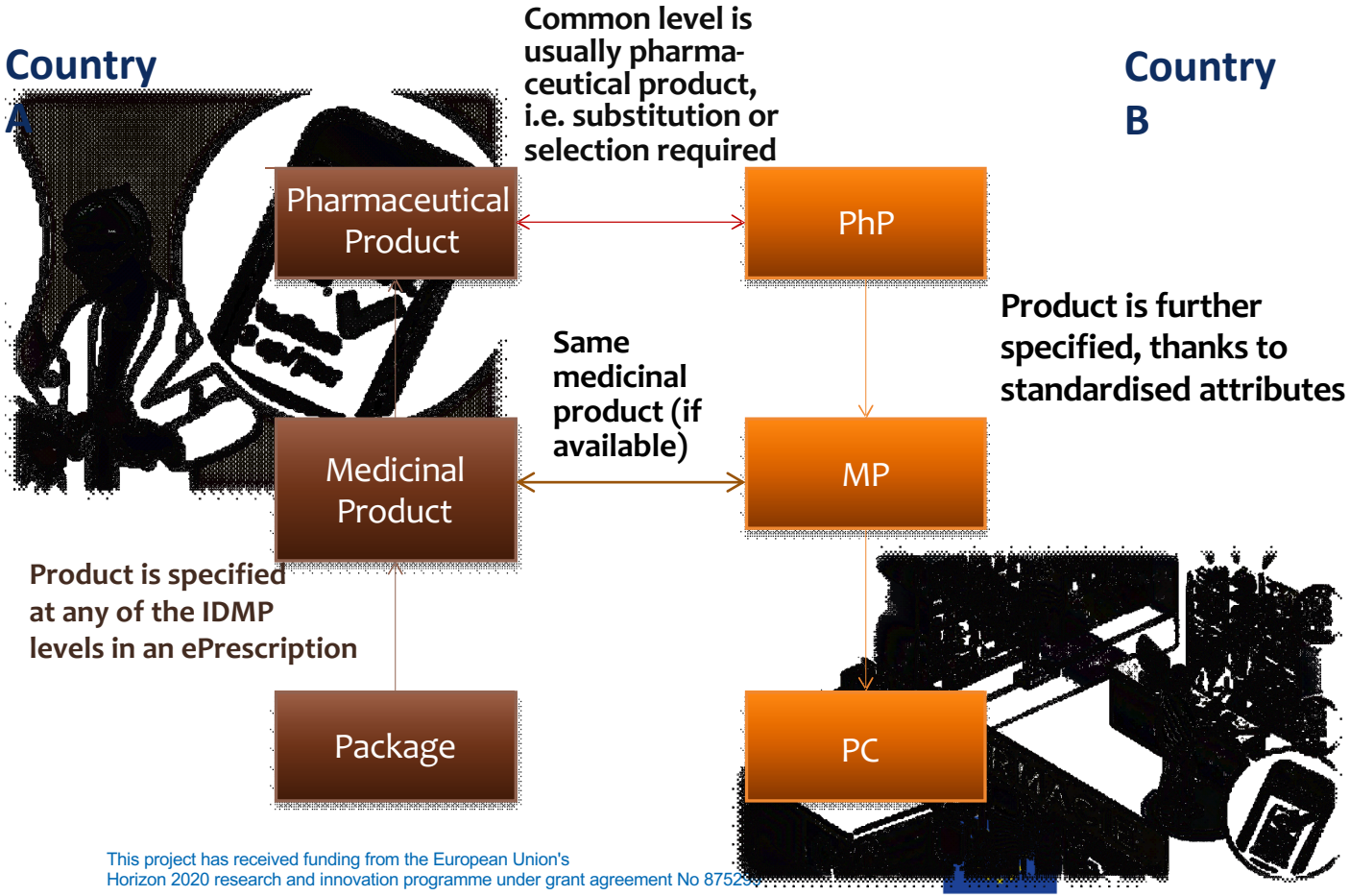
Use Case: xBorder ePrescription & dispensation process



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Changes foreseen on EU eHealth Digital Services Infrastructure (eHDSI)

- **Functional specifications revised** to include the adoption of ISO IDMP
  - **Revision** of the CEF eHDSI **Master ValueSet Catalogue (MVC)** for the ValueSets affected by the adoption of ISO IDMP coding
- **Guidelines and recommendations for implementation** of eP / eD and PS processes
- **The Implementation Guides of eP/eD and PS** are used by Member States to **implement the HL7 CDA documents and by the CEF eHDSI Solution Provider**
- Relevant CEF eHDSI **Change Proposals will be drafted** and submitted to the CEF eHDSI
  - These Change Proposals will **address technical specifications and the OpenNCP components** and functionalities

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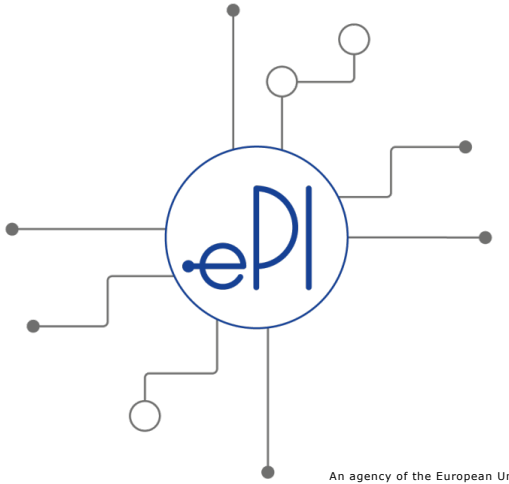
Can we re-use data/aligned with other projects in the pipeline/on the horizon?

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

HMA
Heads of Medicines Agencies

European Commission

Electronic Product Information (ePI) for EU medicines



ePI key principles

1. **ePI and EU common standard definitions**
2. **Expansion of access to information on medicines**
3. Accessibility to users with diverse abilities
4. Creation of efficiencies in administration of regulatory procedures
5. Complementarity to paper package leaflet

ePI key principles

6 Open access to regulator-approved information

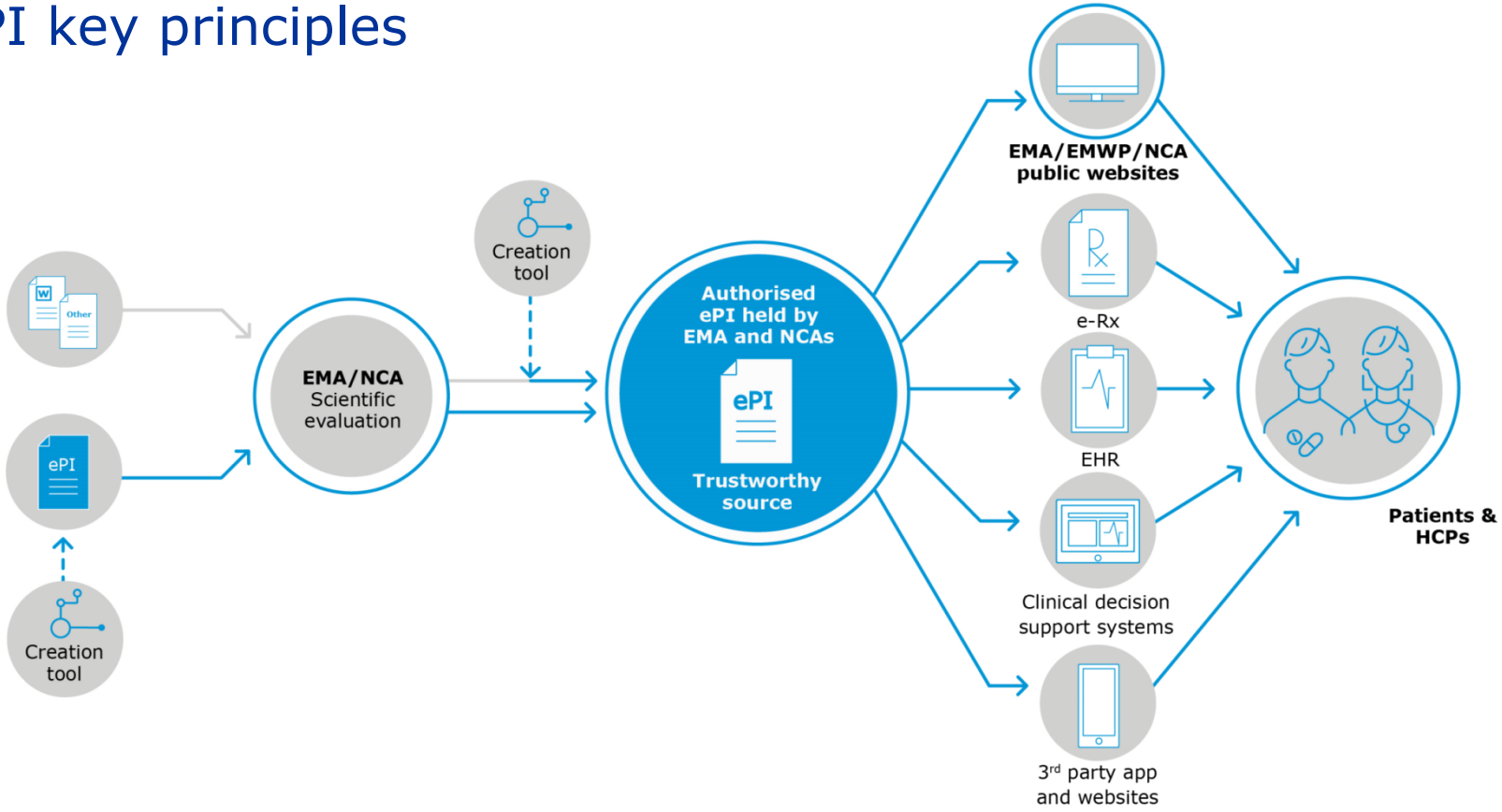
7 Data protection

8 Flexibility in implementation

9 Support for multilingual PI

10 **Interoperability with EU and global initiatives**

ePI key principles



ePI-Templates – how it could look like?

They are based on the existing templates (QRD) for the 'paper-version'

1. NAME OF THE MEDICINAL PRODUCT [H1]

{INVENTED NAME} {5 mg} {orodispersible tablet}
{INVENTED NAME} {10 mg} {orodispersible tablet}

2. QUALITATIVE AND QUANTITATIVE COMPOSITION [H1]

Each {orodispersible tablet} contains {5 mg} {donepezil hydrochloride}, equivalent to {4.56 mg} of {donepezil} free base.
Each {orodispersible tablet} contains {10 mg} {donepezil hydrochloride}, equivalent to {9.12 mg} of {donepezil} free base.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM [H1]

{INVENTED NAME} {5 mg} {orodispersible tablet} are white, round tablets debossed 'XXXXX' on one side and '5' on the other side.

{INVENTED NAME} {10 mg} {orodispersible tablet} are yellow, round tablets debossed 'XXXXX' on one side and '10' on the other side.

Method of administration

{INVENTED NAME} should be taken orally, in the evening, just prior to retiring. The tablet should be placed on the tongue and allowed to disintegrate before swallowing with or without water, according to patient preference.

4.3 Contraindications

Hypersensitivity to {donepezil hydrochloride}, piperidine derivatives, or to any of the excipients listed in section 6.1.

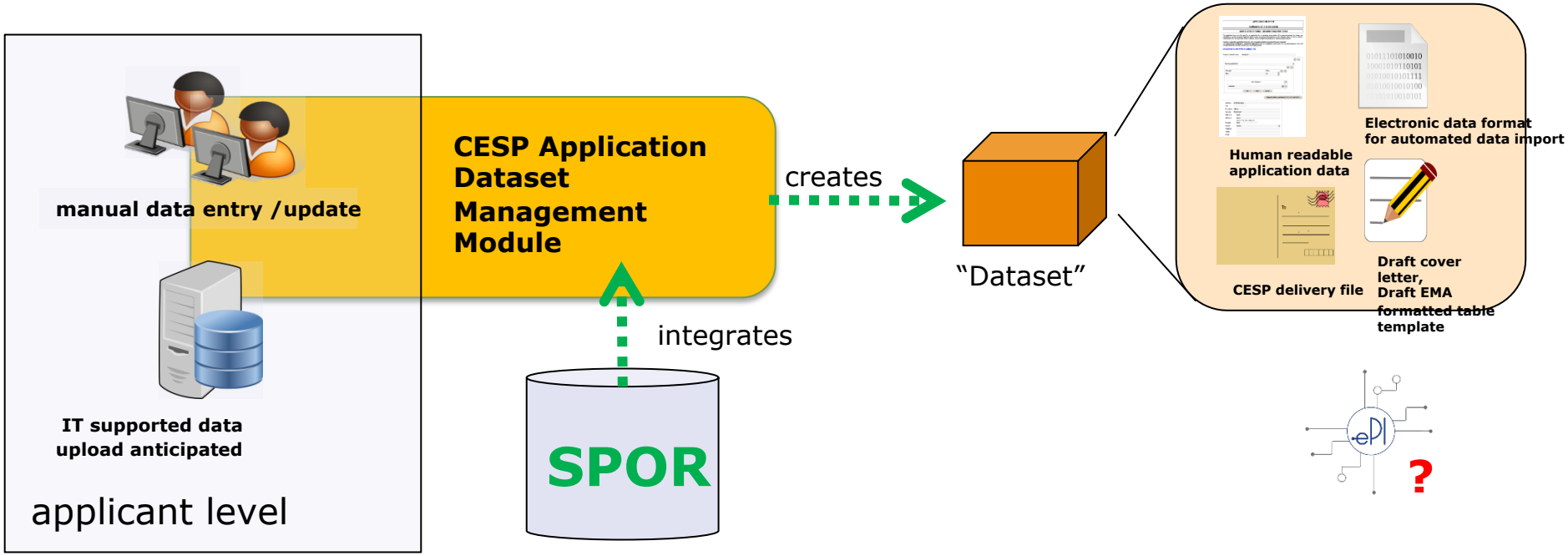
4.4 Special warnings and precautions for use [H2]

The use of {INVENTED NAME} in patients with severe Alzheimer's dementia, other types of dementia or other types of memory impairment (e.g., age-related cognitive decline), has not been investigated.

Conclusions:

- **eAF (and future CESP) is the carrier for the data entry in regulatory processes**
- PMS is the product master data used for regulatory processes (master data is the data that it is submitted once and reused multiple times)
- ePI is the statutory product information, as authorised during the regulatory processes.

CESP Dataset? This is UNICOM WP 3!



Thank you very much for your attention!

... and many thanks to

- ***Georg Neuwirther (AGES)***
- ***HMA WG 'Better use of Medicines'***
- ***ePI Roadmap WG***
- ***EMA***
- ***UNICOM***
- ***and the other usual suspects***

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