

EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

# EMA-HMA-EC ePI pilot & beyond

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RoteListe ePI Summit 2024

Presented by Elizabeth Scanlan on 5 March 2024  
ePI Product Owner, European Medicines Agency

An agency of the European Union



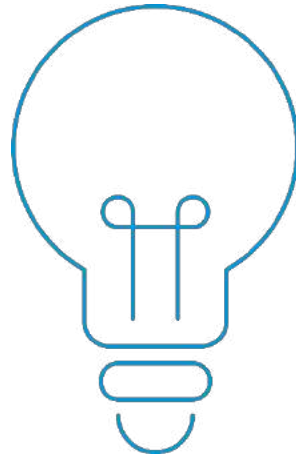


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The presenter does not have any conflict of interests.

**ePI** is authorised, statutory product information for human medicines (i.e. **summary of product characteristics, package leaflet and labelling**) in a semi-structured format created using the **EU ePI Common Standard**. ePI is adapted for electronic handling and allows dissemination via the web, e-platforms and print.



Key principles outline ePI benefits:  
published January 2020



# Benefits for patients & healthcare professionals.. ..regulators & companies

- Patient apps
- Digital & Video content
- Accessibility features
- Update alerts
- Targeted searches



- Rapid updates
- Link to national language ePI
- Timely access to up-to-date information in patient's language at point of need

- Support mitigation of medicine shortages
- Optimise signal validation
- Administrative efficiencies



*Agreement of a common standard will avoid a situation where multiple different standards are developed and used in different parts of the EU, which would generate unnecessary complexity, impede access to information and require multiple interfaces between standards, restricting flow of data.*

**EU ePI common standard** based on FHIR to support a harmonised ePI across the EU network

**F**ast

**H**ealthcare

**I**nteroperability

**R**esources

FHIR is: a set of XML (and/or JSON)  
health data resources, plus a REST  
API for accessing them



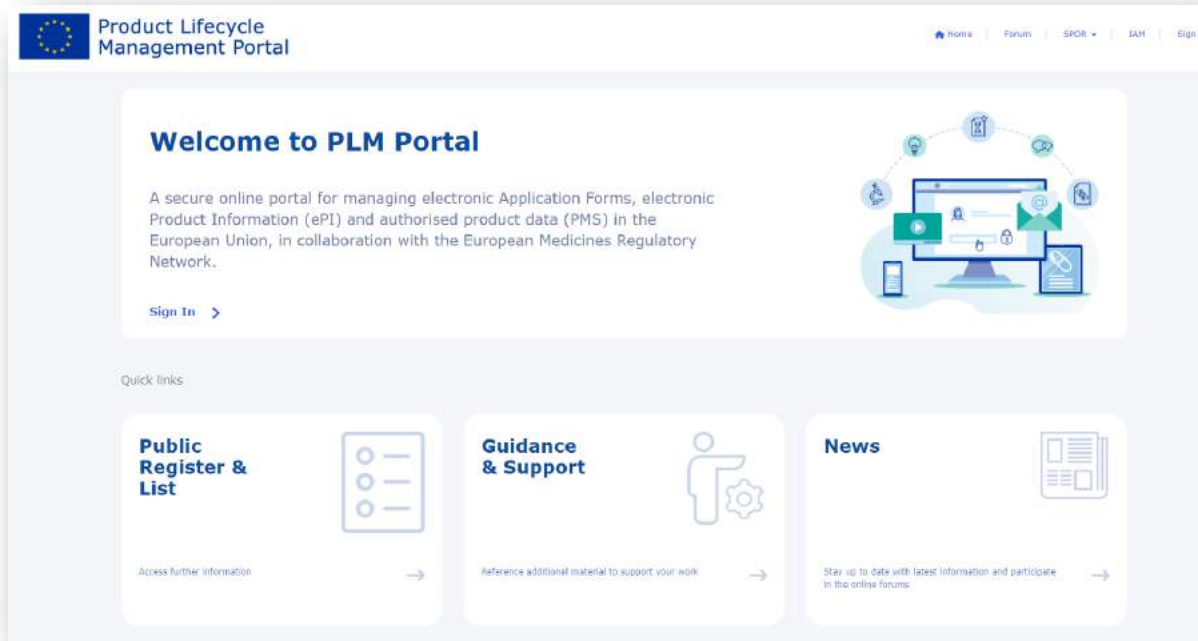
Adopted EU Common Standard for ePI published on GitHub:

<https://github.com/EuropeanMedicinesAgency/EU-ePI-common-standard>

<https://plm-portal.ema.europa.eu/>



Developed with funding by the European Union



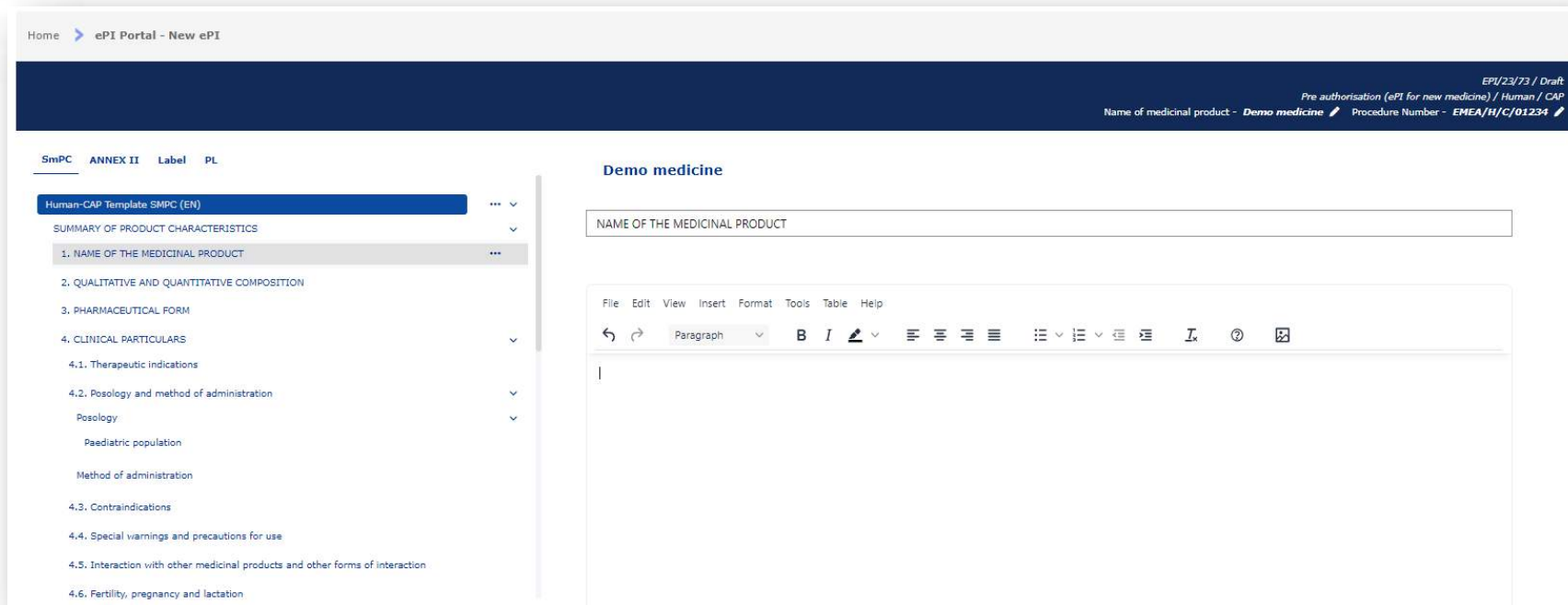
The screenshot shows the homepage of the Product Lifecycle Management Portal. At the top left is the EMA logo and the text 'Product Lifecycle Management Portal'. On the right, there are navigation links for Home, Forum, SPOR, IAM, and Sign In. The main content area features a 'Welcome to PLM Portal' section with a description: 'A secure online portal for managing electronic Application Forms, electronic Product Information (ePI) and authorised product data (PMS) in the European Union, in collaboration with the European Medicines Regulatory Network.' Below this is a 'Sign In' button. A 'Quick links' section contains three cards: 'Public Register & List' with a list icon and a link to 'Access further information'; 'Guidance & Support' with a person and gear icon and a link to 'Reference additional material to support your work'; and 'News' with a newspaper icon and a link to 'Stay up to date with latest information and participate in the online forums'.

From the same portal, applicants can manage ePI, electronic application forms and product data.

ePI features:

- ePI authoring & management
- Rich-text editing
- ePI export to FHIR/Word
- Repository & API

## Navigation within and across ePI documents



Home > ePI Portal - New ePI

EPI/23/73 / Draft  
Pre authorisation (ePI for new medicine) / Human / CAP  
Name of medicinal product - Demo medicine Procedure Number - EMEA/H/C/01234

SmpC ANNEX II Label PL

Human-CAP Template SMPC (EN) ...

SUMMARY OF PRODUCT CHARACTERISTICS ...

1. NAME OF THE MEDICINAL PRODUCT ...

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

3. PHARMACEUTICAL FORM

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

4.2. Posology and method of administration

Posology

Paediatric population

Method of administration

4.3. Contraindications

4.4. Special warnings and precautions for use

4.5. Interaction with other medicinal products and other forms of interaction

4.6. Fertility, pregnancy and lactation

Demo medicine

NAME OF THE MEDICINAL PRODUCT

File Edit View Insert Format Tools Table Help

Paragraph B I

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**Enable EMA & national regulators using ePI in live procedures to assess tooling and business processes**



**Collect feedback from companies creating ePI & using the API**



**Support ePI team in determining outstanding functional requirements & inform roadmap to implementation**





## Centralised

- 1) Type II — EN only
- 2) Art 61(3) — EN only
- 3) Renewal of Marketing Authorisation — EN only
- 4) Type IA — EN only
- 5) Type IB — EN only

No grouping/worksharing procedures or parallel variations

- Straightforward, shorter procedures piloted.
- EN only for CAPs, as translations will require advanced FHIR upload functionality



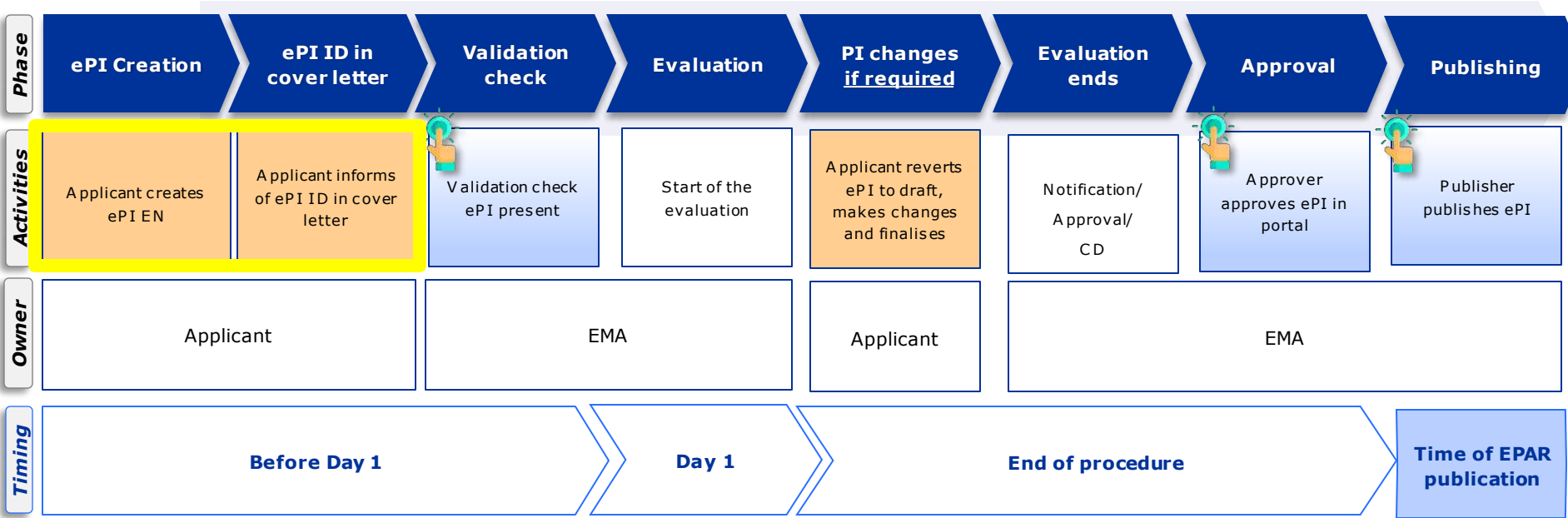
## National

- 1) AEMPS: ~5 procedures
- 2) DKMA: ~5 procedures
- 3) MEB: ~5 procedures
- 4) MPA: ~5 procedures

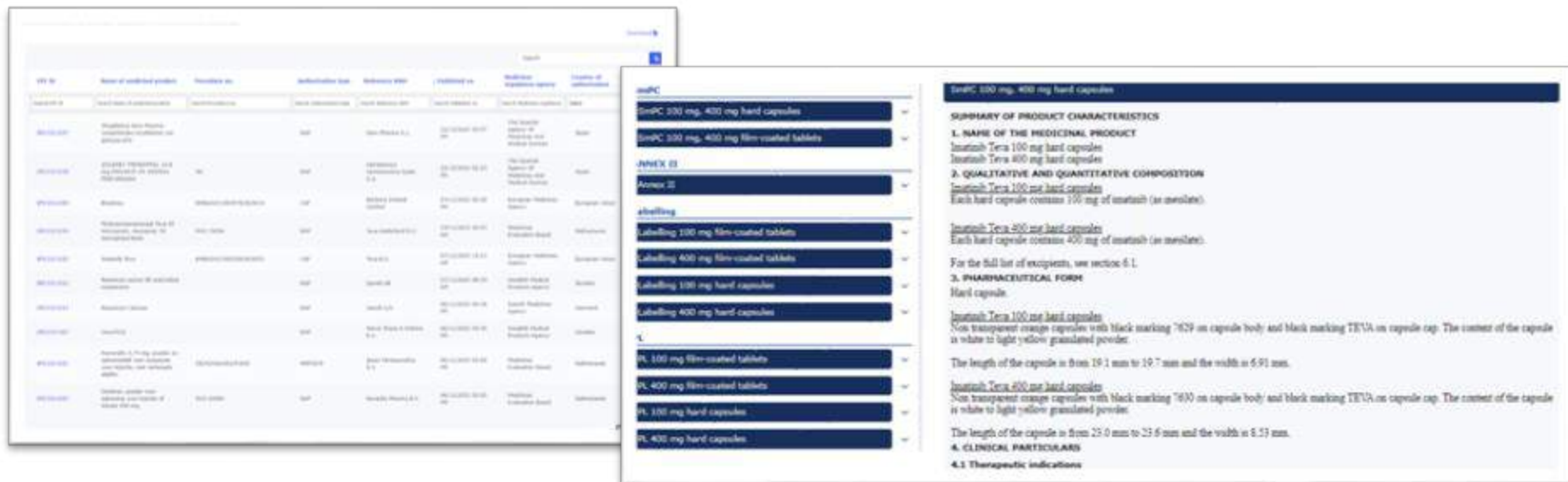
### Legend

- AEMPS:** Spanish Medicines and Healthcare Products Agency
- DKMA:** Danish Medicine Agency
- MEB:** Medicines Evaluation Board (Netherlands Medicines Agency)
- MPA:** Swedish Medical Product Agency

# Pilot ePI business process



- Duration: July 2023 – July 2024
- First ePIs published: <https://plm-portal.ema.europa.eu/ePIAll/>



The image shows a screenshot of the ePI portal. On the left is a table listing various medicinal products. On the right is a detailed view of the ePI for 'TevaPC 100 mg, 400 mg hard capsules'.

EMA ID	Name of medicinal product	Marketing authorisation holder	Authorisation type	Reference number	Valid from	Medicine classification	Number of authorisations
EMA1000001	Medicine A	Holder A	MA	EMA1000001	2023-01-01	Human	1
EMA1000002	Medicine B	Holder B	MA	EMA1000002	2023-01-01	Human	1
EMA1000003	Medicine C	Holder C	MA	EMA1000003	2023-01-01	Human	1
EMA1000004	Medicine D	Holder D	MA	EMA1000004	2023-01-01	Human	1
EMA1000005	Medicine E	Holder E	MA	EMA1000005	2023-01-01	Human	1
EMA1000006	Medicine F	Holder F	MA	EMA1000006	2023-01-01	Human	1
EMA1000007	Medicine G	Holder G	MA	EMA1000007	2023-01-01	Human	1
EMA1000008	Medicine H	Holder H	MA	EMA1000008	2023-01-01	Human	1
EMA1000009	Medicine I	Holder I	MA	EMA1000009	2023-01-01	Human	1
EMA1000010	Medicine J	Holder J	MA	EMA1000010	2023-01-01	Human	1

**TevaPC 100 mg, 400 mg hard capsules**

**SUMMARY OF PRODUCT CHARACTERISTICS**

**1. NAME OF THE MEDICINAL PRODUCT**  
 Inotrolic Tera 100 mg hard capsules  
 Inotrolic Tera 400 mg hard capsules

**2. QUALITATIVE AND QUANTITATIVE COMPOSITION**  
 Inotrolic Tera 100 mg hard capsules  
 Each hard capsule contains 100 mg of inotrolic (as mesilate).

**Inotrolic Tera 400 mg hard capsules**  
 Each hard capsule contains 400 mg of inotrolic (as mesilate).

For the full list of excipients, see section 6.1.

**3. PHARMACEUTICAL FORM**  
 Hard capsule.

**Inotrolic Tera 100 mg hard capsules**  
 Non-transparent orange capsules with black marking '629' on capsule body and black marking TEVA on capsule cap. The content of the capsule is white to light yellow granulated powder.

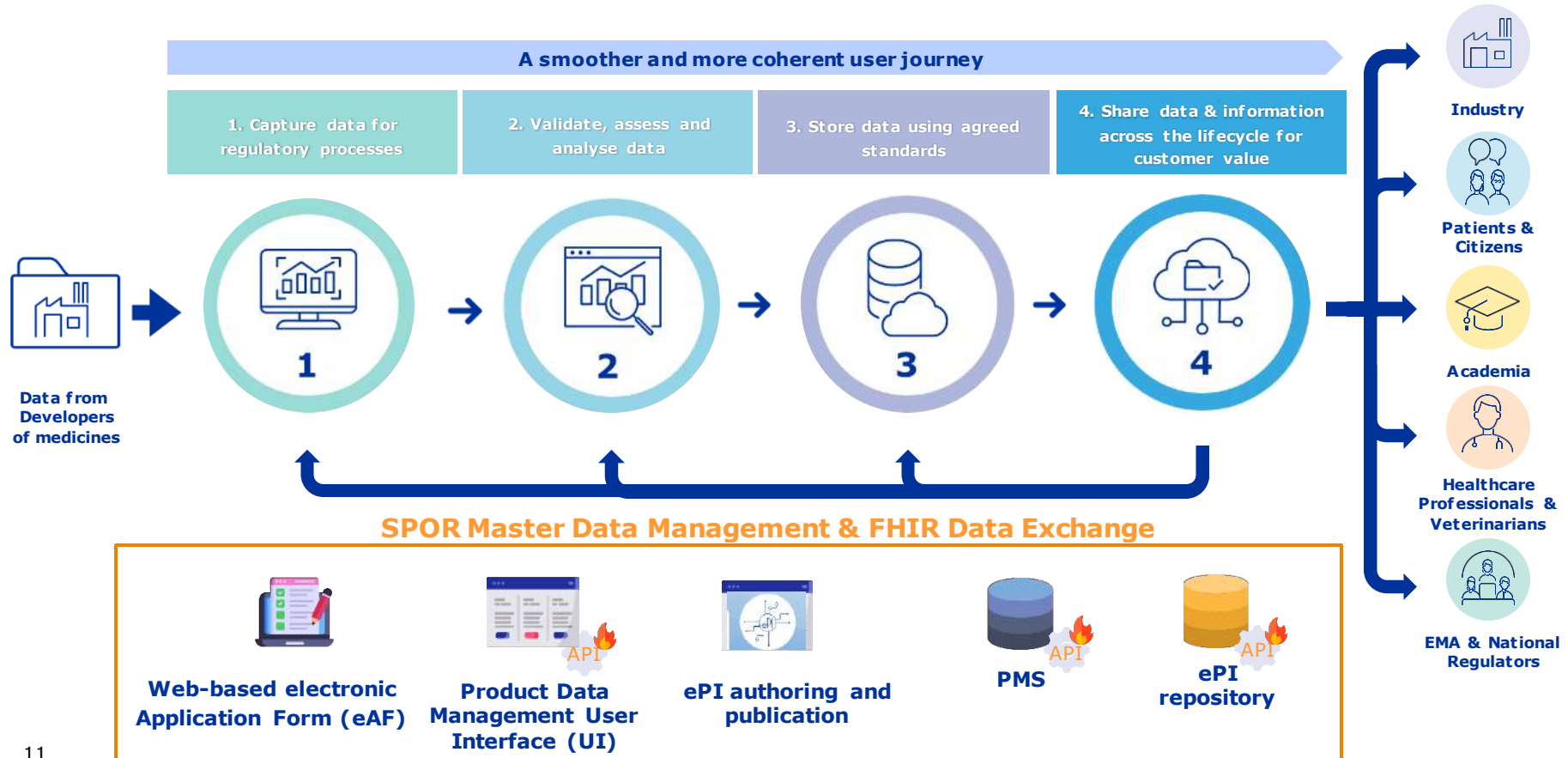
The length of the capsule is from 19.1 mm to 19.7 mm and the width is 5.91 mm.

**Inotrolic Tera 400 mg hard capsules**  
 Non-transparent orange capsules with black marking '600' on capsule body and black marking TEVA on capsule cap. The content of the capsule is white to light yellow granulated powder.

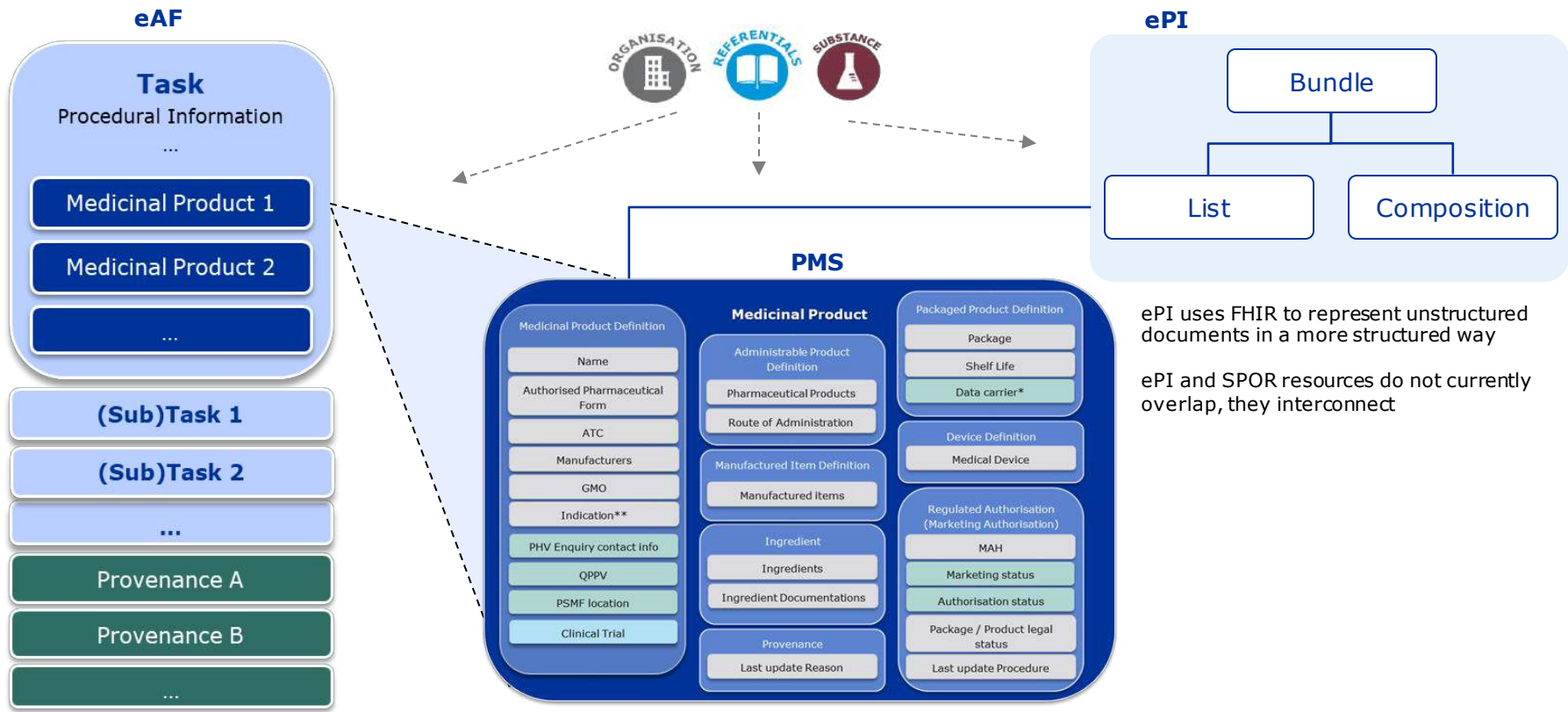
The length of the capsule is from 25.0 mm to 25.6 mm and the width is 8.33 mm.

**4. CLINICAL PARTICULARS**

**4.1 Therapeutic indications**



# FHIR in European Medicines Regulatory Network

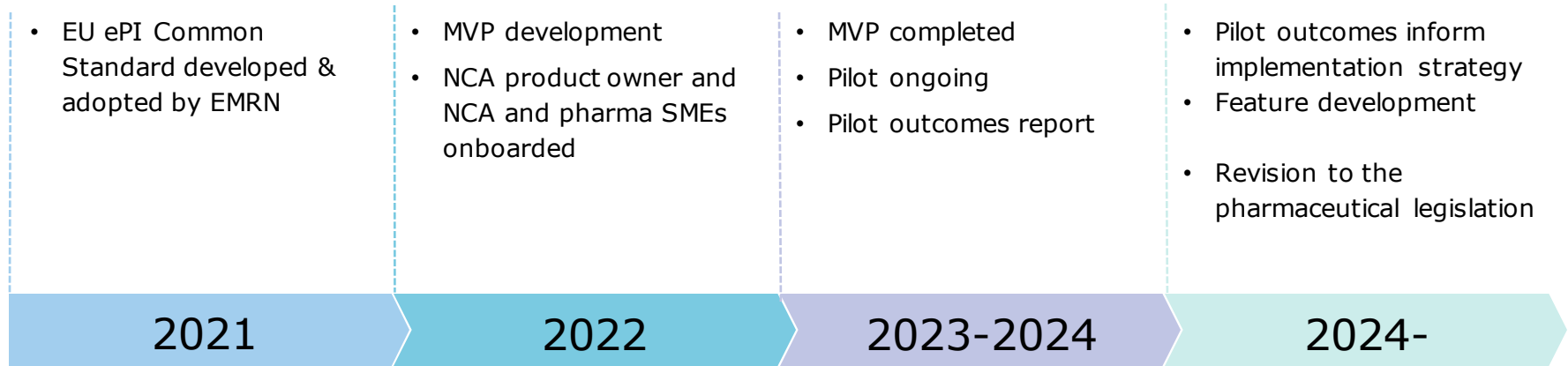


eAF FHIR messages includes/overlaps with the PMS product data  
12

PMS uses FHIR to represent IDMP-compatible Products and Substances

ePI uses FHIR to represent unstructured documents in a more structured way

ePI and SPOR resources do not currently overlap, they interconnect



Next **system demo** live on YouTube and EMA website on 26<sup>th</sup> March



# Thank you for your interest

## Further information

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**Send us a question** Go to [www.ema.europa.eu/contact](http://www.ema.europa.eu/contact)

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**ePI Summit**  
2024



**UNOCOM**

Up-scaling the global univocal identification of medicines

# ePI in the Medicinal Products Life Cycle, at National and Cross-Border Level

**Marcello Melgara**

UNICOM WP "Piloting Leader  
Lombardy Region DG Welfare / ARIA SpA, Milan - Italy

***Berlin, 05/03/2024***







**ePI Summit**  
2024

**UNOCOM**

Up-scaling the global univocal identification of medicines

**Global patient safety through semantic interoperability - the univocal identification of medicinal products**

***And their Understanding***



**MyHealth@EU**  
**MyData@EU**

Gravitate  Health



## Improving Patient Safety – a Never Ending Story

UN  COM

- ▶ **Only national markets for medicinal products**
- ▶ **Marketing strategies of pharmaceutical industry**
- ▶ **Data quality/legacy data for (older) medicines**
- ▶ **Product Information leaflets are in the “National” language**
- ▶ **Absence of ‘fit-for purpose’, globally agreed standards (concepts, data models, resources), coding systems, and implementation guidelines to ensure high quality data at all levels of use and for core/all actors**

***Data on medicines are probably the most widely used ones of any type of patient and health data, with the largest number of actors involved***



**The UNICOM project is helping to ensure that any medicine and what it contains can be accurately identified anywhere in the world. We are working to improve patient safety and enable better healthcare for all.**

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

## The Challenge

- ▶ A central issue in medicine-related events is the univocal identification of drugs
- ▶ It hinders the fast and reliable reporting, and integration of pharmacovigilance events
- ▶ “Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine-related problem”

## Mission

[www.ema.europa.eu/en/human-regulatory/overview/pharmacovigilance-overview](http://www.ema.europa.eu/en/human-regulatory/overview/pharmacovigilance-overview)

- ▶ Enabling the univocal identification of medicinal products by supporting and accelerating the
  - further development,
  - implementation, and
  - diffusion of ISO IDMP standards (IDentification of Medicinal Products)
- ▶ across European health systems, to
- ▶ facilitate the free flow of semantically coded interoperable drug information
- ▶ Across all data users, covering the full life cycle of a medicine
  - ▷ **Including “understandability” Patients / Health Professional**

- **Across health systems, the *same* medicinal product (MP) may have *different names***
- **Across countries, the *same* name may identify a *different* product (with a different *active* substance)**

Source: WHO Uppsala Monitoring Centre (UMC). WHODrug Best Practices. VER-SION 5.0 - 2017. Available from [https://www.who-umc.org/media/3128/whodrug-best-practices-vers-50\\_new.pdf](https://www.who-umc.org/media/3128/whodrug-best-practices-vers-50_new.pdf)

- **Across EU Member States, the number and kind of MPs authorised for national marketing differ very considerably (due to marketing strategies of producers, plus three different marketing authorisation procedures at EU and national levels)**
- **On the *same* medicinal product, e.g. one authorised via the ‘Centralised Procedure’ of EMA, national MP data bases regularly may contain *divergent* data**



- **EU national databases of authorised drugs contain between 5,000 to 20,000 (> 50,000 in DE) medicinal products, whereas the EMA database records > 500,000 for all EU Member States**
- **E.g., in cross-border ePrescription (eP) services this necessitates *substitution* in many, if not the majority of instances**
- **Substitution is only possible if the pharmacist can safely identify the medicine specified in the foreign prescription**
- **Similar challenges apply to the electronic recording of MPs in *other healthcare contexts***

**The missing univocal identification of medicines hampers timely global *pharmacovigilance* reporting and warnings**



**Conceptual Solution: Semantic Interoperability Across  
Data Users**





## Health system interoperability

*facilitates the recording, sharing, understanding and acting on patient and other health information among linguistically disparate medical professionals, patients and other actors within and across health systems in a collaborative manner*

### Barriers:

Absence of 'fit-for purpose', globally agreed **standards** (concepts, data models, resources), **coding systems** and **implementation guidelines**

- ▶ What is your role in the life-cycle of a medicinal product?



**Semantic interoperability will facilitate data sharing across the full life cycle and all actors involved in handling MP information**

- **Pharmaceutical companies**
- **National Medicinal Products Regulatory Authorities (NMAs)**
- **Pharmacovigilance Systems (patient safety)**
- **Providers of medicinal product dictionaries**
- **Clinical software producers (EHR, Hospital Information, CDS, CPOE, PS, ePrescribing systems)**
- **Healthcare professionals using these systems**
- **Pharmacy Systems (Order Systems, Supply Chain/Logistics/Stock Management Systems)**
- **eProduct Information/Patients/Intelligent apps for patient empowerment**
- **National ePrescription Systems**
- **xBorder digital health services**
- **Clinical trials/medical research**
- **Health systems & Public Health**

**and across different languages, alphabets, health cultures**

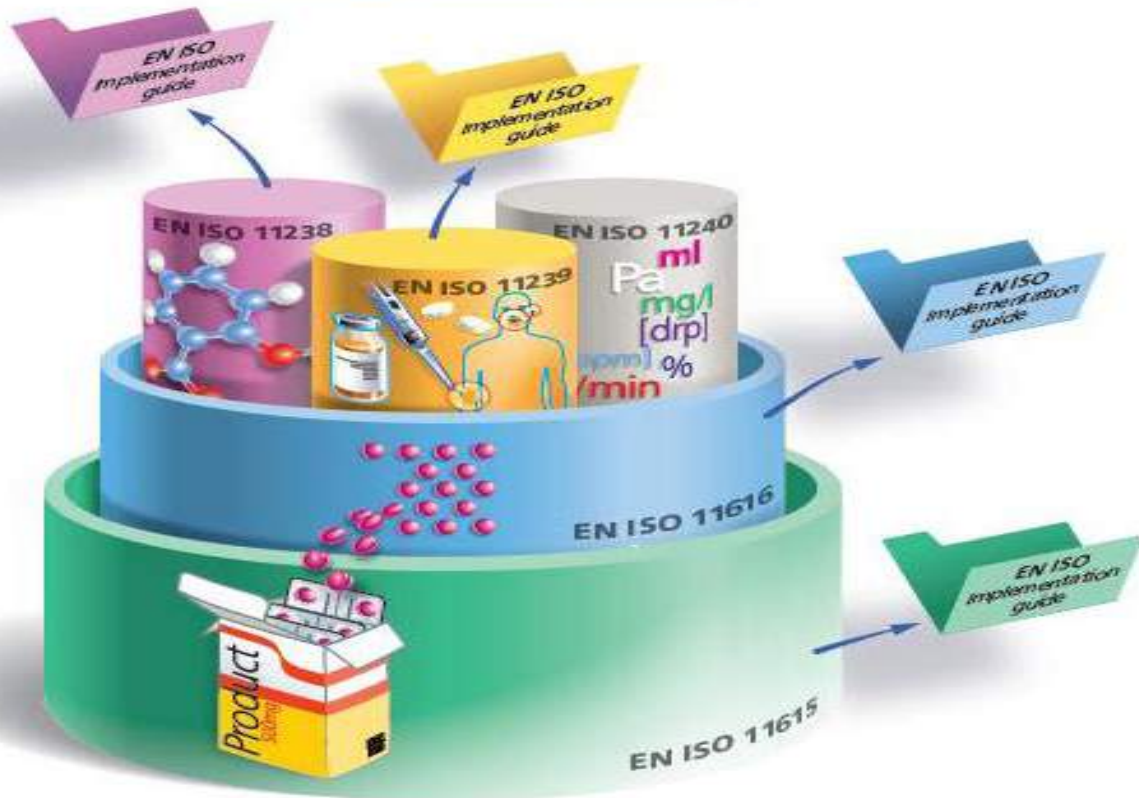


## Concrete Solution:

# International Organization for Standardization (ISO) Identification of Medicinal Products (IDMP) Suite of Standards, and their harmonised adoption among NCAs

## IDMP

Identification of Medicinal Products  
Data elements and structures  
for the unique identification and exchange

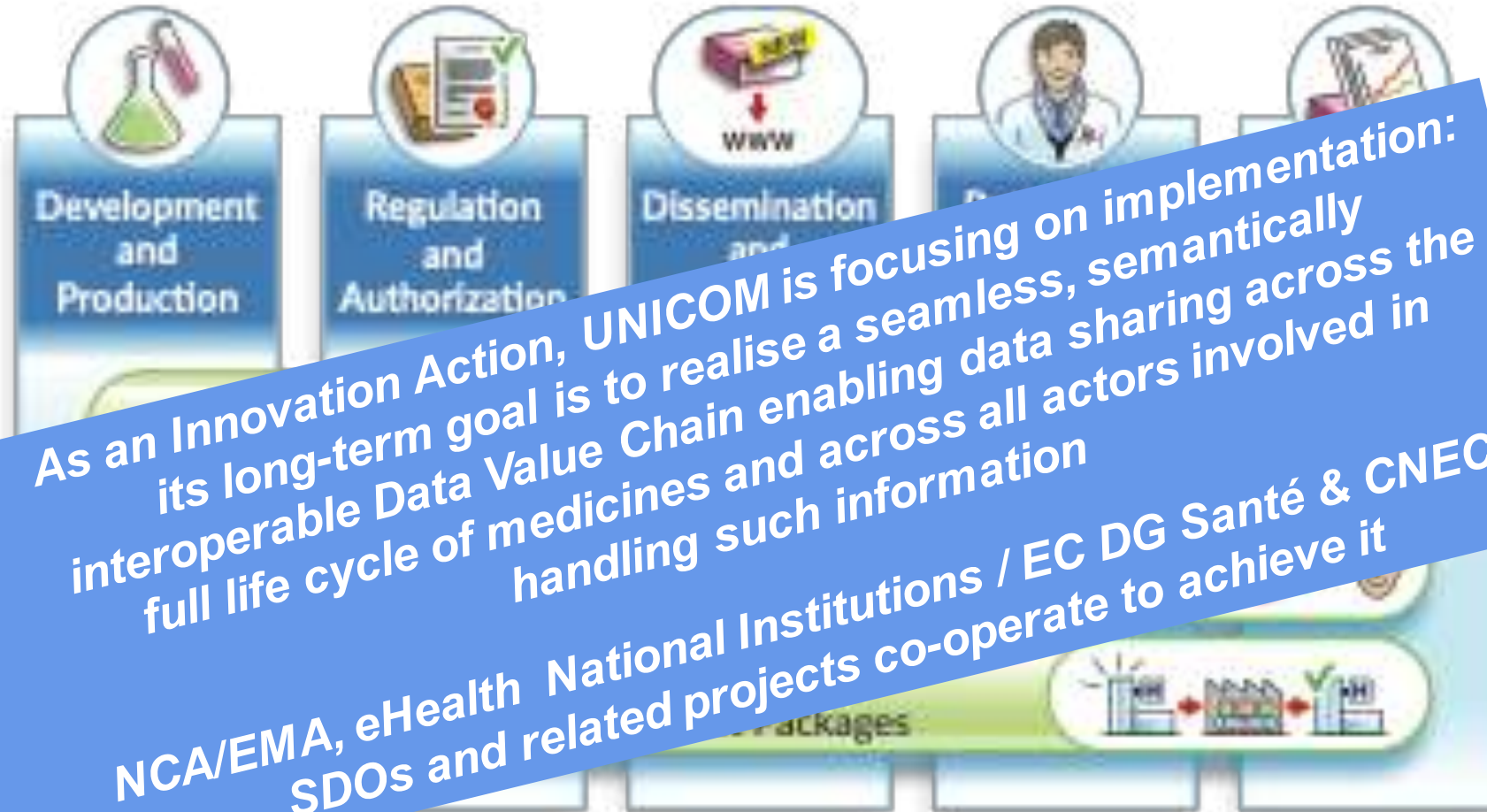


The ISO IDMP standards establish definitions and concepts and describe data elements and their structural relationships that are required for the unique identification of:

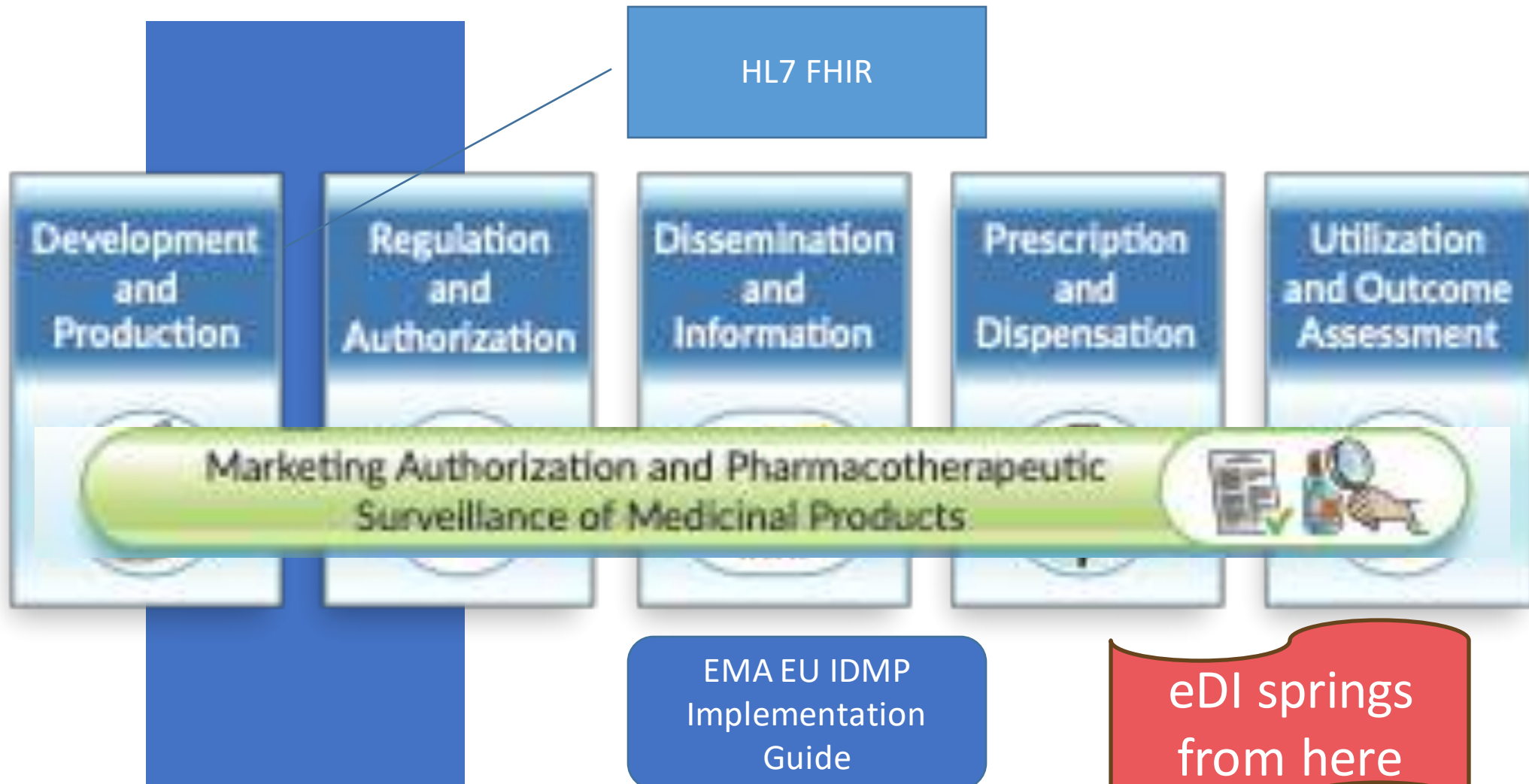
- **Medicinal Products** (MPID) and **Packages** (PCID) - ISO 11615
- **Pharmaceutical Products** (PhPID) - ISO 11616
- **Substances** (Substance ID) - ISO 11238
- **Pharmaceutical Dose Forms**, units of presentation, routes of administration and packaging - ISO 11239
- **Units of Measurement** (UCUM) - ISO 11240

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

- ▶ What is your role in the life-cycle of a medicinal product?







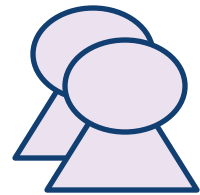
# IDMP/FHIR compatible Electronic Application Forms

## PLM: Product Life Cycle Management

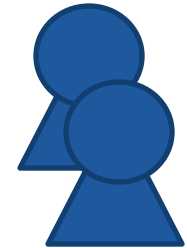


**Web Tool supporting IDMP/FHIR compatible application dataset formats**

**New**



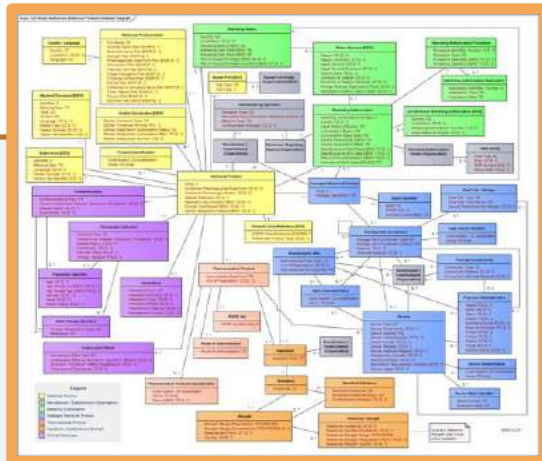
Applicants



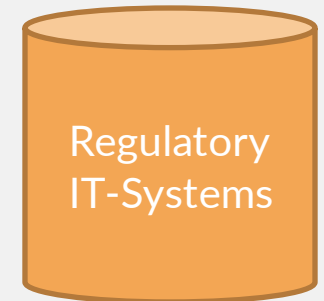
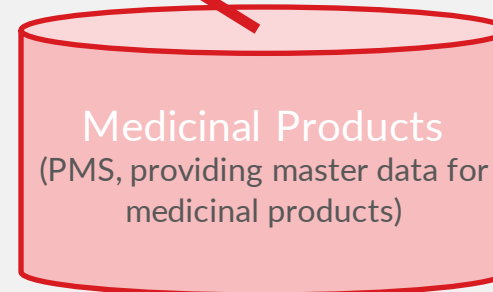
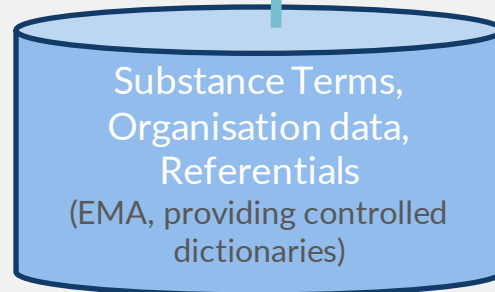
Regulators

**New Retrieving master data**

**New IDMP/FHIR format**



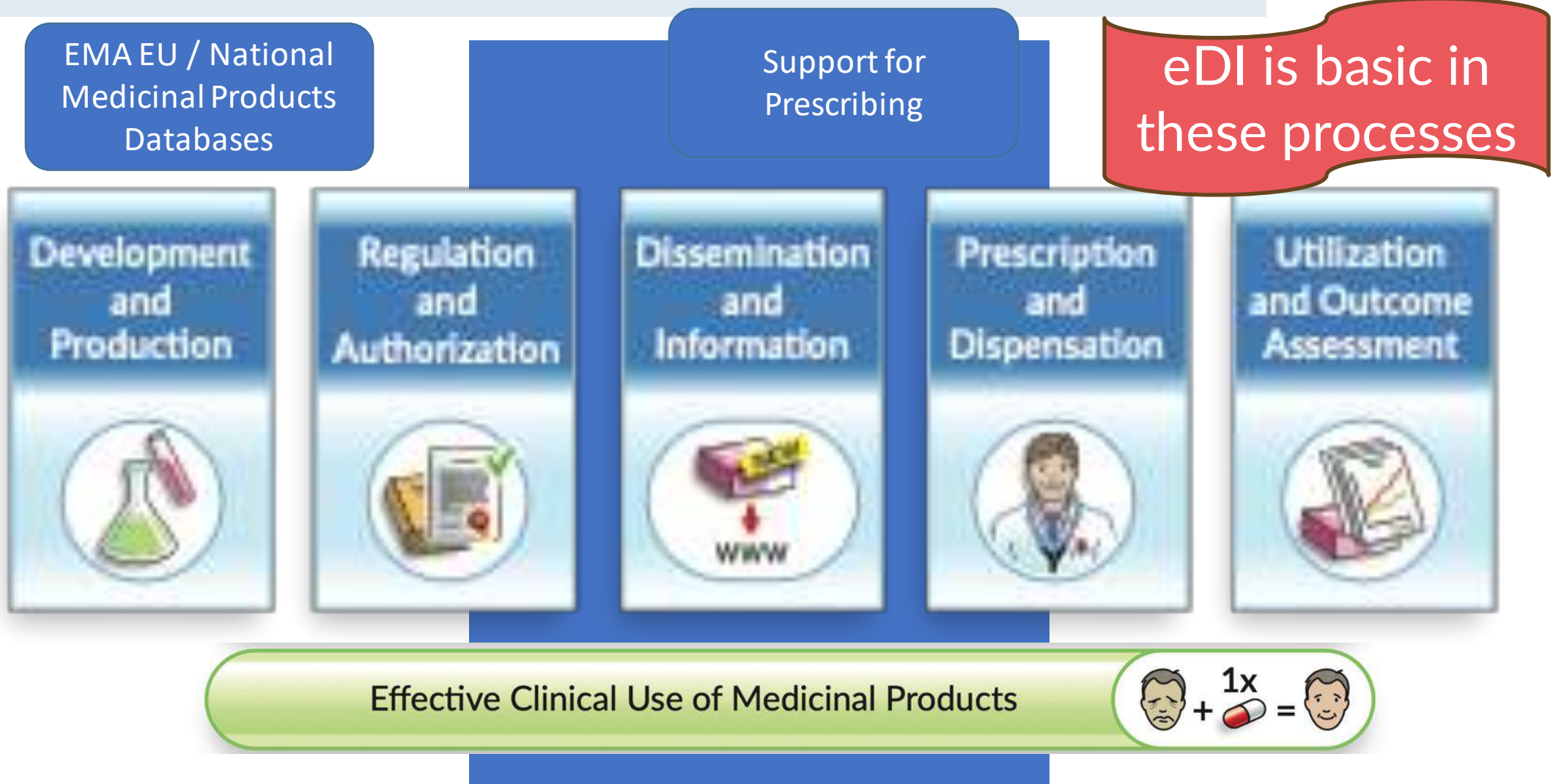
ISO IDMP Data Model



**See also collaboration with UNICOM WP4**



# Dissemination and Information



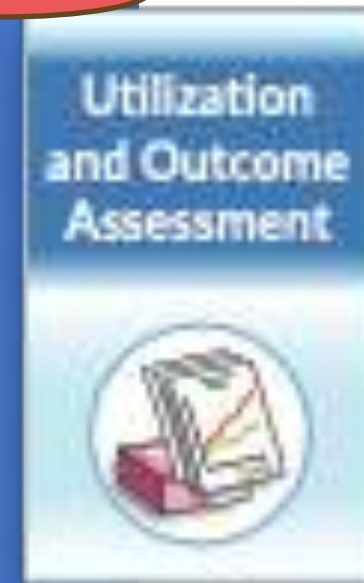
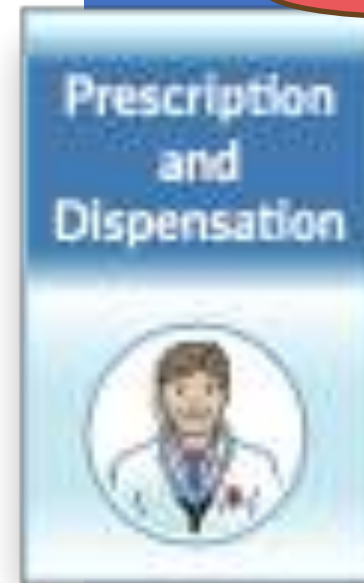


# Dispensation at National and Cross-Border level

EMA EU / National  
Medicinal Products  
Databases

Support for  
Dispensing

eDI: a support in  
these processes



Effective Clinical Use of Medicinal Products

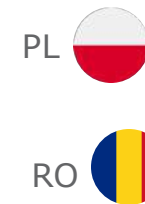
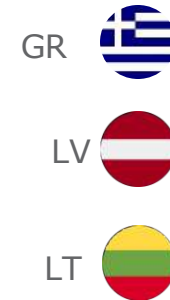
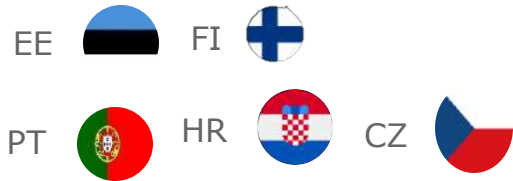


# MyHealth@EU Roadmap



## More and more Member States going live with the services

EP

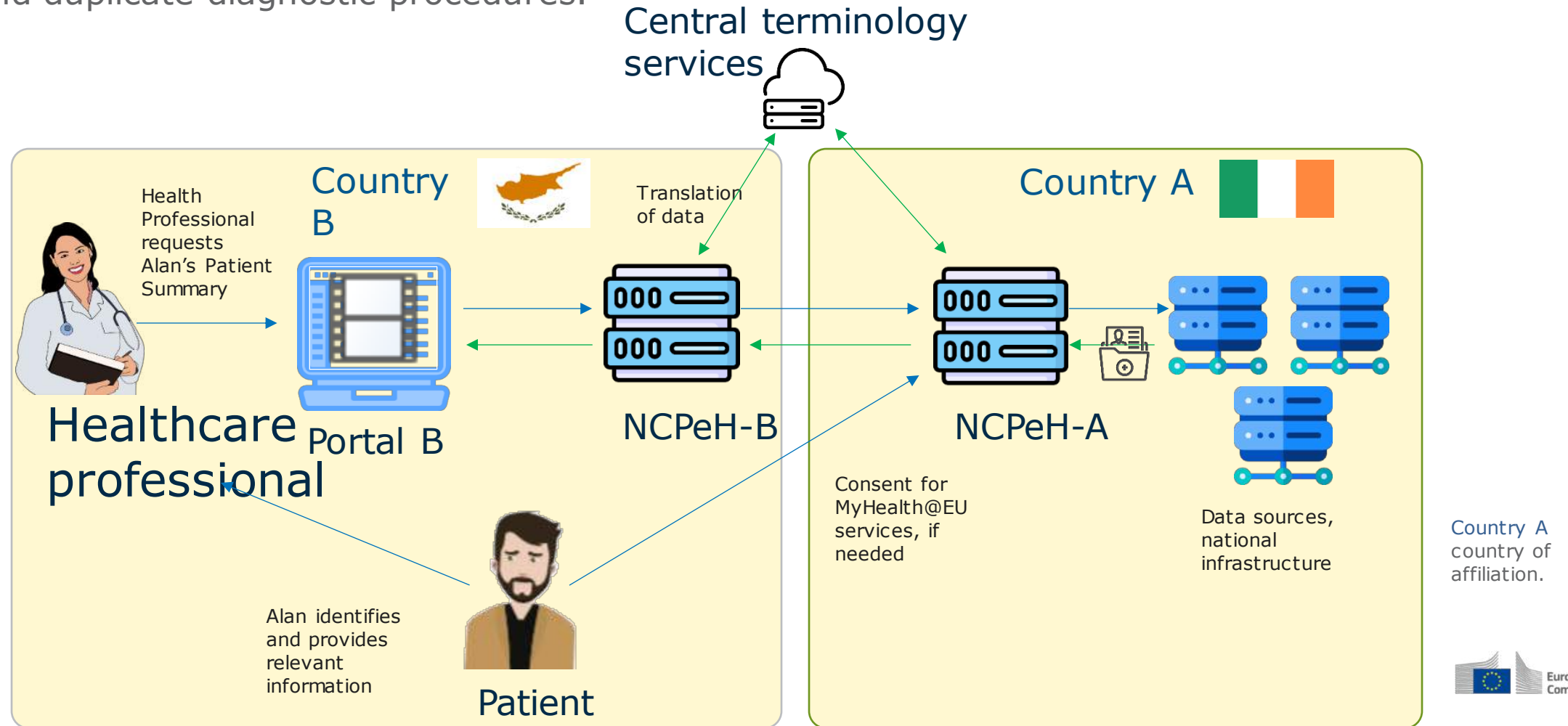


PS

# Current supporting MyHealth@EU infrastructure

The current MyHealth@EU infrastructure connects Member States National Contact Points for eHealth (NCPeH) giving **healthcare professionals access to the patient's data**.

In this scenario Patient Summary is returned and displayed in the portal to the healthcare professional in their own language thereby **enhancing the patient's treatment**. **Reducing the potential for clinical errors** and duplicate diagnostic procedures.



- ▶ In case of more than one EMA attribute is available, the **red ones** should be preferred
  - ▷ Presented in a flat list (to facilitate the presentation), but **IT MUST** be considered as a structured model.

eHDSI data elements	Preferred coding system	Attributes from EMA IG version V2.1 (2021-02)	
		#	Attribute
Active Ingredient	SPOR-SMS	5.5.1.	Substance (code)
		<b>5.5.3.1.</b>	<b>Reference Substance (moiety)</b>
Ingredient role	SPOR-RMS	5.1.	Ingredient role
ATC code	WHO - ATC	<b>1.13.3.</b>	<b>ATC Code (s)</b>
Medicinal Product Code		-	Pharmaceutical Product Identifier (PhPID)
		1.2.	Medicinal product identifier (MPID)
		4.1.	Packaged Medicinal Product Identifier (PCID)
		1.1	Product Management Service Identifier (PMS ID)
Marketing Authorisation Holder	SPOR-OMS	2.8.	Marketing Authorisation Holder (Organisation)
Brand Name of the Medicine		1.14.1.	Full name
Medicinal Product Package	EDQM/UCUM	4.3.	Pack size
		<b>4.7.1.</b>	<b>Package item (container) type</b>
		<b>4.7.5.</b>	<b>Package item (container) quantity</b>
Package size	EDQM/UCUM	4.10.2.	Manufactured Item Quantity
Strength of the Medicinal Product	EDQM/UCUM	5.5.2.2.2.	Strength (Presentation single value or low limit)
		5.5.2.3.2.	Strength (Concentration single value or low limit)
		<b>5.5.3.3.2.</b>	<b>Reference strength (Presentation single value or low limit)</b>
Pharmaceutical Dose Form	EDQM	6.2.	Administrable Dose Form
		<b>1.5.</b>	<b>Authorised Pharmaceutical Form</b>
		4.10.3.	Manufactured Dose Form
Quantity Unit	EDQM	<b>6.3</b>	<b>Unit of presentation</b>
		4.10.1.	Unit of presentation
Route of Administration	EDQM	<b>6.6.</b>	<b>Route of Administration</b>

Obtain the coded data from NCAs/EMA

ePrescription and Patient Summary contain posology and instructions as coded data

EMA EU / National Medicinal Products Databases

Support for cross-border understanding of local / substituted medicinal products

eDI: the basic tool for patients

Development and Production

Regulation and Authorization

Dissemination and Information

Prescription and Dispensation

Utilization and Outcome Assessment

Effective Clinical Use of Medicinal Products

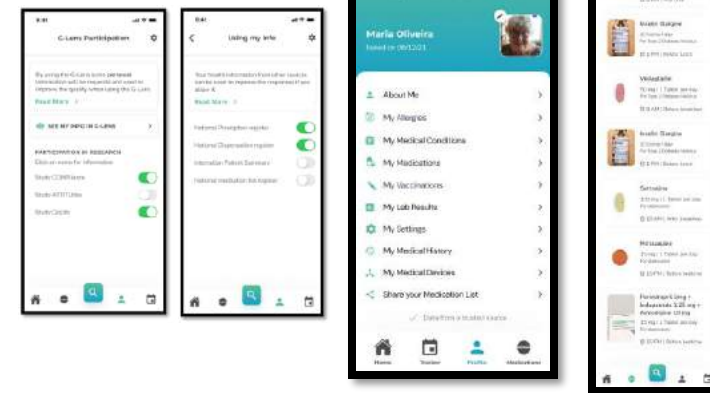






# Illustrating work in GRAVITATE HEALTH

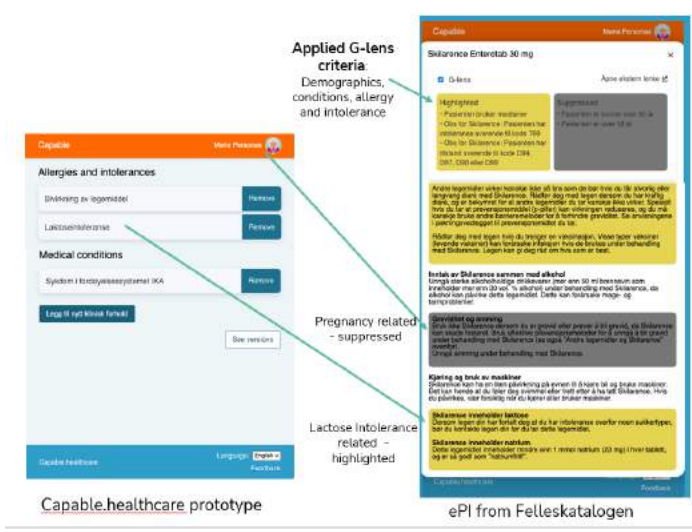
Defining the G-lens design methodology - personas



User experience - information services - mock-up -

User advisory group and healthcare ecosystems – ‘patient voice’ and capacity building. Active external engagement, connections and presence.

Accessing cross-border product information (preferred EU language)\*



Example of basic G-lens taking Patient Summary info for focusing of product information\*

\* A global HL7 FHIR standard for ePI is in development based on this work. See [here](#).

Multi-lingual focused information  
ePrescription – (e)Dispensation

FHIR ePI IG  
medicinal product info

Cross-border mobility  
- trust and safety -



- 1 List
- 2 Bundle
- 3 Composition
- 4 Binary
- 5 Organization
- 6 RegulatedAuthorization
- 7 MedicinalProductDefinition
- 8 PackagedProductDefinition
- 9 AdministrableProductDefinition
- 10 ManufacturedItemDefinition
- 11 Ingredient
- 12 ClinicalUseDefinition
- 13 Substance



## IMPROVING ACCESS UNDERSTANDING

*Language – Focusing Content*  
Risk Minimization – Patient Safety



**STANDARDS**  
**EEHRxF – EHDS**  
**ISO IDMP → PhPID**  
**FHIR Interoperability**



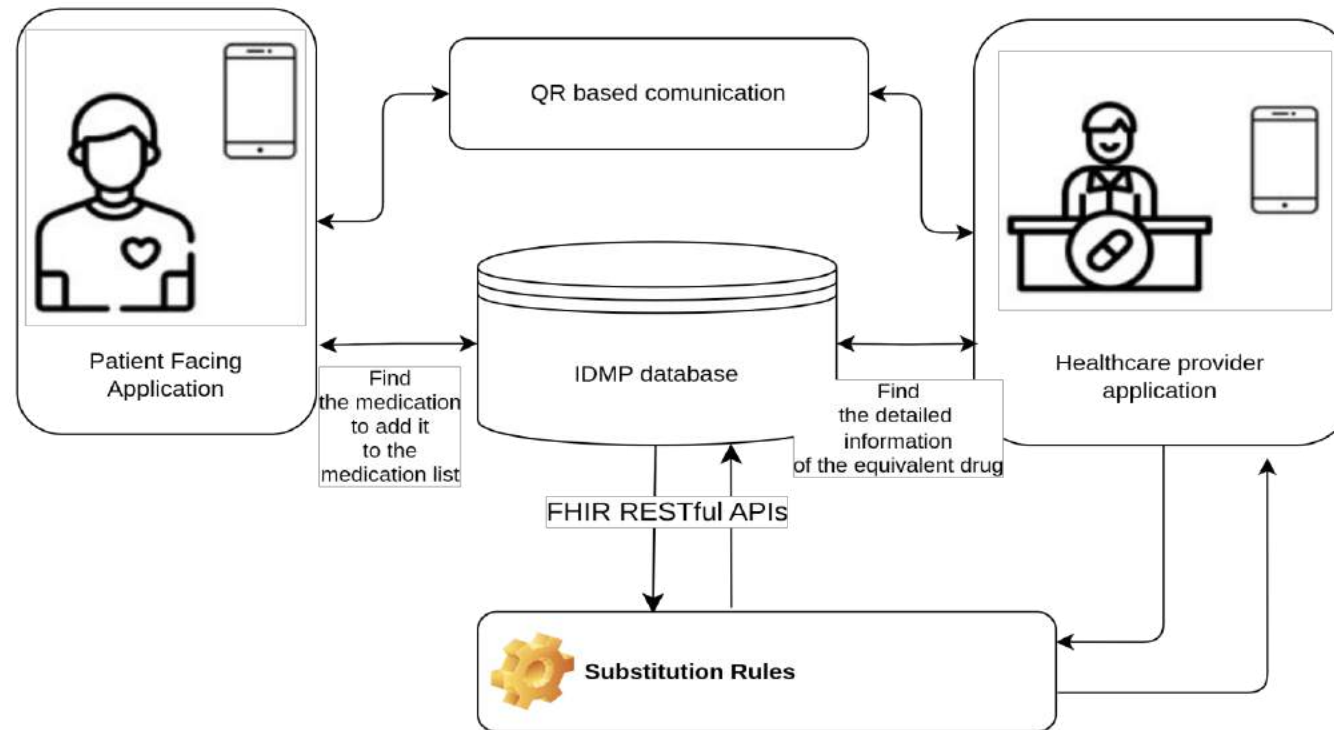
Dispense  
Demonstrate  
Substitute (if need)  
**SUSTAINABLY  
DEPLOY**

Main resources that the application is able to retrieve are:

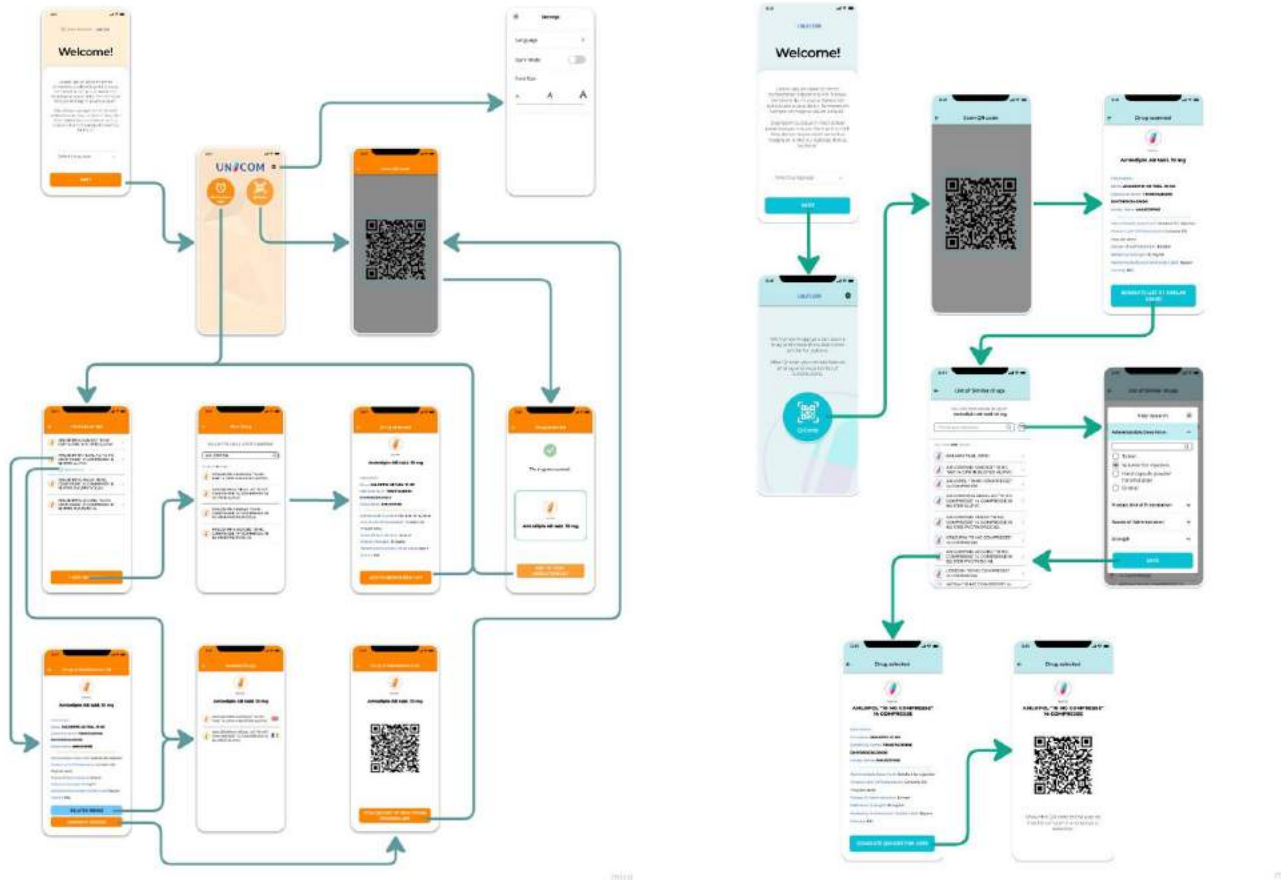
1. The user and their settings
2. The medication list

Main functionalities that the application is capable of performing are:

1. Retrieve the medicine
2. Finding cross-border equivalent drugs















## Main features

- Usage of the Smart Substitution component
- Access through FHIR API to IDMP Database
- Interaction with other required API's
- **Open source**

API Documentation: [UNICOM - WP6 API](#)

-  ePI represents a significant step ahead, by providing structured documents with coded sections
-  This works well into a specific Country, but going cross-border issues of interoperability / understandability arise, especially due to the need of substituting with locally registered medicinal products
-  ISO PhPID may help in finding Equivalent medications, with ePI in different languages, however PhPID does not include excipients, frequent cause of allergies
-  ISO MPID / PCID may help finding the same medicinal products registered in other Countries
-  The great step ahead would be taking full advantage of EMA/SPOR, ISO IDMP based coded data, to include coded info into the ePI, allowing the translation process like MyHealth@EU ePrescription and Patient Summary

which include Posology, Instructions for the patient and Allergies (as for the PS)

-  **The information presented is derived from the UNICOM Innovation Action, which receives funding from the European Commission Directorate General for Communications Networks, Content and Technology, in the context of the European Horizon 2020 research and innovation programme under grant agreement No 875299 - support which is gratefully acknowledged.**
-  **Neither the European Commission nor any person acting on behalf of the Commission is responsible for the use which might be made of the information presented. The views expressed are solely those of the author(s) and do not necessarily reflect those of the European Commission or any other organisation.**
-  **We are most grateful to colleagues at the participating organisations as well as external experts who contribute and critically review project work.**

# Thank you!



**Christian Hay,**  
Sr Consultant Healthcare



**Anne Moen**  
Faculty of Medicine, University of  
Oslo &  
Coordinator, Gravitate-  
Health Public-Private Partnership  
[//www.gravitatehealth.eu](http://www.gravitatehealth.eu)

*...and many other colleagues 😊*



- Dr Robert A. Stegwee
- *Chair, CEN Technical Committee 251 Health Informatics*

**UNCOM**

## Further Information on UNICOM

[unicom-project.eu](http://unicom-project.eu)

Twitter: [@unicom\\_idmp](https://twitter.com/unicom_idmp)

[linkedin.com/company/unicom-idmp](https://linkedin.com/company/unicom-idmp)

UN  COM

# **IDMP Status of requirements and impact on electronic Product Information (Structured Content Authoring)**

Member ISO-Technical Committee 215 Health Informatics

Former Member DITA Technical Committee, OASIS

Senior Consultant IDMP / CEO SeicoDyne GmbH

IDMP Evangelist

Co-Architect of ISO 11615 (IDMP)

Member Municipal Parliament City of Emmen

Member Advisory Board Refdata-Stiftung Schweiz

Member IDMP Advisory Board of Swissmedic

SeicoDyne GmbH

6020 Emmenbrücke

[christian.kravogel@seicodyne.com](mailto:christian.kravogel@seicodyne.com)

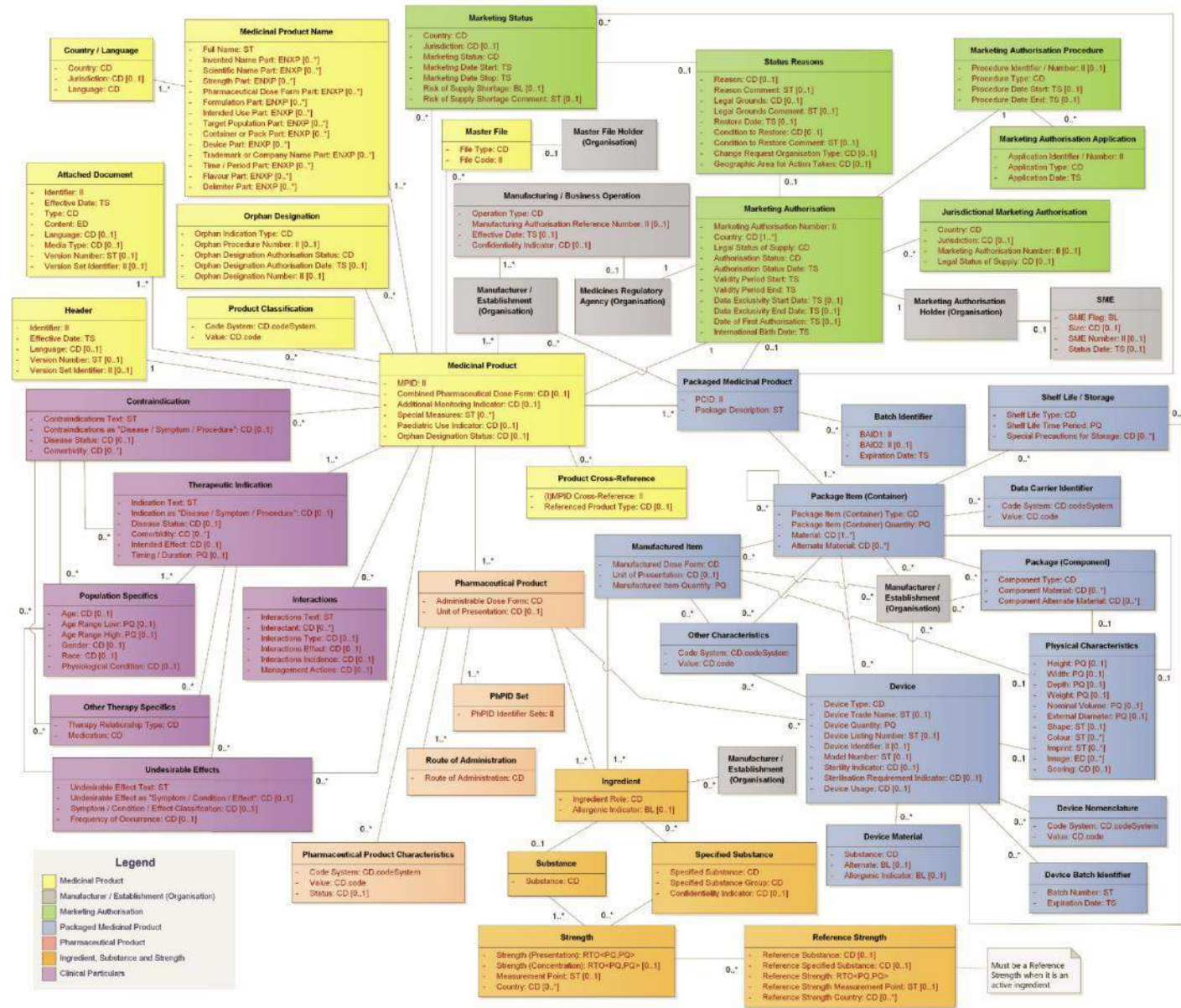
079 797 5445

[www.kravogel.ch](http://www.kravogel.ch)





# Datamodel > data structuring and data analysis

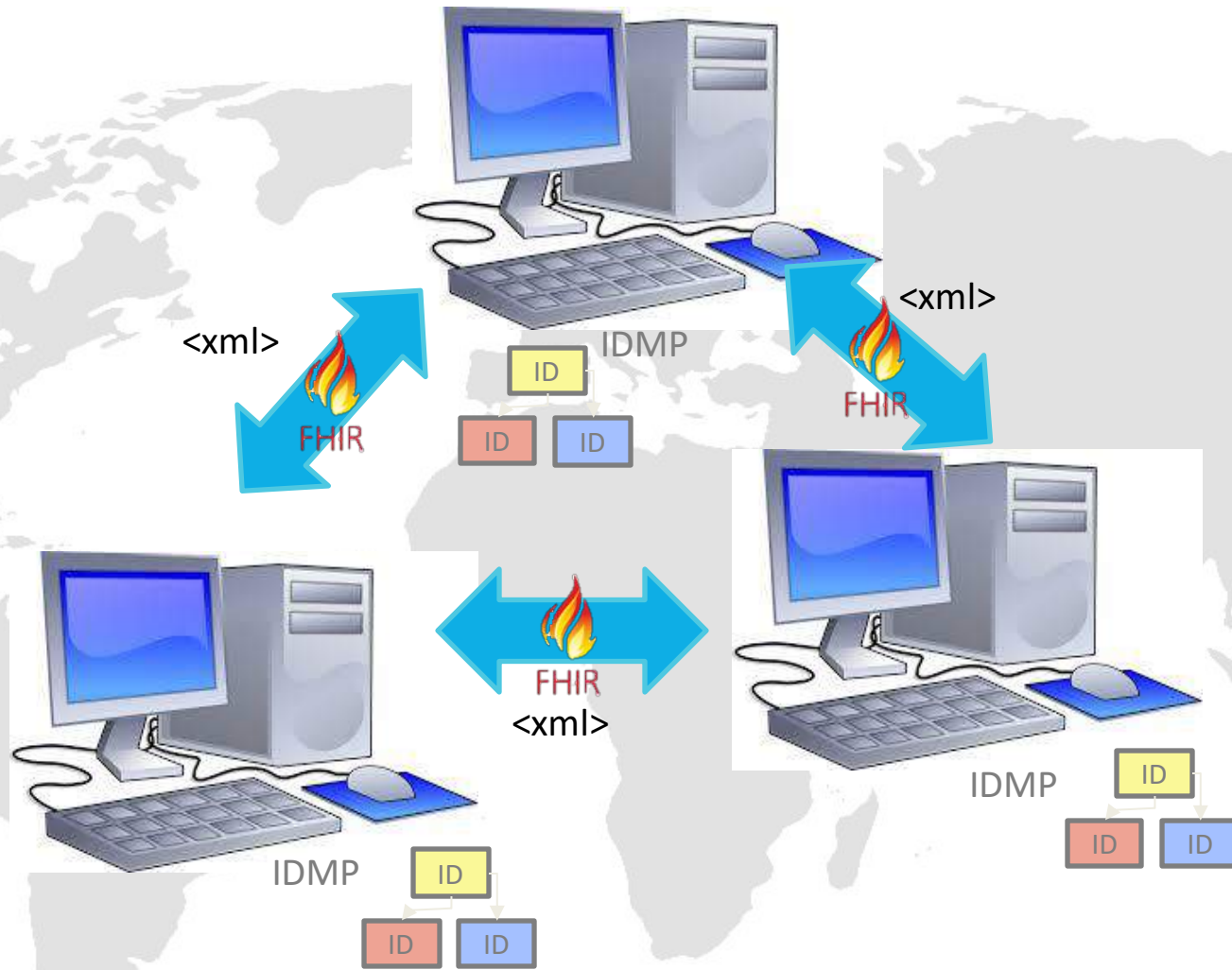




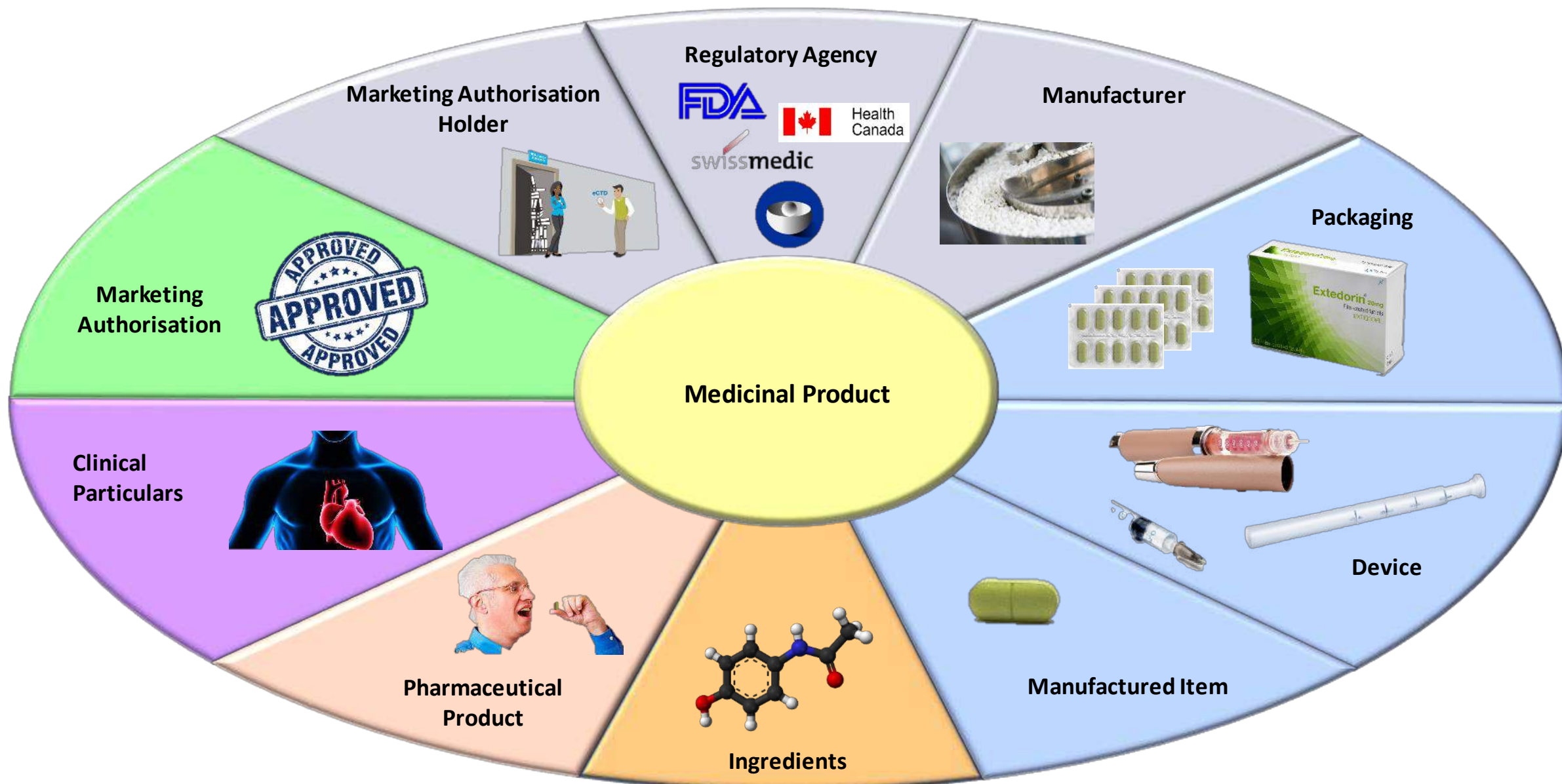
# IDMP is also about Controlled Vocabularies

Substances		Products		Organisations	
SPOR Home Lists Documents					
Home / Lists					
Page 1 of 7					
List Identifier	List Name	List Owner			
▶ 200000000013	Administration Method	EDQM			
▶ 200000000009	Basic Dose Form	EDQM			
▶ 200000000008	Combination Package	EDQM			
▶ 200000000006	Combined Pharmaceutical Dose Form	EDQM			
▶ 200000000007	Combined Term	EDQM			
▶ 100000073349	Dosage Form Category	EDQM			
▶ 100000073350	Dosage Form Term Type	EDQM			
▶ 200000000012	Intended Site	EDQM			
▶ 100000073346	Packaging	EDQM			
▶ 200000000005	Patient Friendly	EDQM			
▶ 200000000004	Pharmaceutical Dose Form	EDQM			
▶ 200000000010	Release Characteristics	EDQM			
▶ 100000073345	Routes and Methods of Administration	EDQM			
▶ 200000000118	State of Matter	EDQM			
▶ 200000000011	Transformation	EDQM			
▶ 200000000014	Units of Presentation	EDQM			

# It is about Quick data exchange



# ISO 11615 – Medicinal Product





# IDMP and the Medicines Regulatory Agencies



Source: The Guardian

Implementation Started



Source: Bigstockphoto

Implementation Started



Source: CBC News

Implementation Started



Source: [www.swissmedic.ch](http://www.swissmedic.ch), FOPH Wikipedia

In Preparation (Fast Follower)



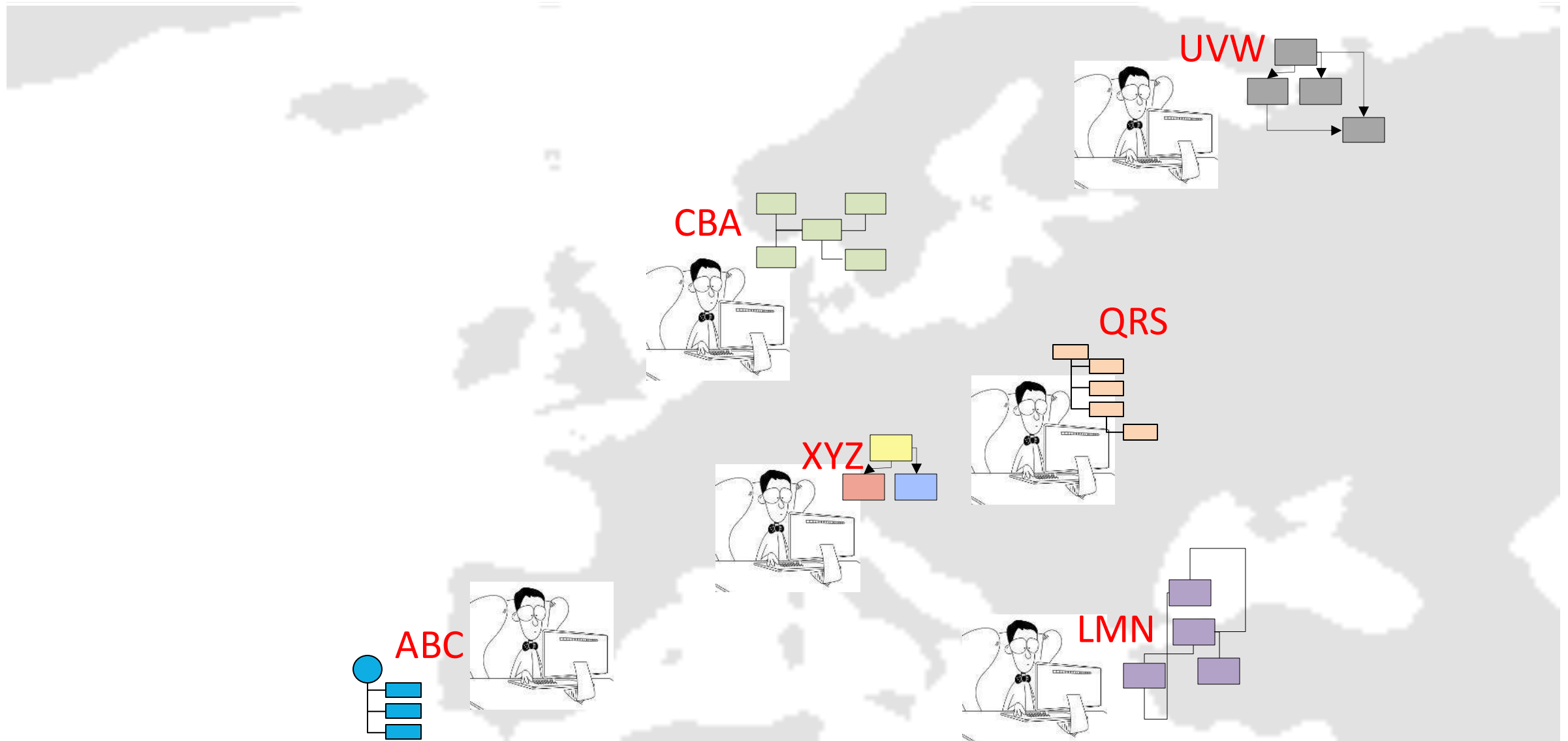
Source: AgriBrasilis

In Preparation



**Once-Only >> Single-Sourcing**

# Multi-Source



# Monolytic & Prosa

- 3 Strength
- 5 Pack Sizes
- 4 Indications
- 6 Countries

5 mg AT / LI de, en	10 mg AT / LI de, en	20 mg AT / LI de, en	5 mg DE de, en	5 mg FR fr	10 mg FR fr	20 mg FR fr	5 mg BE fr, nl, de	10 mg GB en	5 mg CH / LI de, fr	10 mg CH / LI de, fr
		Ind. D		Ind. D	Ind. D	Ind. D	Ind. D	Ind. D		
Ind. C	Ind. C	Ind. C		Ind. C	Ind. C	Ind. C	Ind. C		Ind. C	Ind. C
Ind. B	Ind. B	Ind. B	Ind. B	Ind. B	Ind. B	Ind. B	Ind. B		Ind. B	Ind. B
Ind. A	Ind. A	Ind. A	Ind. A	Ind. A	Ind. A	Ind. A				



# "What does this look like in reality?"

## Monolytic & Prosa

1 Product

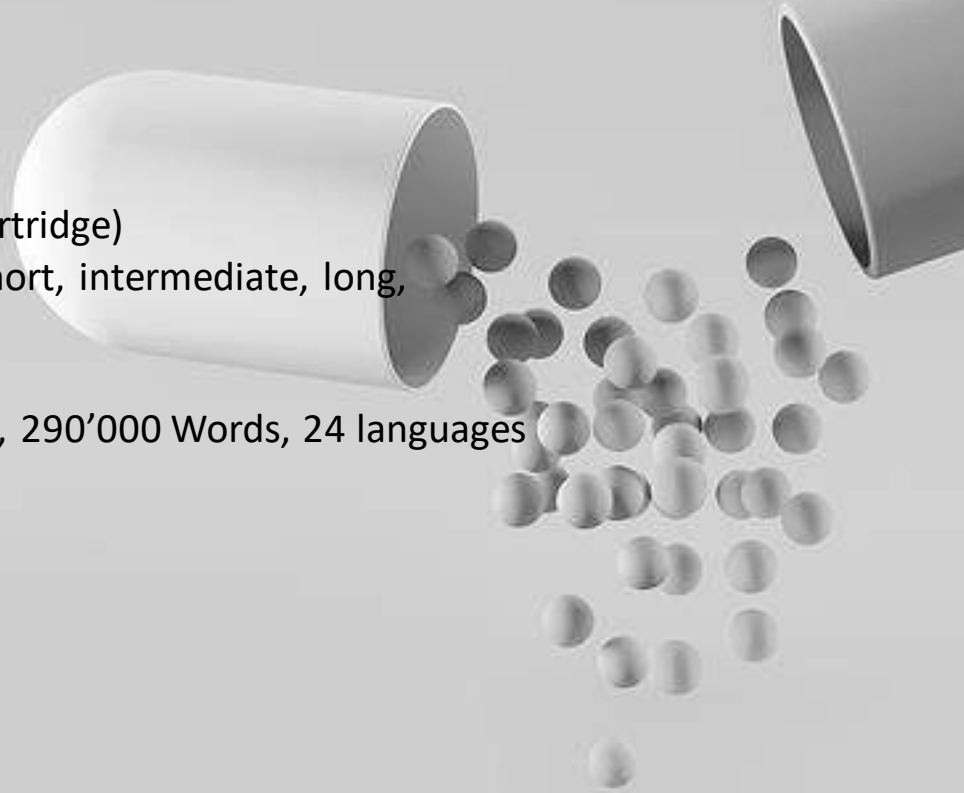
Approx. 80 variations

























- 2 strength (40 IU, 100 IU)

- 6 dose forms (Vial, Pen, Cartridge)

- 10 formulations (e.g. for short, intermediate, long, fast and mixed acting)

Each document: 1000 pages, 290'000 Words, 24 languages



 [redacted]	bg	35.273 KB
 [redacted]	cs	37.317 KB
 [redacted]	da	37.536 KB
 [redacted]	de	74.346 KB
 [redacted]	el	44.700 KB
 [redacted]	en	48.528 KB
 [redacted]	es	64.413 KB
 [redacted]	et	29.531 KB
 [redacted]	fi	39.980 KB
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 [redacted]	hu	51.834 KB
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 [redacted]	it	46.247 KB
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 [redacted]	lv	40.388 KB
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 [redacted]	nl	55.160 KB
 [redacted]	no	55.605 KB
 [redacted]	pl	40.770 KB
 [redacted]	pt	42.519 KB
 [redacted]	ro	42.221 KB
 [redacted]	sk	41.233 KB
 [redacted]	sl	60.401 KB
 [redacted]	sv	29.059 KB

## The Old Way: Microsoft Word



### Page 2

#### 1. NAME OF THE MEDICINAL PRODUCT

Insuman Rapid 100 IU/ml solution for injection in a vial

#### 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains 100 IU insulin human (equivalent to 3.5 mg). Each vial contains 5 ml of solution for injection, equivalent to 500 IU insulin. One IU (International Unit) corresponds to 0.035 mg of anhydrous human insulin.

Insuman Rapid is a neutral insulin solution (regular insulin).

Human insulin is produced by recombinant DNA technology in *Escherichia coli*.

For a full list of excipients, see section 6.1.

#### 3. PHARMACEUTICAL FORM

Solution for injection in a vial.

Clear, colourless solution of water-like consistency.

### Page 3

#### 4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients.

Insuman Rapid must not be used in external or implanted insulin pumps or in peristaltic pumps with silicone tubing.

#### 4.4 Special warnings and precautions for use

Patients hypersensitive to Insuman Rapid for whom no better tolerated preparation is available must only continue treatment under close medical supervision and – where necessary – in conjunction with anti-allergic treatment.

In patients with an allergy to animal insulin intradermal skin testing is recommended prior to a transfer to Insuman Rapid, since they may experience immunological cross-reactions.

In patients with renal impairment, insulin requirements may be diminished due to reduced insulin metabolism. In the elderly, progressive deterioration of renal function may lead to a steady decrease in insulin requirements.

In patients with severe hepatic impairment, insulin requirements may be diminished due to reduced capacity for gluconeogenesis and reduced insulin metabolism.

In case of insufficient glucose control or a tendency to hyper- or hypoglycaemic episodes, the patient's adherence to the prescribed treatment regimen, injection sites and proper injection technique and all other relevant factors must be reviewed before dose adjustment is considered.

### Page 11

#### 1. NAME OF THE MEDICINAL PRODUCT

Insuman Rapid 40 IU/ml solution for injection in a vial

#### 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains 40 IU insulin human (equivalent to 1.4 mg). Each vial contains 4 ml of solution for injection, equivalent to 160 IU insulin. One IU (International Unit) corresponds to 0.035 mg of anhydrous human insulin.

Insuman Rap

**60 % Match**

Human insulin is produced by recombinant DNA technology in *Escherichia coli*.

For a full list of excipients, see section 6.1.

#### 3. PHARMACEUTICAL FORM

Solution for injection in a vial.

Clear, colourless solution of water-like consistency.

### Page 12

#### 4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients.

Insuman Rapid must not be used in external or implanted insulin pumps or in peristaltic pumps with silicone tubing.

#### 4.4 Special warnings and precautions for use

Patients hypersensitive to Insuman Rapid for whom no better tolerated preparation is available must only continue treatment under close medical supervision and – where necessary – in conjunction with anti-allergic treatment.

In patients with an allergy to animal insulin intradermal skin testing is recommended prior to a transfer to Insuman Rapid, since they may experience immunological cross-reactions.

In patients with renal impairment, insulin requirements may be diminished due to reduced insulin metabolism. In the elderly, progressive deterioration of renal function may lead to a steady decrease in insulin requirements.

In patients with severe hepatic impairment, insulin requirements may be diminished due to reduced capacity for gluconeogenesis and reduced insulin metabolism.

In case of insufficient glucose control or a tendency to hyper- or hypoglycaemic episodes, the patient's adherence to the prescribed treatment regimen, injection sites and proper injection technique and all other relevant factors must be reviewed before dose adjustment is considered.

**100 % Match**

### Page 20

#### 1. NAME OF THE MEDICINAL PRODUCT

Insuman Rapid 100 IU/ml solution for injection in a cartridge

#### 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains 100 IU insulin human (equivalent to 3.5 mg). Each cartridge contains 3 ml of solution for injection, equivalent to 300 IU insulin. One IU (International Unit) corresponds to 0.035 mg of anhydrous human insulin.

Insuman Rapid is a neutral insulin solution (regular insulin).

Human insulin is produced by recombinant DNA technology in *Escherichia coli*.

For a full list of excipients, see section 6.1.

#### 3. PHARMACEUTICAL FORM

Solution for injection in a cartridge.

Clear, colourless solution of water-like consistency.

### Page 21

#### 4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients.

Insuman Rapid must not be used in external or implanted insulin pumps or in peristaltic pumps with silicone tubing.

#### 4.4 Special warnings and precautions for use

Patients hypersensitive to Insuman Rapid for whom no better tolerated preparation is available must only continue treatment under close medical supervision and – where necessary – in conjunction with anti-allergic treatment.

In patients with an allergy to animal insulin intradermal skin testing is recommended prior to a transfer to Insuman Rapid, since they may experience immunological cross-reactions.

In patients with renal impairment, insulin requirements may be diminished due to reduced insulin metabolism. In the elderly, progressive deterioration of renal function may lead to a steady decrease in insulin requirements.

In patients with severe hepatic impairment, insulin requirements may be diminished due to reduced capacity for gluconeogenesis and reduced insulin metabolism.

In case of insufficient glucose control or a tendency to hyper- or hypoglycaemic episodes, the patient's adherence to the prescribed treatment regimen, injection sites and proper injection technique and all other relevant factors must be reviewed before dose adjustment is considered.

## The Old Way: Microsoft Word



24 languages

bg	35.273 KB
cs	37.317 KB
da	37.536 KB
de	74.346 KB
el	44.700 KB
en	48.528 KB
es	64.413 KB
et	29.531 KB
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lv	40.388 KB
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nl	55.160 KB
no	55.605 KB
pl	40.770 KB
pt	42.519 KB
ro	42.221 KB
sk	41.233 KB
sl	60.401 KB
sv	29.059 KB

Monolytic documents

Total: > 90 % identical paragraphs

Same paragraphs are reused many times

### 6.4 Special precautions for storage

Unopened cartridges:

Store in a refrigerator (2°C - 8°C).

Do not freeze.

Do not put next to the freezer compartment or a freezer pack.

Keep the cartridge in the outer carton in order to protect from light.

26 x

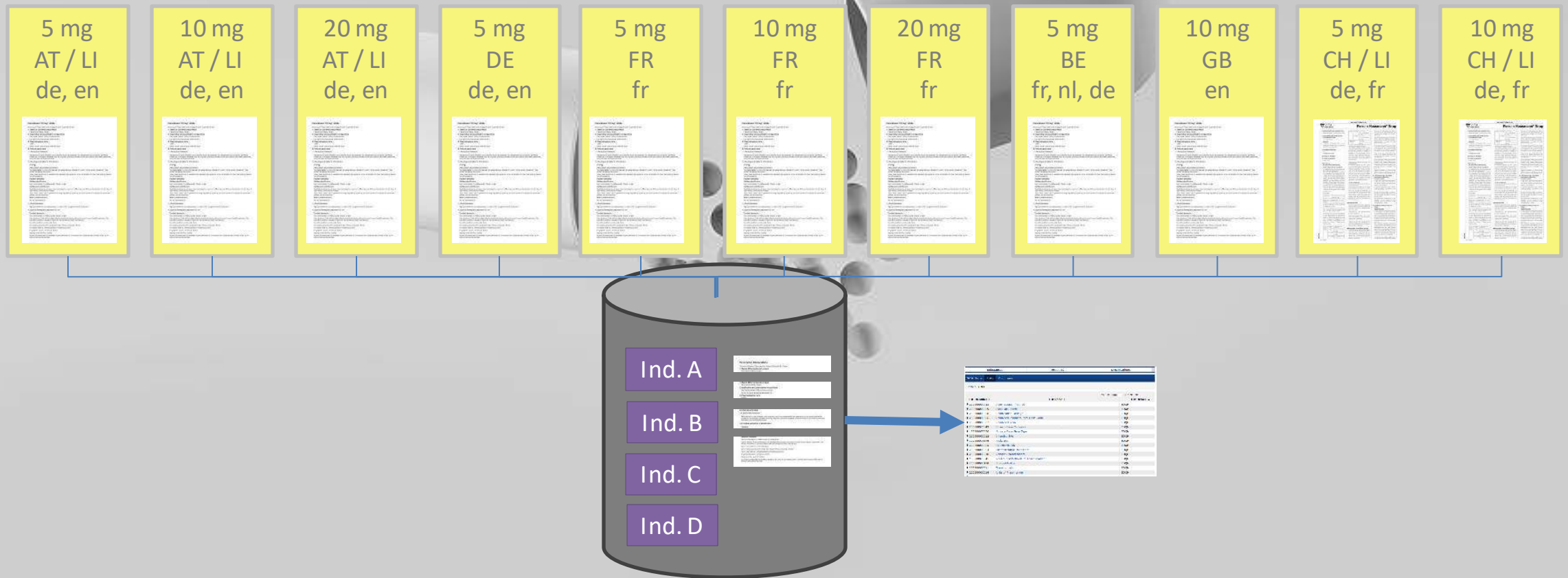
133 x

110 x

8 x

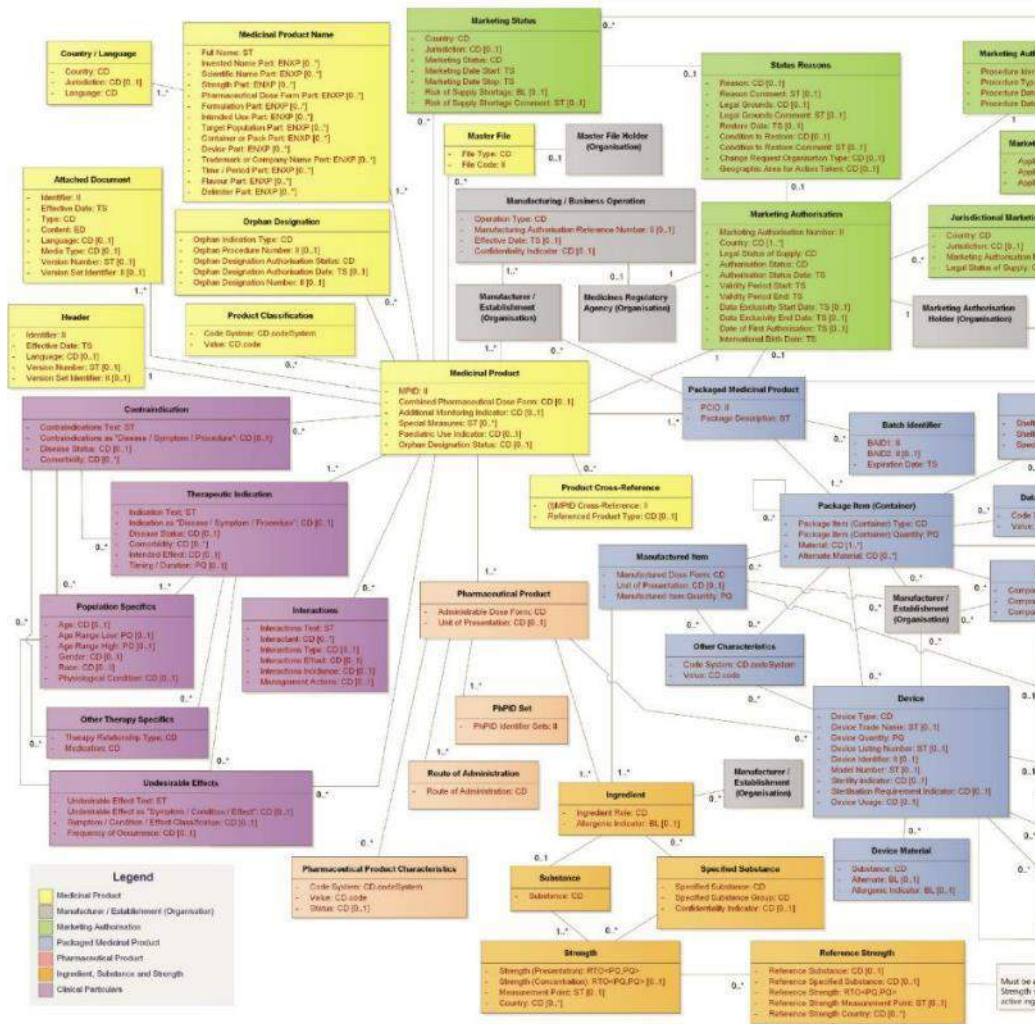
39 x

# Structure Contents – Single Sourcing





# IDMP and Controlled Vocabularies



Substances	Products	Organisations
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SPOR Home Lists Documents

Home / Lists

Page 1 of 7

List Identifier	List Name	List Owner
20000000013	Administration Method	EDQM
20000000009	Basic Dose Form	EDQM
20000000008	Combination Package	EDQM
20000000006	Combined Pharmaceutical Dose Form	EDQM
20000000007	Combined Term	EDQM
10000073349	Dosage Form Category	EDQM
10000073350	Dosage Form Term Type	EDQM
20000000012	Intended Site	EDQM
10000073346	Packaging	EDQM
20000000005	Patient Friendly	EDQM
20000000004	Pharmaceutical Dose Form	EDQM
20000000010	Release Characteristics	EDQM
10000073345	Routes and Methods of Administration	EDQM
20000000018	State of Matter	EDQM
20000000011	Transformation	EDQM
20000000014	Units of Presentation	EDQM

	A	B	C
1	Owner	Swissmedic	
2	Listenname (DE)	List Name (EN)	CH
3	Kennzeichnung zur zusätzlichen Überwachung	Additional Monitoring Indicator	756
4	Spezielle Massnahmen	Special Measures	756
5	Zugelassen für die Anwendung bei Kindern	Paediatric Use Indicator	756
6	Heilmittelcode	Heilmittelcode	756
7	Orphan Zulassungsstatus	Orphan Designation Authorisation Status	756
8	Bezugsarzneimittel	Referenced Product Type	756
9	Anhang Typ	Attached Document Type	756
10	Zulassungstyp	Regulatory Authorisation Type	756
11	Abgabekategorie	Legal Status of Supply	756
12	Zulassungsstatus	Authorisation Status	756
13	Art des Verfahrens	Marketing Authorisation Procedure Type	756
14	Antragstyp	Marketing Authorisation Application Type	756
15	Vermarktungsstatus	Marketing Status	756
16	Weitere Eigenschaften (Verpacktes Arzneimittel)	Other Characteristics (Packaged Medicinal Product)	756
17	Besondere Vorsichtsmassnahmen für die Aufbewahrung	Special Precautions for Storage	756
18	Physikalische Eigenschaften, Bruchkerbe	Physical Characteristics, Scoring	756
19	Funktion des Inhaltsstoffes	Ingredient Role	756

# "What does this look like in reality?"

	B	C
1	ISO	
2		
3	en-GB	de-CH
4	Medicinal Product	Arzneimittel
5	MPID	MPID
6	Domain	Domäne
7	Type (Authorised, Investigational)	Typ
8	Authorised Pharmaceutical Form	Zugelassene Darreichungsform
9	Combined Pharmaceutical Dose Form	Kombinierte Darreichungsform
10	Additional Monitoring Indicator	Kennzeichnung zur zusätzlichen Überwachung
11	Special Measures	Spezielle Massnahmen
12	Paediatric Use Indicator	Zugelassen für die Anwendung bei Kindern
13	Orphan Designation Status	Orphan Drug Status
14	Limitation (FOPH)	Limitierung (BAG)
15	Full Limitation Text (FOPH)	Gesamter Wortlaut der Limitierung (BAG)
16	Orphan Designation	Orphan Drug Status
17	Orphan Indication Type	Orphan Indikation
18	Orphan Procedure Number	Orphan Prozessnummer
19	Orphan Designation Authorisation Status	Orphan Zulassungsstatus
20	Orphan Designation Authorisation Date	Orphan Zulassungsdatum
21	Orphan Designation Number	Orphan Drug Nummer

Substances	Products	Organisations
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SPOR Home Lists Documents

Home / Lists

Page 1 of 7

List Identifier	List Name	List Owner
▶ 200000000013	Administration Method	EDQM
▶ 200000000009	Basic Dose Form	EDQM
▶ 200000000008	Combination Package	EDQM
▶ 200000000006	Combined Pharmaceutical Dose Form	EDQM
▶ 200000000007	Combined Term	EDQM
▶ 10000073349	Dosage Form Category	EDQM
▶ 10000073350	Dosage Form Term Type	EDQM
▶ 200000000012	Intended Site	EDQM
▶ 10000073346	Packaging	EDQM
▶ 200000000005	Patient Friendly	EDQM
▶ 200000000004	Pharmaceutical Dose Form	EDQM
▶ 200000000010	Release Characteristics	EDQM
▶ 10000073345	Routes and Methods of Administration	EDQM
▶ 200000000118	State of Matter	EDQM
▶ 200000000011	Transformation	EDQM
▶ 200000000014	Units of Presentation	EDQM

CD	0..1
CD	0..1

	A	B	C
1	Owner	Swissmedic	
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18	Physikalische Eigenschaften, Bruchkerbe	Physical Characteristics, Scoring	756
19	Funktion des Inhaltsstoffes	Ingredient Role	756







# "What does this look like in reality?"

```
File Edit Selection View Go Run Terminal Help
IDE: Eclipse
Project: bag-epi-fhir
...
1 Profile: IDMPMedicinalProductDefinition
2 Name: MedicinalProductDefinition
3 ID: "idmp-medicinal-product-definition"
4 Title: "IDMP Medicinal Product Definition"
5 Description: "Profile of the MedicinalProductDefinition resource for representing the detailed data of medicinal products."
6 * about = "idmp-medicinal-product-definition"
7
8 // * PBT
9
10 * identifier-system 1..
11 * identifier-system = SPAR // variable for SPC Naming System
12 * identifier-value 1..
13
14 // * system
15 * domain = "http://hl7.org/fhir/medicinal-product-definition"
16 * domain-coding "slicing discriminator" type = "value"
17 * domain-coding "slicing discriminator" path = "system"
18 * domain-coding "slicing rules" = "open"
19 * domain-coding "status"
20
21 * subvalue 1..
22 * domain-coding "domain" system = "http://hl7.org/fhir/medicinal-product-definition"
23 * domain-coding "system" system = "http://hl7.org/fhir/medicinal-product-definition"
24 * domain-coding "code" 1..
25
26 * extension url = "http://hl7.org/fhir/medicinal-product-definition"
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28 * extension url = "http://hl7.org/fhir/medicinal-product-definition"
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95 * extension url = "http://hl7.org/fhir/medicinal-product-definition"
96 * extension url = "http://hl7.org/fhir/medicinal-product-definition"
97 * extension url = "http://hl7.org/fhir/medicinal-product-definition"
98 * extension url = "http://hl7.org/fhir/medicinal-product-definition"
99 * extension url = "http://hl7.org/fhir/medicinal-product-definition"
100 * extension url = "http://hl7.org/fhir/medicinal-product-definition"
...

```



Home - CH EPL (R5) v0.1.0

file:///C:/projects/bag-epi-fhir/output/index.html

## CH EPL (R5) 0.1.0 - 0-build

Home Documentation Use Case Examples Profiles Extensions Terminology Artifacts

Table of Contents > Home

CH EPL (R5) - Local Development build (v0.1.0) built by the FHIR (HL7® FHIR® Standard) Build Tools. See the Directory of published versions!

### 1 Home

Official URL: <a href="http://fhir.ch/ig/ch-ep1/implementationguide/ch-fhir-ig-ch-ep1">http://fhir.ch/ig/ch-ep1/implementationguide/ch-fhir-ig-ch-ep1</a>	Version: 0.1.0
Active as of 2023-11-10	Computable Name: CH_EPL
Copyright/Legal: CC0-1.0	

### 1.1 Introduction

CH EPL is a project of the Swiss Federal Office of Public Health (FOPH), to enable to receive IDMP/FHIR based medicinal product information from Swissmedic and the marketing authorisation holders and to export the Spezialitätenliste in FHIR.

### 1.2 IDMP Dependencies

This implementation guide is dependent on

- FHIR Medicinal Product Definition
- FHIR Regulated Authorization
- FHIR Packaged Product Definition
- FHIR Manufactured Item Definition
- FHIR Ingredient

- Introduction
- IDMP Dependencies
- Documentation
- Collaboration
- IP Statements
- Cross Version Analysis
- Dependency Table
- Globals Table



- ## Software Vendors
- IDMP Tools
  - Master Data Management Systems
  - eCTD Tools
  - Structured Content Authoring Tools



```
88 <name>
89 <productName value="Wonderdrug 20 mg, Filmcoated Tablets"/>
90 <part>
91 <part value="Wonderdrug"/>
92 <type>
93 <coding>
94 <system
95 value="http://hl7.org/fhir/medicinal-product-name-part-type"/>
96 <code value="InventedNamePart"/>
97 <display value="Invented Name Part"/>
98 </coding>
99 </type>
100 </part>
```

# From SmPC/PIL to IDMP

## Controlled Vocabularies

- Authorities: EMA RMS
- EDQM
- UCUM
- MSSO
- WHO
- Snomed
- Etc.

## Heuristic Algorithm

1. Name of the medicinal product  
Cuprior 100mg Fosvario

2. Qualitative and quantitative composition  
Clemastinle 100mg  
For the full list of excipients, see section 6.1.

3. Pharmaceutical form  
Fosvario

4. Clinical particulars

4.1 Therapeutic indications  
Cuprior 100mg Fosvario are recommended for the treatment of candidal vaginitis.

4.2 Posology and method of administration  
The pessaries should be inserted into the vagina, as high as possible, using the applicator provided. This is best achieved when lying back with legs bent up.  
Adults:  
Two pessaries should be inserted daily (preferably at night) for three consecutive days. Alternatively, one pessary may be inserted daily for six days, preferably at night. A second treatment may be carried out if necessary.  
There is no separate storage schedule for the elderly.  
Cuprior pessaries need moisture in the vagina in order to dissolve completely; otherwise undissolved pieces of the pessary might crumble out of the vagina. Pieces of undissolved pessary may be noticed by women who experience vaginal dryness. To help prevent this it is important that the pessary is inserted as high as possible into the vagina at bedtime.  
Children:  
Not for use in children under 16.  
For instructions on handling and disposal see section 6.6.

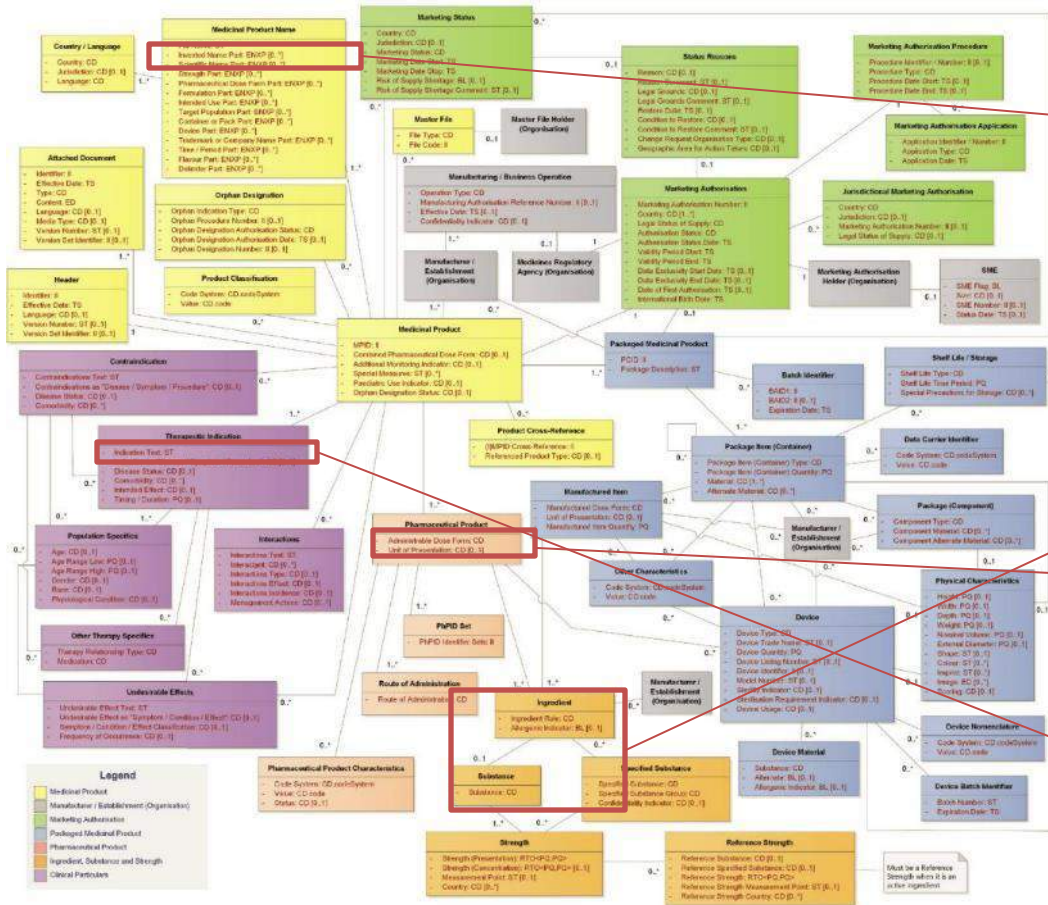
4.3 Contraindications  
Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

perceived symptoms  
if any of the  
with usually  
PIL to IDMP  
etc.  
following  
in the treatment  
the risk of the pessary  
before the onset of  
at women. Animal  
does (see section  
vaginitis, harmful  
tion of a physician or  
cation.  
veral, systemic  
absorption is minimal after administration and is unlikely to lead to systemic effects.  
Clemastinle may be used during lactation.  
Fertility:  
No human studies of the effects of clemastinle on fertility have been performed. However, animal studies have not demonstrated any effects of the drug on fertility.

```
1 <?xml version="1.0" encoding="UTF-8"?>
2 <Bundle xmlns="http://hl7.org/fhir">
3   <id value="08f553cb-1404-4972-bf14-2023a9599557">
4     <meta>
5       <profile
6         | | value="http://fhir.ch/ig/ch-epi/StructureDefinition/idmp-bundle"/>
7     </meta>
8     <type value="collection"/>
9     <entry>
10      <fullUrl
11        | | value="http://example.org/MedicalProductDefinition/Cuprior-150mg-Film-coated-tablet"/>
12      <resource>
13        <MedicalProductDefinition>
14          <id value="Cuprior-150mg-Film-coated-tablet"/>
15          <meta>
16            <profile
17              | | value="http://fhir.ch/ig/ch-epi/StructureDefinition/idmp-medicalproductdefinition"/>
18            </meta>
19            <extension
20              | | url="http://fhir.ch/ig/ch-epi/StructureDefinition/authorizedDoseForm">
21              | | <valueCodeableConcept>
22                <coding>
23                  <system value="urn:oid:0.4.0.127.0.16.1.1.2.1"/>
24                  <code value="102210007"/>
25                  <display value="Film-coated tablet"/>
26                </coding>
27              </valueCodeableConcept>
28            </extension>
29            <extension
30              | | url="http://fhir.ch/ig/ch-epi/StructureDefinition/fullLimitationText">
31              | | <valueString
32                | | value="CUPRIOR wird vergütet zur Behandlung der Kupferspeicherkrankheit (Morbus Wilson) bei Erwachsenen, Jugendlichen und
33                | | Kindern im Alter von 5 Jahren oder älter, die eine Behandlung mit D-Penicillamin nicht vertragen. Die Behandlung muss von Gastroenterologen
34                | | oder Hepatologen mit Erfahrung bei der Behandlung von Patienten mit Morbus Wilson initiiert und überwacht werden."/>
35            </extension>
36            <identifier>
37              <system value="http://fhir.ch/ig/ch-epi/IDSystem-ch-IPID"/>
38              <value value="CH-7840109110007-6771901"/>
39            </identifier>
40            <coding>
41              <system
42                | | value="http://fhir.ch/ig/ch-epi/CodeSystem/ch-swissmedic-domain"/>
43              <code value="HAM"/>
44              <display value="Human Arzneimittel"/>
45            </coding>
46            <indication
47              | | value="Cuprior wird angewendet zur Behandlung von Morbus Wilson bei Erwachsenen, Jugendlichen und Kindern im Alter von 5
48              | | Jahren oder älter mit Unverträglichkeit gegenüber einer D-Penicillamin Therapie."/>
49            </indication>
50            <legalStatusOfSupply>
51              <coding>
52                <system
53                  | | value="http://fhir.ch/ig/ch-epi/CodeSystem/ch-swissmedic-legal-status-of-supply"/>
54                <code value="758005004003"/>
55                <display
56                  | | value="Abgabe auf ärztliche oder tierärztliche Verschreibung (B)"/>
57              </coding>
58            </legalStatusOfSupply>
59            <pediatricUseIndicator>
60              <coding>
61                <system
62                  | | value="http://fhir.ch/ig/ch-epi/CodeSystem/ch-swissmedic-pediatric-use-indicator"/>
63                <code value="No"/>
64                <display value="Nicht zugelassen für die Anwendung bei Kindern"/>
65              </coding>
66            </pediatricUseIndicator>
67          </MedicalProductDefinition>
68        </resource>
69      </entry>
70    </Bundle>
```

# From IDMP to SmPC/PIL



1. Name of the medicinal product

Canesten 100mg Pessary.

2. Qualitative and quantitative composition

Clotrimazole 100mg.

For the full list of excipients, see section 6.1.

3. Pharmaceutical form

Pessaries.

4. Clinical particulars

4.1 Therapeutic indications

Canesten 100mg Pessaries are recommended for the treatment of...



# From IDMP to SmPC/PIL

```
1 <?xml version="1.0" encoding="UTF-8"?>
2 <Bundle xmlns="http://hl7.org/fhir"
3 <id value="08f553cb-1404-4972-bf14-2023a5f59955"/>
4 <meta>
5 <profile
6 | | | value="http://fhir.ch/gch-epi/StructureDefinition/ch-idmp-bundle"/>
7 </meta>
8 <type value="collection"/>
9 <entry>
10 <fullUrl
11 | | | value="http://example.org/MedicinalProductDefinition/Cuprior-150mg-FilmcoatedTablet"/>
12 </fullUrl>
13 <resource>
14 <MedicinalProductDefinition
15 <id value="Cuprior-150mg-FilmcoatedTablet"/>
16 <meta>
17 <profile
18 | | | value="http://fhir.ch/gch-epi/StructureDefinition/ch-idmp-medicinalproductdefinition"/>
19 </meta>
20 <extension
21 | | | uri="http://fhir.ch/gch-epi/StructureDefinition/authorizedDoseForm">
22 | | | <valueCodeableConcept>
23 | | | <coding>
24 | | | <system value="urn:oid:0.4.0.127.0.16.1.1.2.1"/>
25 | | | <code value="102210001"/>
26 | | | <display value="Film-coated tablet"/>
27 | | | </coding>
28 | | | </valueCodeableConcept>
29 </extension>
30 <extension
31 | | | uri="http://fhir.ch/gch-epi/StructureDefinition/fullLimitationText">
32 | | | <valueString
33 | | | value="CUPRIOR wird vergeset zur Behandlung der Kupferspeicherkrankheit (Morbus Wilson) bei Erwachsenen, Jugendlichen und
34 | | | Kindern im Alter von 5 Jahren oder älter, die eine Behandlung mit D-Penicillamin nicht vertragen. Die Behandlung muss von Gastroenterologen
35 | | | oder Hepatologen mit Erfahrung bei der Behandlung von Patienten mit Morbus Wilson initiiert und überwacht werden."/>
36 </extension>
37 <identifier
38 <system value="http://fhir.ch/gch-epi/IDSystem-ch-MPID"/>
39 <value value="CH-7640109110007-6771901"/>
40 </identifier>
41 <domain
42 <coding>
43 | | | <system
44 | | | value="http://fhir.ch/gch-epi/CodeSystem/ch-swissmedico-domain"/>
45 | | | <code value="HAM"/>
46 | | | <display value="Human Arzneimittel"/>
47 </coding>
48 </domain>
49 <indication
50 | | | value="Cuprior wird angewendet zur Behandlung von Morbus Wilson bei Erwachsenen, Jugendlichen und Kindern im Alter von 5
51 | | | Jahren oder älter mit Unverträglichkeit gegenüber einer D-Penicillamin Therapie."/>
52 </indication>
53 <legalStatusOfSupply>
54 <coding>
55 | | | <system
56 | | | value="http://fhir.ch/gch-epi/CodeSystem/ch-swissmedico-legal-status-of-supply"/>
57 | | | <code value="758005004003"/>
58 | | | <display value="Abgabe auf ärztliche oder tierärztliche Verschreibung (B)"/>
59 </coding>
60 </legalStatusOfSupply>
61 <pediatricUseIndicator>
62 <coding>
63 | | | <system
64 | | | value="http://fhir.ch/gch-epi/CodeSystem/ch-swissmedico-pediatric-use-indicator"/>
65 | | | <code value="No"/>
66 | | | <display value="Nicht zugelassen für die Anwendung bei Kindern"/>
67 </coding>
68 </pediatricUseIndicator>
69 </MedicinalProductDefinition>
70 </resource>
71 </entry>
72 </Bundle>
```



1. Name of the medicinal product  
Cuprior 100mg Pessary.

2. Qualitative and quantitative composition  
Clebriamole 100mg  
For the full list of excipients, see section 6.1.

3. Pharmaceutical form  
Pessary.

4. Clinical particulars

4.1 Therapeutic indications  
Cuprior 100mg Pessaries are recommended for the treatment of candidal vaginitis.

4.2 Ecology and method of administration  
The pessaries should be inserted into the vagina, as high as possible, using the applicator provided. This is best achieved when lying back with legs bent up.  
Adults:  
Two pessaries should be inserted daily (preferably at night) for three consecutive days. Alternatively, one pessary may be inserted daily for six days, preferably at night. A second treatment may be carried out if necessary.  
There is no separate dosage schedule for the elderly.  
Caution: pessaries need moisture in the vagina in order to dissolve completely; otherwise undissolved pieces of the pessary might erode out of the vagina. Pieces of undissolved pessary may be noticed by women who experience vaginal dryness. To help prevent this it is important that the pessary is inserted as high as possible into the vagina as bedtime.  
Children:  
Not for use in children under 16.  
For instructions on handling and disposal see section 6.6.

4.3 Contraindications  
Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Experienced symptoms  
if any of the  
with usually  
PIL to IDMP

not  
following

not been observed  
be used again if the  
is more than  
soon.

interaction  
may cause damage to  
lives may be reduced.  
days after using this

is risk of the pessary  
before the onset of

contraindication.  
Do not use tampons, intravaginal douches, spermicides or other vaginal products while using this product.  
Vaginal intercourse should be avoided in case of vaginal infection and while using this product because the partner could become infected.  
When used in pregnancy, the pessary should be inserted without using an applicator (see "Pregnancy").

not women. Animal  
does (see section  
not/and, harmful

tion of a physician or  
center.

over, systemic  
absorption is minimal after administration and is unlikely to lead to systemic effects.  
Clebriamole may be used during lactation.  
Fertility:  
No human studies of the effects of clebriamole on fertility have been performed, however, animal studies have not demonstrated any effects of the drug on fertility.



# "What does this look like in reality?"

new paragraph

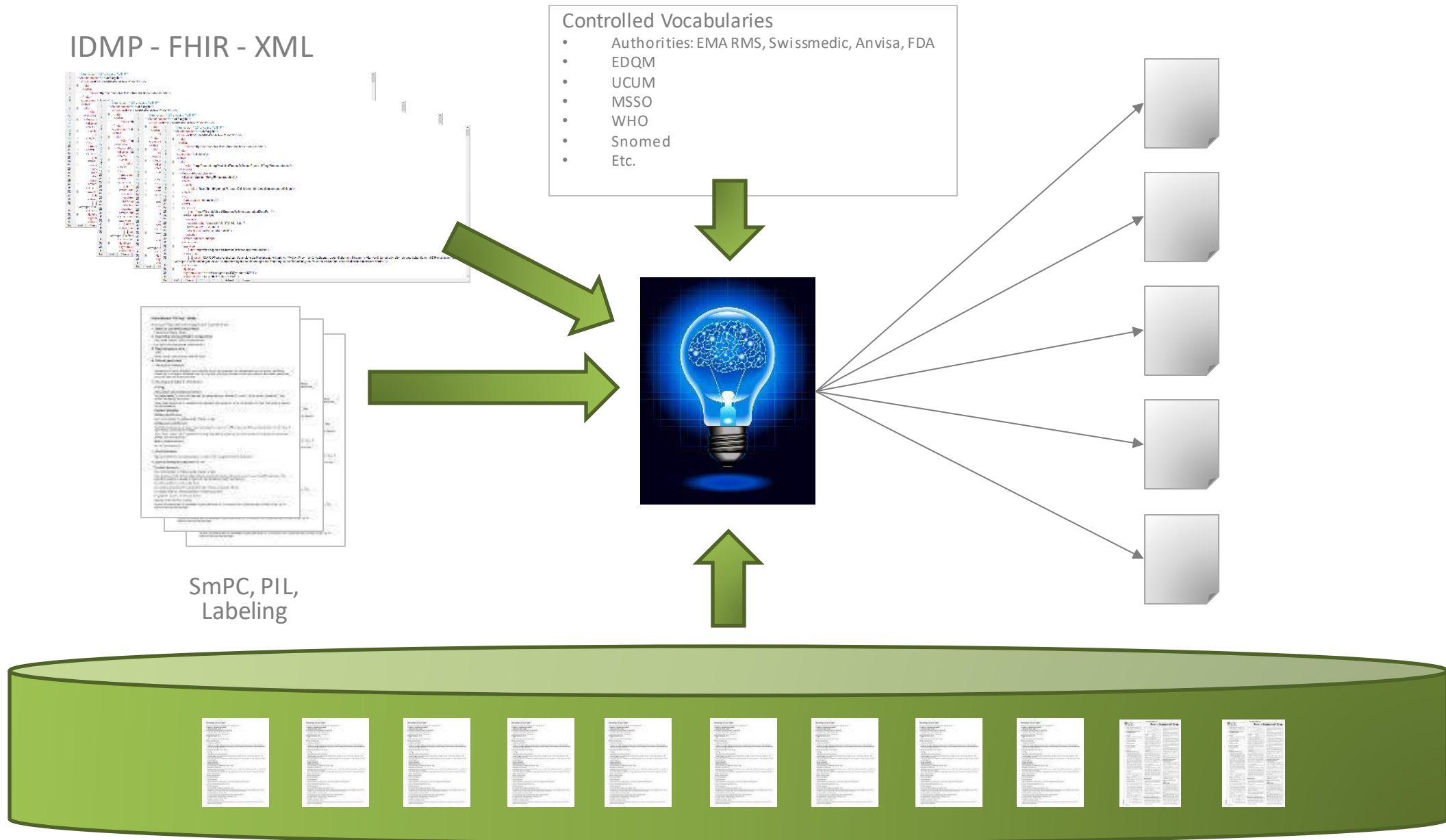
## IDMP - FHIR - XML

```
88 <name>
89 <productName value="Wonderdrug 20 mg, Filmcoated"
90 <part>
91 <part value="Wonderdrug"/>
92 <type>
93 <coding>
94 <system
95 <value value="http://hl7.org/fhir/medicinal-product-na
96 <code value="InventedNamePart"/>
97 <display value="Invented Name Part"/>
98 </coding>
99 </type>
100 </part>
```

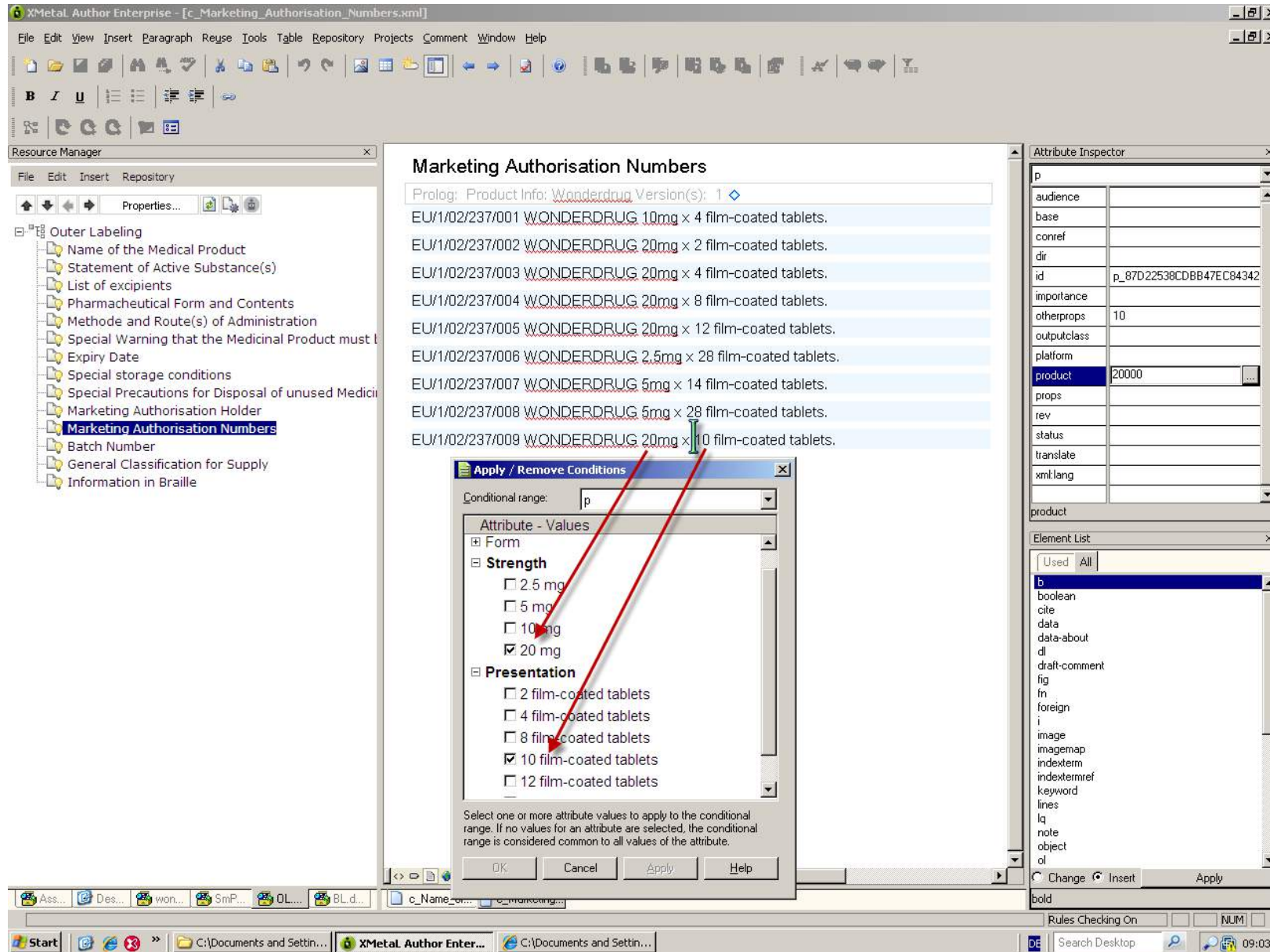
```
712 <strength>
713 <presentationRatio>
714 <numerator>
715 <value value="20"/>
716 <unit value="mg"/>
717 <system value="http://unitsofmeasure.org"/>
718 <code value="mg"/>
719 </numerator>
720 <denominator>
721 <value value="1"/>
722 <unit value="Tablet"/>
723 <system value="http://unitsofmeasure.org"/>
724 <code value="{Tablet}"/>
725 </denominator>
726 </presentationRatio>
727 </strength>
728 </substance>
729 </Ingredient>
730 </resource>
731 </entry>
732 </Bundle>
```



# User of Artificial Intelligence



# "What does this look like in reality?"



The screenshot displays the XMetal Author Enterprise software interface. The main window shows a list of Marketing Authorisation Numbers (MANs) for a product named 'Wonderdrug'. The list includes details such as the product name, strength, and presentation for various EU countries. An 'Apply / Remove Conditions' dialog box is open, allowing the user to select specific attribute values to apply to the conditional range. The dialog box shows the 'Conditional range' set to 'p' and the 'Attribute - Values' section expanded to show 'Form' and 'Strength'. Under 'Strength', the '20 mg' option is selected. Under 'Presentation', the '10 film-coated tablets' option is selected. The 'Attribute Inspector' panel on the right shows the 'product' attribute set to '20000'. The 'Element List' panel at the bottom right shows a list of elements, with 'b' selected. The Windows taskbar at the bottom shows the Start button and several open applications, including XMetal Author Enterprise.

Resource Manager

Outer Labeling

- Name of the Medical Product
- Statement of Active Substance(s)
- List of excipients
- Pharmaceutical Form and Contents
- Method and Route(s) of Administration
- Special Warning that the Medicinal Product must be used
- Expiry Date
- Special storage conditions
- Special Precautions for Disposal of unused Medicinal Product
- Marketing Authorisation Holder
- Marketing Authorisation Numbers**
- Batch Number
- General Classification for Supply
- Information in Braille

Marketing Authorisation Numbers

Prolog: Product Info: Wonderdrug Version(s): 1

- EU/1/02/237/001 WONDERDRUG 10mg x 4 film-coated tablets.
- EU/1/02/237/002 WONDERDRUG 20mg x 2 film-coated tablets.
- EU/1/02/237/003 WONDERDRUG 20mg x 4 film-coated tablets.
- EU/1/02/237/004 WONDERDRUG 20mg x 8 film-coated tablets.
- EU/1/02/237/005 WONDERDRUG 20mg x 12 film-coated tablets.
- EU/1/02/237/006 WONDERDRUG 2.5mg x 28 film-coated tablets.
- EU/1/02/237/007 WONDERDRUG 5mg x 14 film-coated tablets.
- EU/1/02/237/008 WONDERDRUG 5mg x 28 film-coated tablets.
- EU/1/02/237/009 WONDERDRUG 20mg x 10 film-coated tablets.

Apply / Remove Conditions

Conditional range: p

Attribute - Values

- Form
- Strength
  - 2.5 mg
  - 5 mg
  - 10 mg
  - 20 mg
- Presentation
  - 2 film-coated tablets
  - 4 film-coated tablets
  - 8 film-coated tablets
  - 10 film-coated tablets
  - 12 film-coated tablets

Select one or more attribute values to apply to the conditional range. If no values for an attribute are selected, the conditional range is considered common to all values of the attribute.

OK Cancel Apply Help

Attribute Inspector

p	
audience	
base	
confref	
dir	
id	p_87D22538CDBB47EC84342
importance	
otherprops	10
outputclass	
platform	
product	20000
props	
rev	
status	
translate	
xml.lang	

product

Element List

Used All

- b
- boolean
- cite
- data
- data-about
- dl
- draft-comment
- fig
- fn
- foreign
- i
- image
- imagemap
- indexterm
- indextermref
- keyword
- lines
- lq
- note
- object
- ol

Change Insert Apply

bold

Rules Checking On NUM

Start

C:\Documents and Sett... XMetal Author Enter... C:\Documents and Sett...

Search Desktop 09:03



# "What does this look like in reality?"

ChatGPT

https://chat.openai.com/c/a85cc47f-5c65-4cc0-bd38-e2346587c148

New chat

Today

Convert Pessary to Table

IDMP: Keine Werteliste

Previous 7 Days

Zelleninhalt mit Zahl überprüfen

Deklination und Konjugation.

Text-Vorlesungsoptionen: Anleit

Grüne Kandidatenprofile

Health-IT Standards Expert CEO

Previous 30 Days

Kostendeckungsgrad: Definition

Upgrade plan  
Get GPT-4, DALL-E, and more

Christian Kravogel

ChatGPT 3.5

You

Please convert the following SmPC from

1. Name of the medicinal product

Canesten 100mg Pessary.

2. Qualitative and quantitative composi

Clotrimazole 100mg.

For the full list of excipients, see section

3. Pharmaceutical form

Pessaries.

4. Clinical particulars

4.1 Therapeutic indications

Canesten 100mg Pessaries are recomm

vaginitis.

4.2 Posology and method of administra

Message ChatGPT...

ChatGPT can make mistakes. Con

ChatGPT 3.5

ChatGPT

To convert the Canesten 100mg Pessary to a 200mg Tablet, you would adjust the dosage and form while keeping the active ingredient, clotrimazole, at the same concentration. Here's how the converted SmPC would look:

- Name of the medicinal product**  
Canesten 200mg Tablet.
- Qualitative and quantitative composition**  
Each tablet contains Clotrimazole 200mg.  
For the full list of excipients, see section 6.1.
- Pharmaceutical form**  
Tablets.
- Clinical particulars**
  - Therapeutic indications**  
Canesten 200mg Tablets are recommended for the treatment of candidal vaginitis.
  - Posology and method of administration**  
Adults:  
One tablet should be taken orally daily (preferably at night) for three consecutive days. Alternatively, one tablet may be taken orally daily for six days, preferably at night. A second treatment may be carried out if necessary.  
There is no separate dosage schedule for the elderly.  
Children:  
Not for use in children under 16.  
For instructions on handling and disposal, see section 6.6.
  - Contraindications**  
Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.
  - Special warnings and precautions for use**  
(Same as original)

# A journey towards the future of Labeling

Niklas Jänich & Murali Menon | 05 Mar 2024 | ePI Summit

# Agenda

Where we are  
coming from



What made us start the journey. A look into first steps, challenges and technology as well as business value



Rethinking the  
Labeling process



Learn about the concepts that helped us to rethink the Labeling process and set us up for the future



The journey  
continues



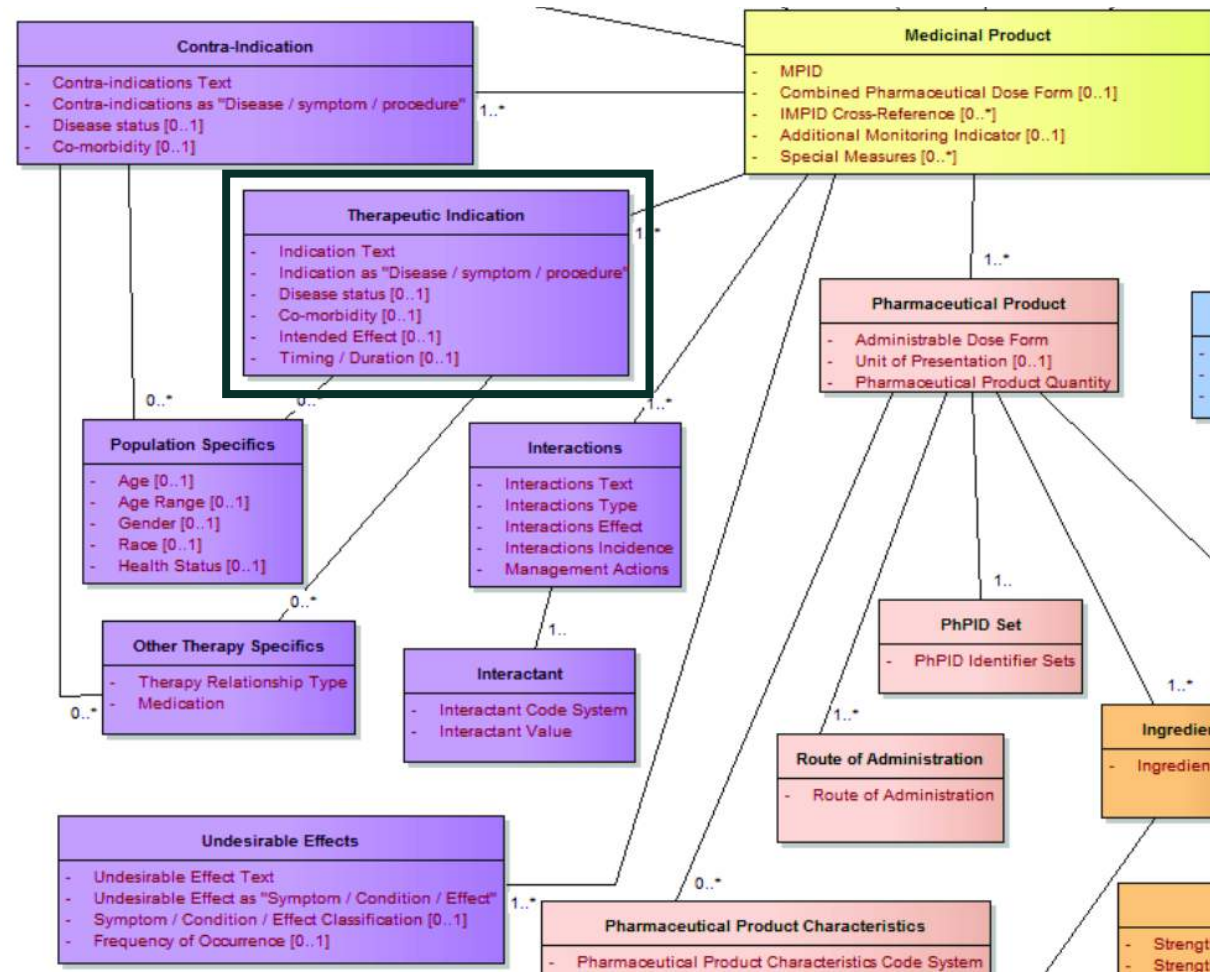
Next steps and strategic direction to further evolve the Labeling process & ePI leveraging structured content





ISO IDMP foresees data elements that contain the actual text in the Labeling documents in addition to coding

## How it all started...



Source: [https://www.ema.europa.eu/en/documents/presentation/presentation-international-activities-idmp-panagiotis-telonis-rik-smithies\\_en.pdf](https://www.ema.europa.eu/en/documents/presentation/presentation-international-activities-idmp-panagiotis-telonis-rik-smithies_en.pdf)

# Business value – IDMP & beyond



## IDMP

Code Core Data Sheets and inherit into local Labeling (e.g. SmPC)



## ePI

Automate internal ePI and structured outputs (e.g. FHIR). Patient centricity.



## Quality/Compliance

Avoid risks related to content propagation and increase oversight



## Speed

Increase speed for content creation and downstream processing



## Regulatory requirements

Fulfil diverse and highly complex requirements around the world



## Integrations

Connect Labeling data across systems and processes

## Key principles

We manage content,  
not documents



We connect  
information items



We re-use content



# The challenges at the example of deviations

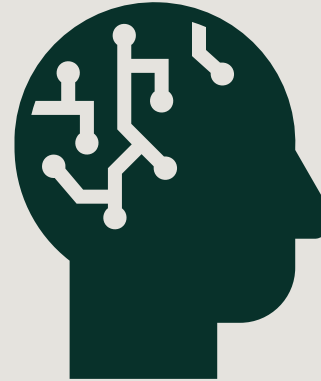
The quick brown fox  
jumps over the lazy dog



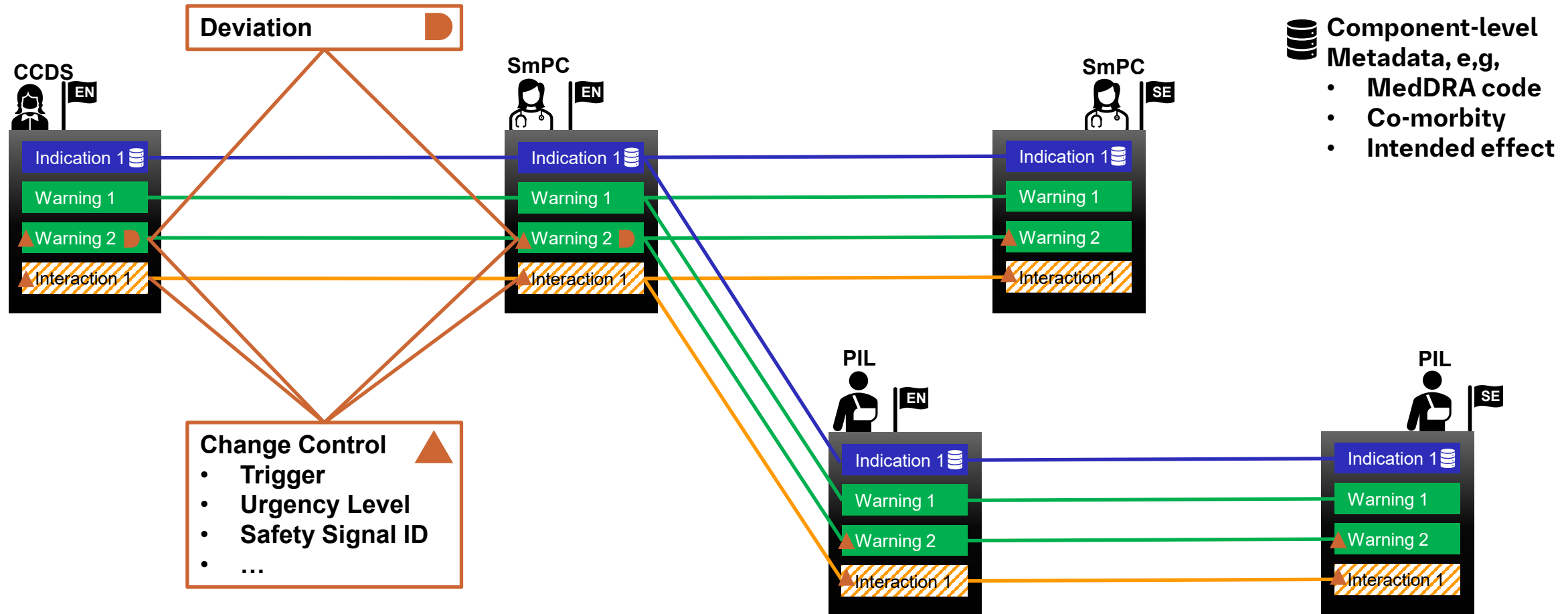
The quick brown fox  
jumps over the boring dog

<b>Different meaning and emphasis</b>	
• based on content	● ●
• based on position	● ●●
• based on position and content	● ●
• based on structure and/or content	● : ● : : ●
<b>Content not implemented (minus deviation)</b>	● □
<b>Additional content (plus deviation)</b>	□ ●

# Rethinking the Labeling process

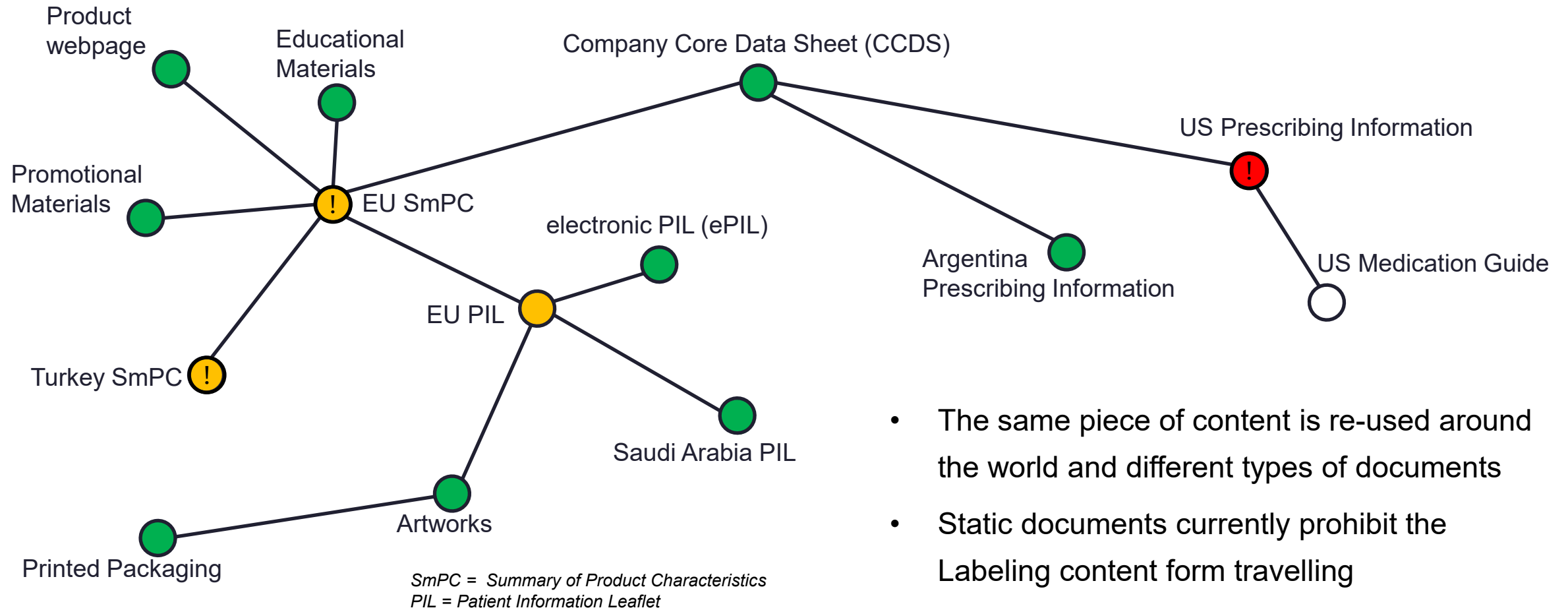


# Labeling content implementation in the new world



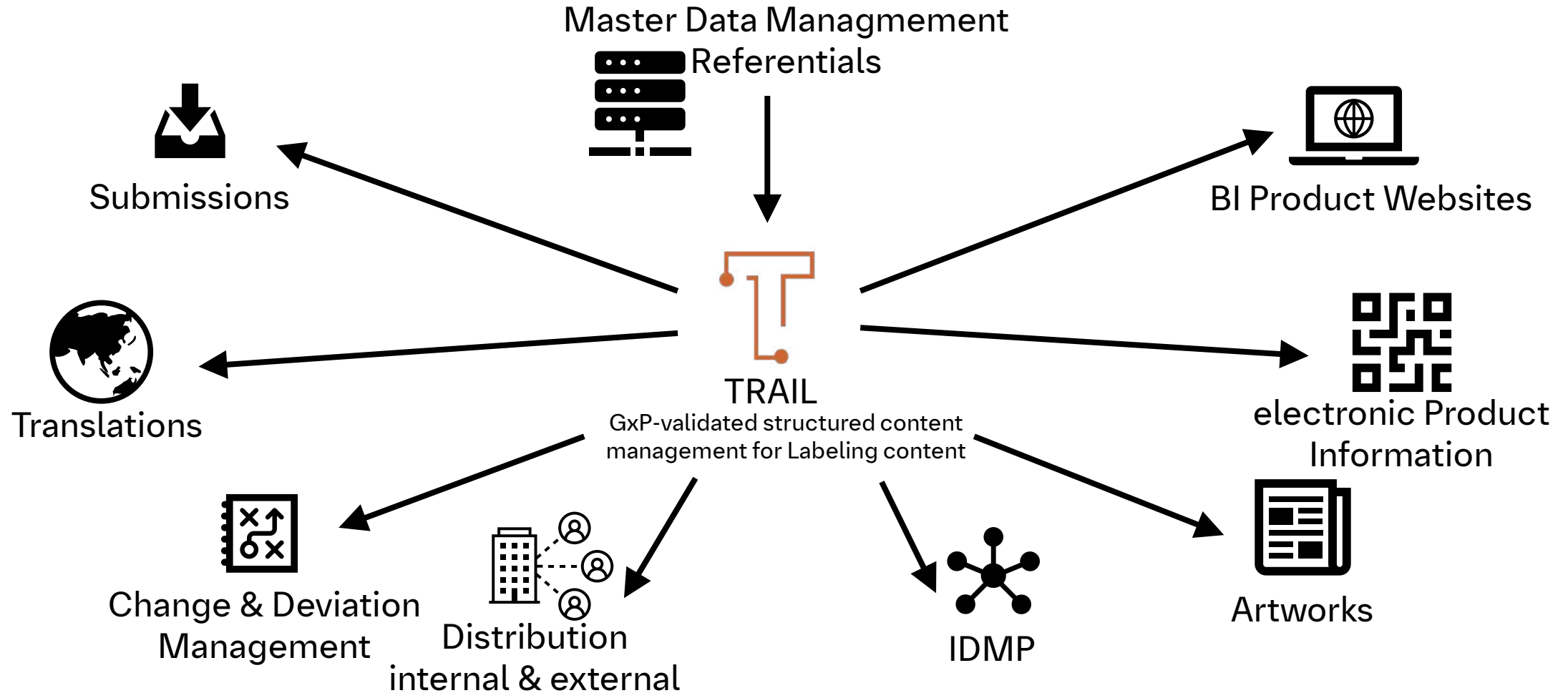


# Labeling content travels around the world



- The same piece of content is re-used around the world and different types of documents
- Static documents currently prohibit the Labeling content form travelling

# Downstream integrations



# Back to ISO IDMP...

```
"section": [
  {
    "title": "4.1 Therapeutic indications",
    "code": {
      "coding": [
        {
          "system": "https://spor.ema.europa.eu/rmswi",
          "code": "100000155538"
        }
      ],
      "text": "4.1 Therapeutic indications"
    },
    "text": {
      "status": "additional",
      "div": "<div
xmlns='http://www.w3.org/1999/xhtml'><p>OFEV is indicated in
adults for the treatment of idiopathic pulmonary fibrosis
(IPF).</p><p>OFEV is also indicated in adults for the
treatment of other chronic fibrosing interstitial lung
diseases (ILDs) with a progressive phenotype (see section
5.1). </p><p>OFEV is indicated in adults for the treatment of
systemic sclerosis associated interstitial lung disease (SSc-
ILD).</p></div>"
    }
  }
]
```

```
"text": [
  {
    "status": "additional",
    "div": "<div xmlns='http://www.w3.org/1999/xhtml'><p>OFEV is
indicated in adults for the treatment of idiopathic pulmonary fibrosis
(IPF) </p></div>",
    "code": {
      "coding": [
        {
          "system":
"https://spor.ema.europa.eu/rmswi/#/lists/100000000006",
          "code": "100000015597"
        }
      ],
      "text": "Idiopathic pulmonary fibrosis"
    }
  },
  {
    "status": "additional",
    "div": "<div xmlns='http://www.w3.org/1999/xhtml'><p>OFEV is
also indicated in adults for the treatment of other chronic fibrosing
interstitial lung diseases (ILDs) with a progressive phenotype (see section
5.1). </p></div>"
  },
  {
    "status": "additional",
    "div": "<div xmlns='http://www.w3.org/1999/xhtml'><p>OFEV is
indicated in adults for the treatment of systemic sclerosis associated
interstitial lung disease (SSc-ILD).</p></div>"
  }
]
```

# The journey continues



# TRAIL capabilities & collaboration on ePI

**TRAIL**  
GxP-validated  
structured Labeling content



- Go-to-Market & Operations
- Go-to-Market
- Regulators
- Compendia



ePI via  
codes on packs



BI Product  
Websites



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

Internal  
Boehringer  
project

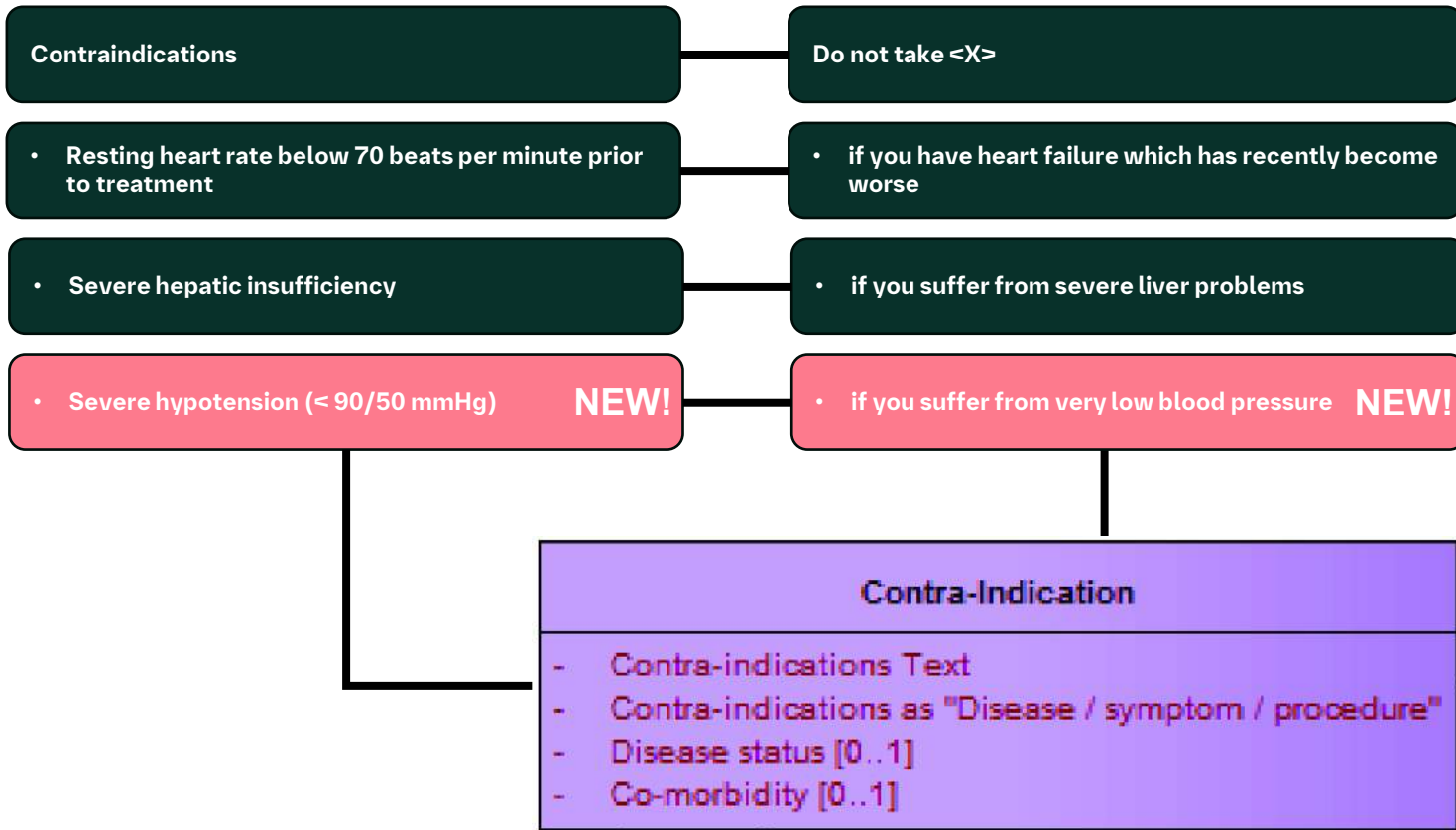
EMA ePI  
pilot



PoCs



# Structured, connected, coded Labeling and the future of ePI



# Questions & Discussion





# A journey towards the future of Labelling

---



# The Docuvera Journey...

## PLATFORM SCALE-UP 2021 - 2024+

Docuvera implementation at multiple large, medium, and small R&D Pharma companies. Scaling our team and partners to meet global demand

## Docuvera<sup>®</sup> BIOPHARMA SOLUTION 2017 LAUNCH

Docuvera – A SaaS SCA Platform solution developed for Life Sciences specific use cases across the drug development lifecycle

Pre-Clinical Research

Clinical Development

FDA/EMA, etc. Review

Post approval Marketing

Phase IV Development

## asc AUTHOR-IT SOFTWARE CO. 23 YEARS EXPERTISE SINCE 2000

ASC – Providing Structured Content Management/Component Authoring (SCM/A) solutions

IT

HighTech

Finance

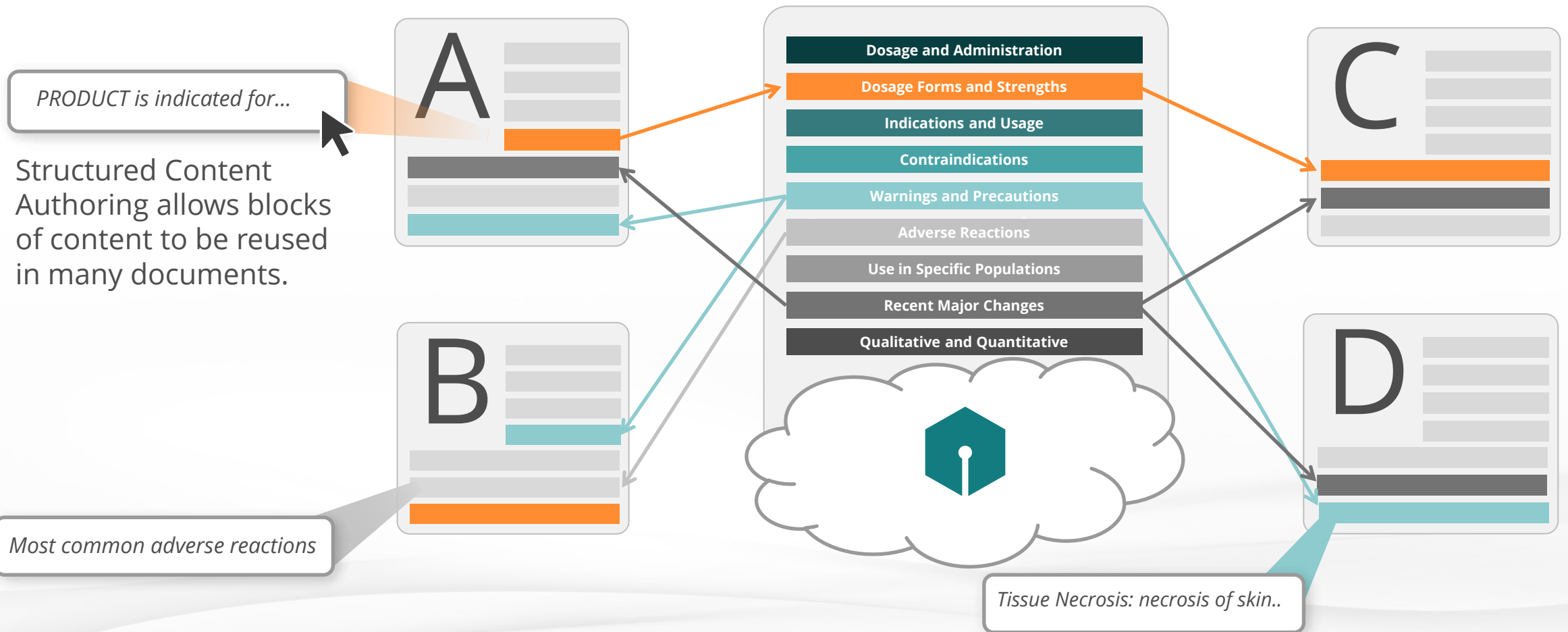
Aviation

Defense

Government

# The Solution

Lower Costs • Increased Compliance • Reduced Time-to-Market





# Differentiation



## Customer Quotes

*"Docuvera is **completely intuitive**"*

*"Docuvera is unique in delivering a superior user experience. We look forward to expanding its use across the company to **drive efficiencies** within and across functional areas."*

*"We selected Docuvera because of the success that they have had with our peers, their **experience in medical/clinical** and the intuitive interface."*

# In collaboration with Boehringer

## Foundational work

- Enterprise grade GXP platform for component authoring
- Built for collaboration, with User Experience in mind
- Track and report on Change Orders and Deviations , global to local
- Component level metadata support for enabling IDMP and ePI standards – JSON, XML, FHIR outputs

Editing: 612- AR · Product Information -es

Change Order: CO-189

Details Components Projects

Change title \*  
PASS 12345

Change description  
Update of the safety profile based on Post-authorization safety study 12345.

Change order status  
In progress

Regulatory urgency level  
2

Change category  
Safety

En un número limitado de pacientes, se observó un rebote en las concentraciones plasmáticas de dabigatrán libre y una prolongación concomitante de las pruebas de coagulación hasta 24 horas después de administrar <Active Pharmaceutical Ingredient - lower case> (ver la sección Propiedades farmacológicas). **(Change with Deviation - translated into es and modified)**

En este sentido, la administración de una segunda dosis de 5 mg de <Local Trade Name>® se podría considerar en las siguientes situaciones

- recurrencia de una hemorragia clínicamente relevantes asociada a tiempos de coagulación prolongados, o

Showing 158 change orders that match your criteria

CO ID	Created date	Created by	Modified date	Modified by	Title
CO-158	Jan 24, 2024 4:33 AM	Susie Winn	Feb 13, 2024 11:50 AM	Susie Winn	New Indications - Bone Infections
CO-51	Oct 10, 2021 8:20 PM	Janet Schorr	Feb 01, 2024 2:13 AM	Susie Winn	Indications - Strained tendons
CO-156	Oct 12, 2023 10:43 AM	Susie Winn	Nov 15, 2023 12:46 AM	Susie Winn	New adverse event - Headaches
CO-155	Oct 03, 2023 11:03 AM	Susie Winn	Nov 15, 2023 12:45 AM	Susie Winn	New Adverse Reaction - Headaches
CO-157	Oct 17, 2023 5:40 PM	Steve Owens	Oct 17, 2023 6:15 PM	Steve Owens	Testing
CO-154	Aug 17, 2023 10:08 AM	Susie Winn	Aug 17, 2023 10:23 AM	Susie Winn	New prescribing information
CO-153	Aug 17, 2023 1:00 AM	Susie Winn	Aug 17, 2023 2:55 AM	Susie Winn	Change to prescribing Agri
CO-152	Aug 07, 2023 8:53 AM	Susie Winn	Aug 15, 2023 11:31 AM	Susie Winn	New Adverse Reaction - Headaches
CO-151	Aug 01, 2023 11:44 AM	Janet Schorr	Aug 15, 2023 11:31 AM	Susie Winn	Indication for bone infection
CO-150	Aug 01, 2023 11:41 AM	Janet Schorr	Aug 07, 2023 4:30 AM	Susie Winn	New AE for headaches
CO-147	Jun 29, 2023 2:24 AM	Susie Winn	Aug 01, 2023 10:26 AM	Janet Schorr	New Indications - Bone Infections
CO-149	Jul 07, 2023 2:57 PM	Susie Winn	Jul 07, 2023 2:57 PM	Susie Winn	New information - demo July 7
CO-148	Jun 29, 2023 8:09 AM	Susie Winn	Jun 29, 2023 8:12 AM	Susie Winn	New Adverse Reaction - Headaches
CO-146	Jun 28, 2023 9:13 AM	Susie Winn	Jun 29, 2023 2:21 AM	Susie Winn	New adverse reaction - Headaches
CO-143	May 11, 2023 12:16 PM	Susie Winn	Jun 28, 2023 12:10 AM	Susie Winn	New Adverse Reaction - Headaches
CO-145	Jun 27, 2023 2:44 PM	Susie Winn	Jun 27, 2023 2:45 PM	Susie Winn	Ppl need to know about this change
CO-144	Jun 27, 2023 10:19 AM	Susie Winn	Jun 27, 2023 10:21 AM	Susie Winn	German preferred conter
CO-142	May 03, 2023 11:24 AM	Susie Winn	May 10, 2023 10:53 AM	Susie Winn	New Adverse Reaction -

Details Projects Deviations

Change title \*  
New Indications - Bone Infections

---

Change description  
Ziftria has been proven to treat bone infections in men and women over the age of 65. All of the Ziftria labels should be changed to reflect this new information.

---

Change order status: In progress | Regulatory urgency level: 2

---

Change category: Safety

---

Reference

---

Signal ID: 123 | Ready for implementation: Not ready

---

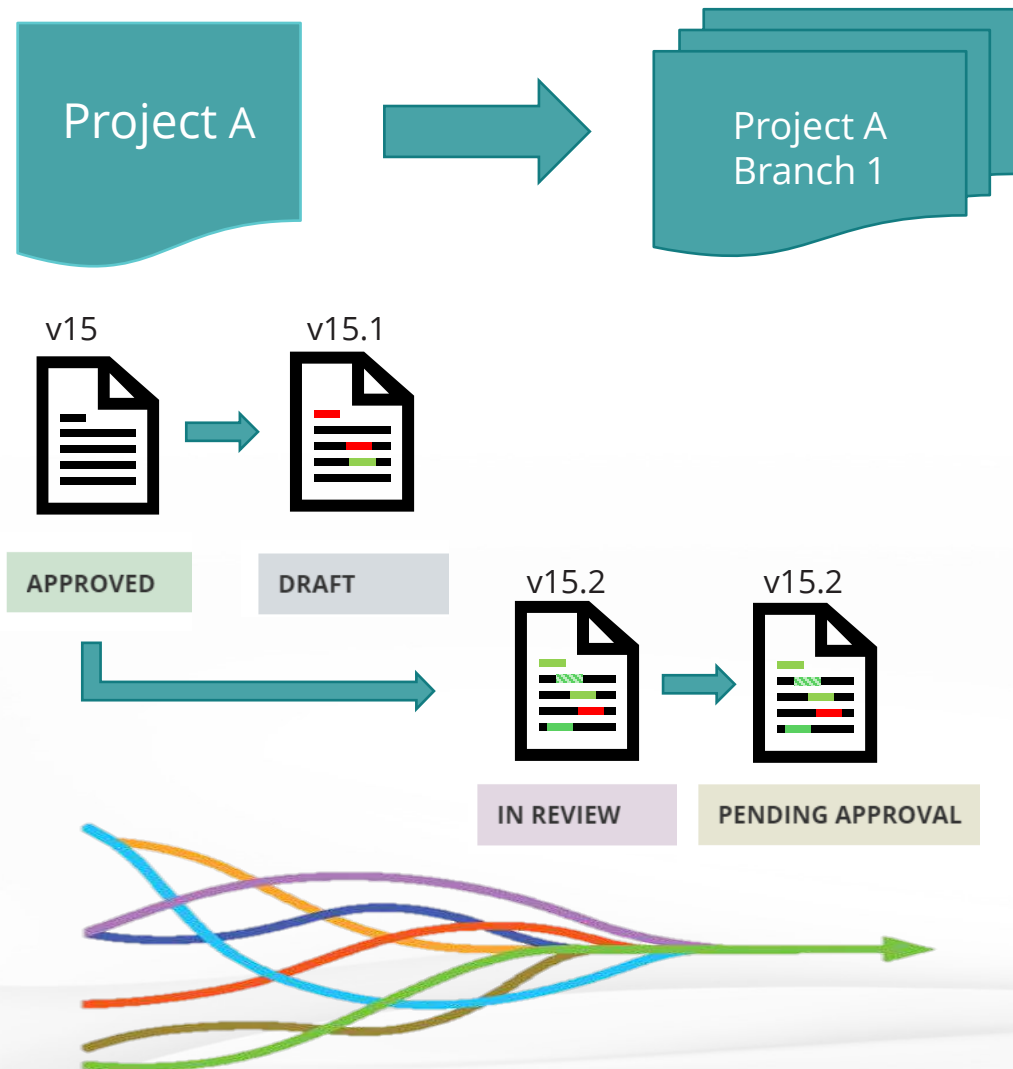
Created date: Jan 24, 2024 | Created by: Susie Winn

Modified date: Feb 13, 2024 | Modified by: Susie Winn

## Advanced features

- Parallel Versions – support several parallel versions of the labels as it moves through its submission lifecycle; branching and merging
- Project Variants – a single product might have multiple strengths or dosage forms, and each of these different combinations requires its own labeling documentation.
- Project Bundling – In the EU, local labeling documents are a set of individual documents that are submitted as a single unit (Annex 1, Annex 2, etc.). Each Annex and the assembled document has very distinct formatting requirements.

# Parallel Version Branching Feature Summary



- Branch projects at need
  - From an approved Basis point
    - System re-enforced and traced
  - Track purpose and progress
    - Branch names, descriptions
  - Individual & Collective audit trail
    - Replace the “document version matrix”
- Parallel Workflows
  - Collaborate, review, internal approvals
    - Full suite of functionality from linear projects
  - HA submission progress
  - Major and Minor versioning shared across all branches
- Compare Branches
  - Side-By-Side Comparison
  - Shared, updated and unique content highlighted
  - Quickly navigate between branches and versions
- Update, Merge, Consolidate
  - A single component
  - A partial consolidation
  - A full merge of branches
  - Visual aides based on analytics



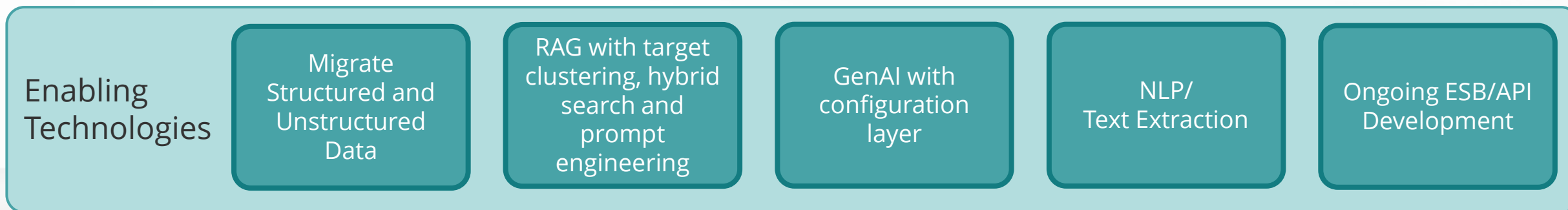
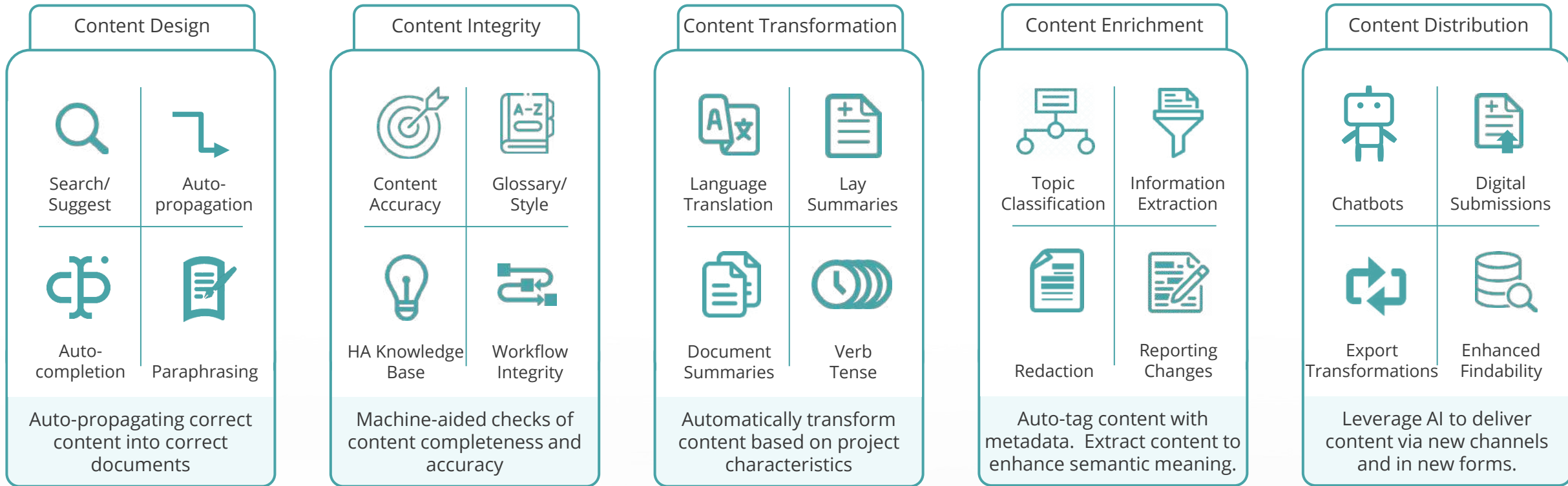
### SMPC: ZIFTRIA > Version history

Version	Branch name	Date ↑	Versioning events	Approved by	Exported	Exported by	Reason(s) for change
1.0.1	SPMC-TM88-HY93	Apr 17, 2024	Minor approval	Alan Approver	Yes	Alice Author	New disclaimer
2.2	SPMC-Ao12-4433	Mar 3, 2024	Minor approval	Alan Approver	Yes	Alice Author	Positive opinion received
2.1+	SMPC-NP69-MNC9	Dec 8, 2023	New version	-	-	-	New version created: General updates
2.1	SPMC-Ao12-4433	Nov 22, 2023	Minor approval	Sarah Approver	Yes	Dave Author	Ready for submission to HA
2.1+	SPMC-BH99-17IK	Nov 5, 2023	New branch	-	-	-	IDMP updates to SMPC required
2.1	SMPC-NP69-MNC9	Oct 18, 2023	Minor approval	Alan Approver	DMS	Alice Author	Updated template
2+	SMPC-NP69-MNC9	Jul 5, 2023	New branch	-	-	-	New version created: General updates
2	SPMC-Ao12-4433	Jun 30, 2023	Major approval	Sarah Approver	-	-	Initial change orders addressed, available for othe...
1+	SPMC-Ao12-4433	Jun 25, 2023	New branch	-	-	-	Adjusting the dosage and administration informati...
1	SPMC-TM88-HY93	Jun 24, 2021	Major approval	Alan Approver	-	-	First Basis point

Adjusting the dosage and administration information to match new findings and reported events

CLOSE

# Looking ahead - Synergies with AI



# **Pharmaceuticals: Carbon Footprint of Package Leaflets – Summary of a Study**

**Dr.-Ing. Norbert Gerbsch, IGES Institute**

Results of a cooperation project with Fraunhofer IML, Dr. Kerstin Dobers and Anna Preut


05 March 2024


# A study commissioned by

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**.B.A.H** Bundesverband der  
Arzneimittel-Hersteller e.V.

 Rote Liste  
Service GmbH

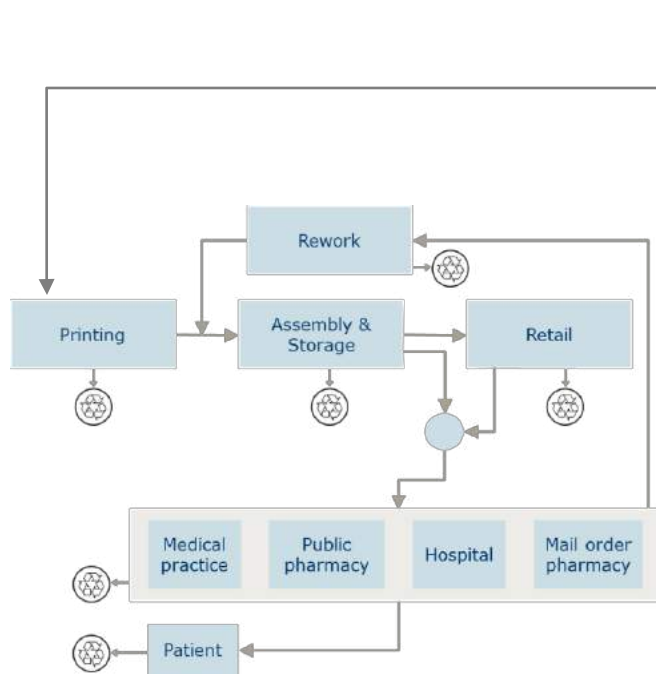
 **BPI** Bundesverband der  
Pharmazeutischen Industrie e.V.

 **vfa.** Die forschenden  
Pharma-Unternehmen

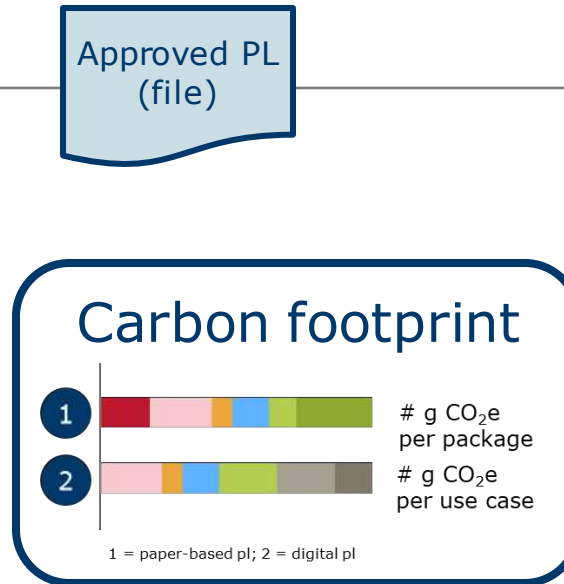
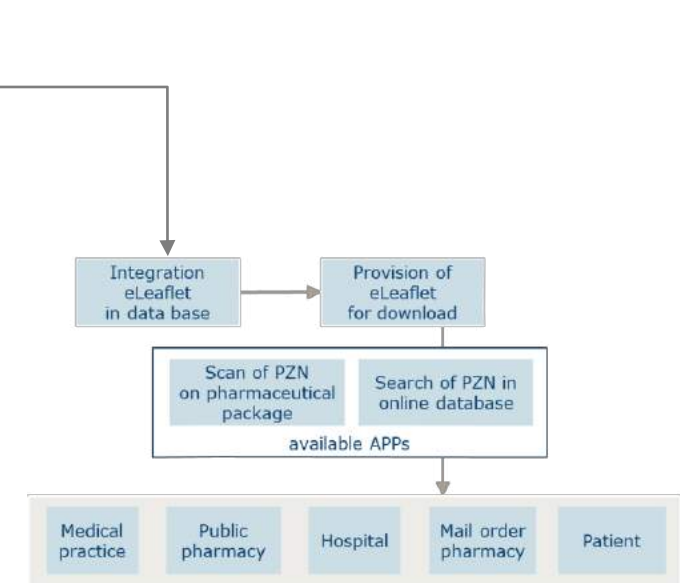
# Carbon footprint as one means for sound decisions and improvements

Objective of the study »Which quantity of greenhouse gas emissions do paper-based & digital package leaflets cause along their life cycle?«

## Paper-based leaflet

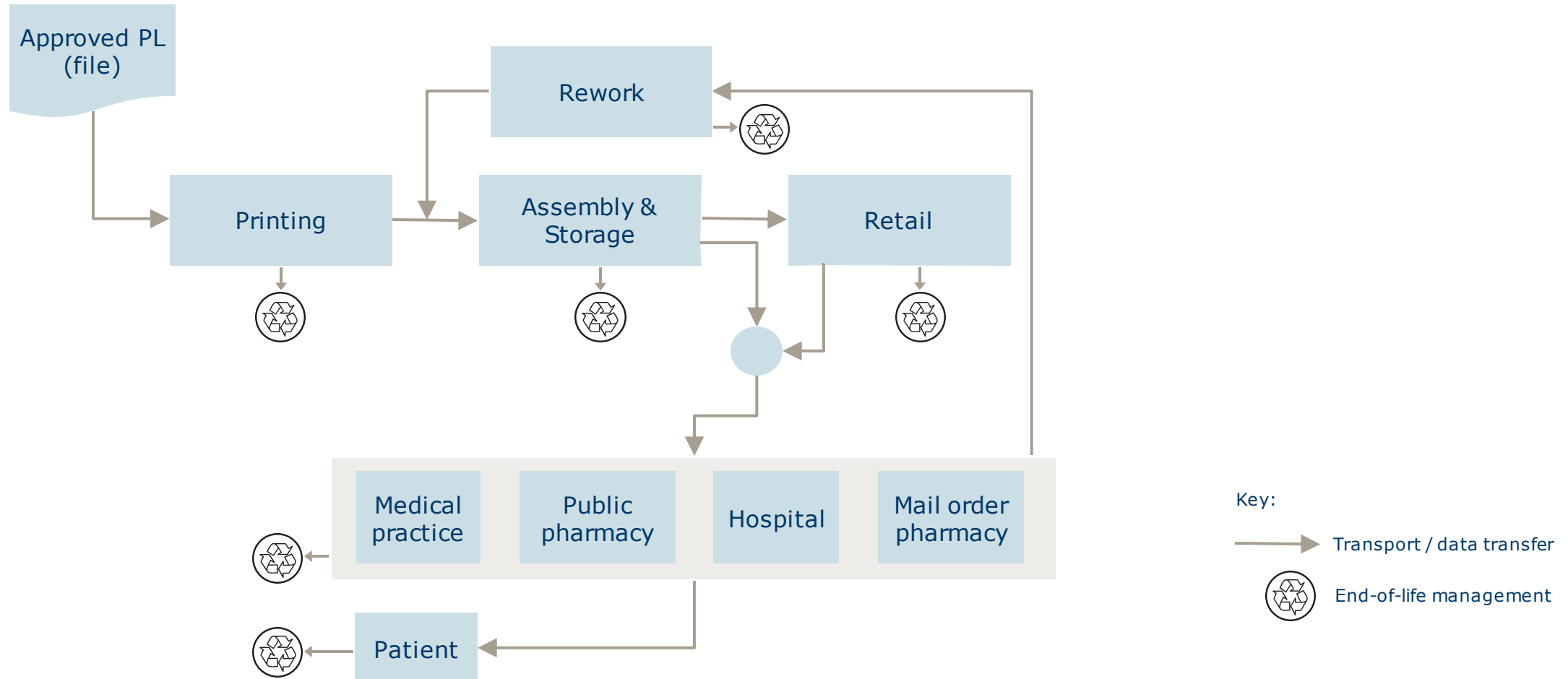


## Digital Leaflet





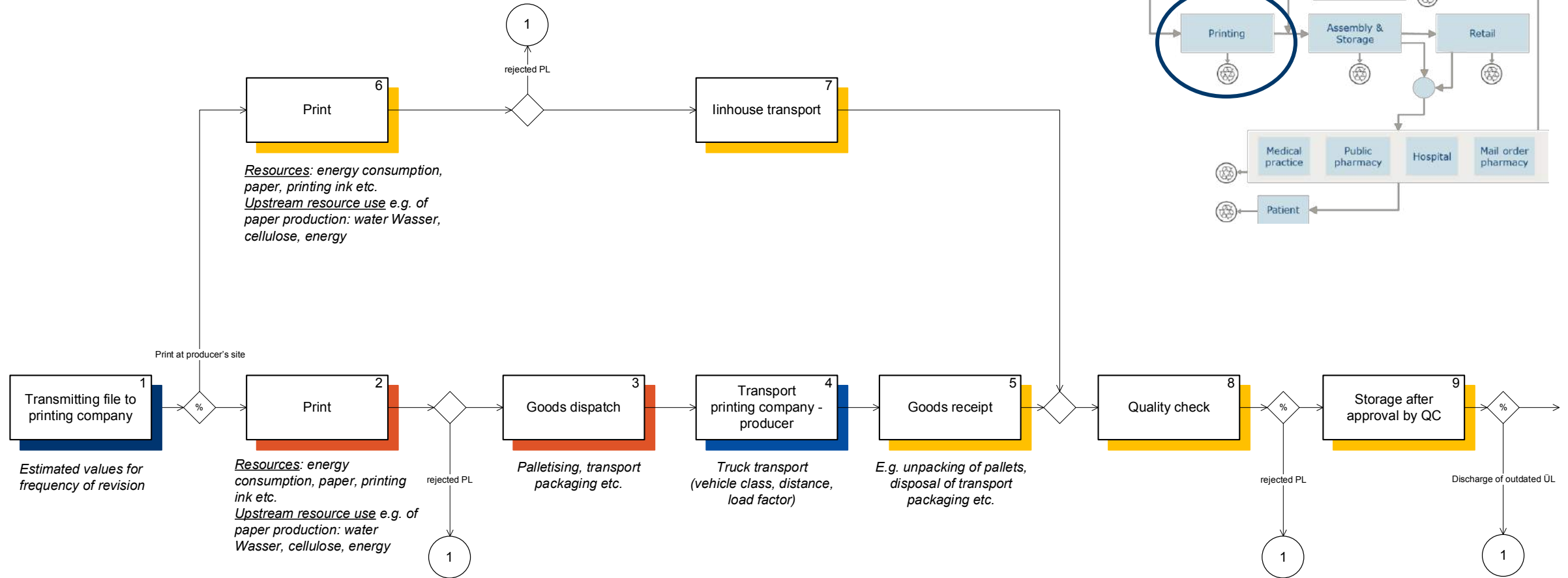
# Life cycle of package leaflets (paper-based)



1.S.002w1

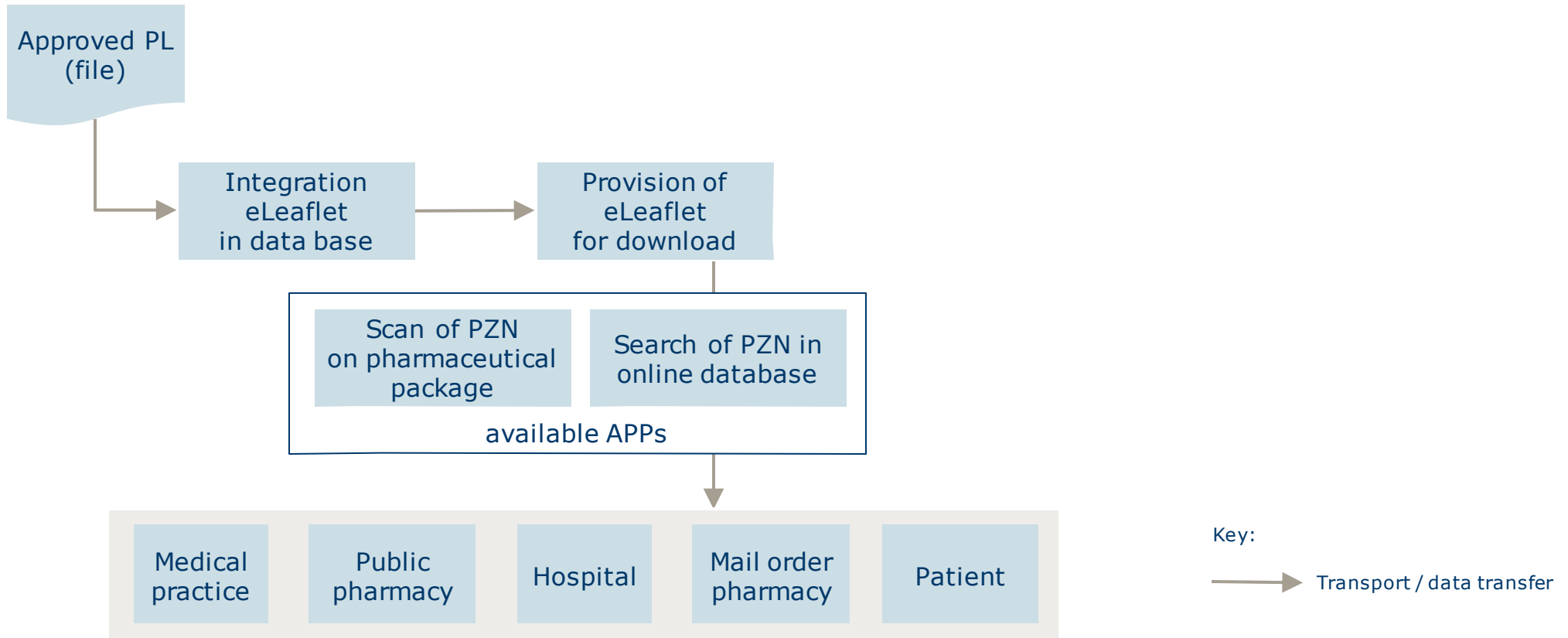
# Life cycle of package leaflets (paper-based)

## Detailed view: File to confirmed printed PL

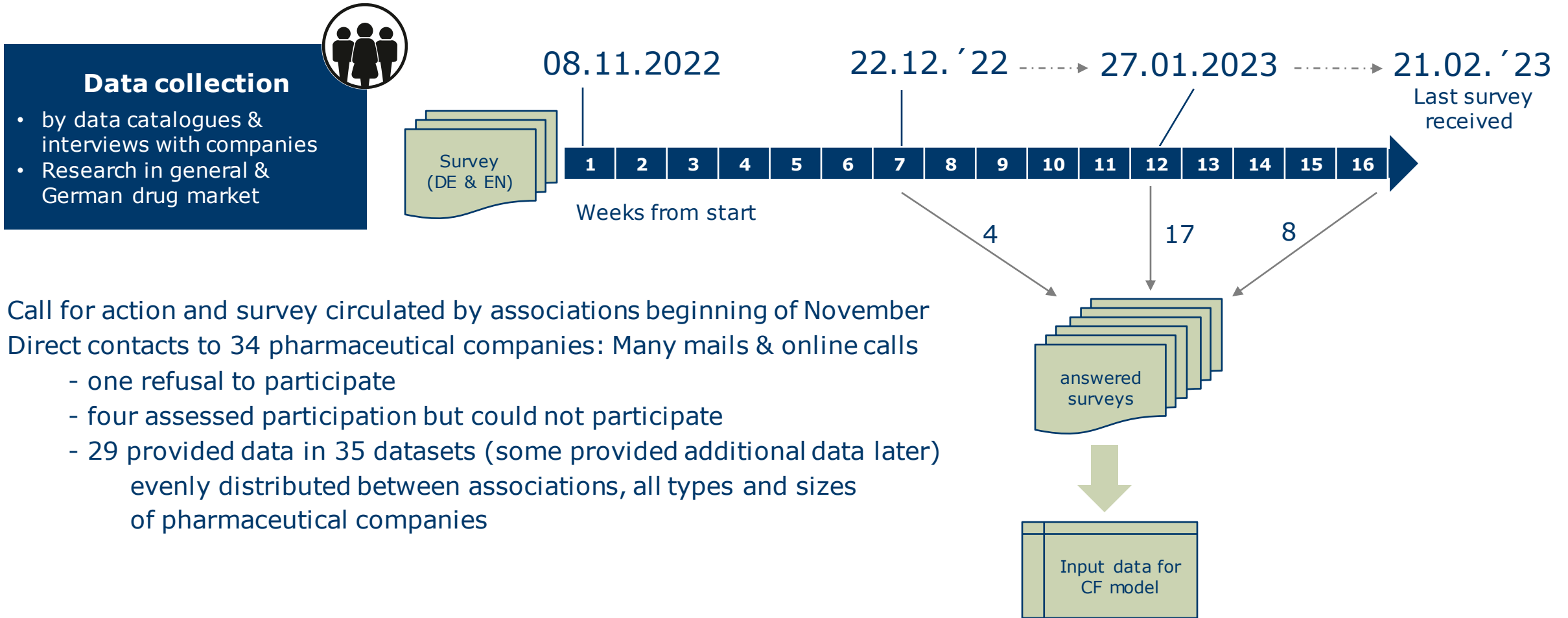


62 Process-Steps, 49 relevant for the study

# Life cycle of package leaflets (digital)



# Overview of Data collection: Reality



Call for action and survey circulated by associations beginning of November  
Direct contacts to 34 pharmaceutical companies: Many mails & online calls

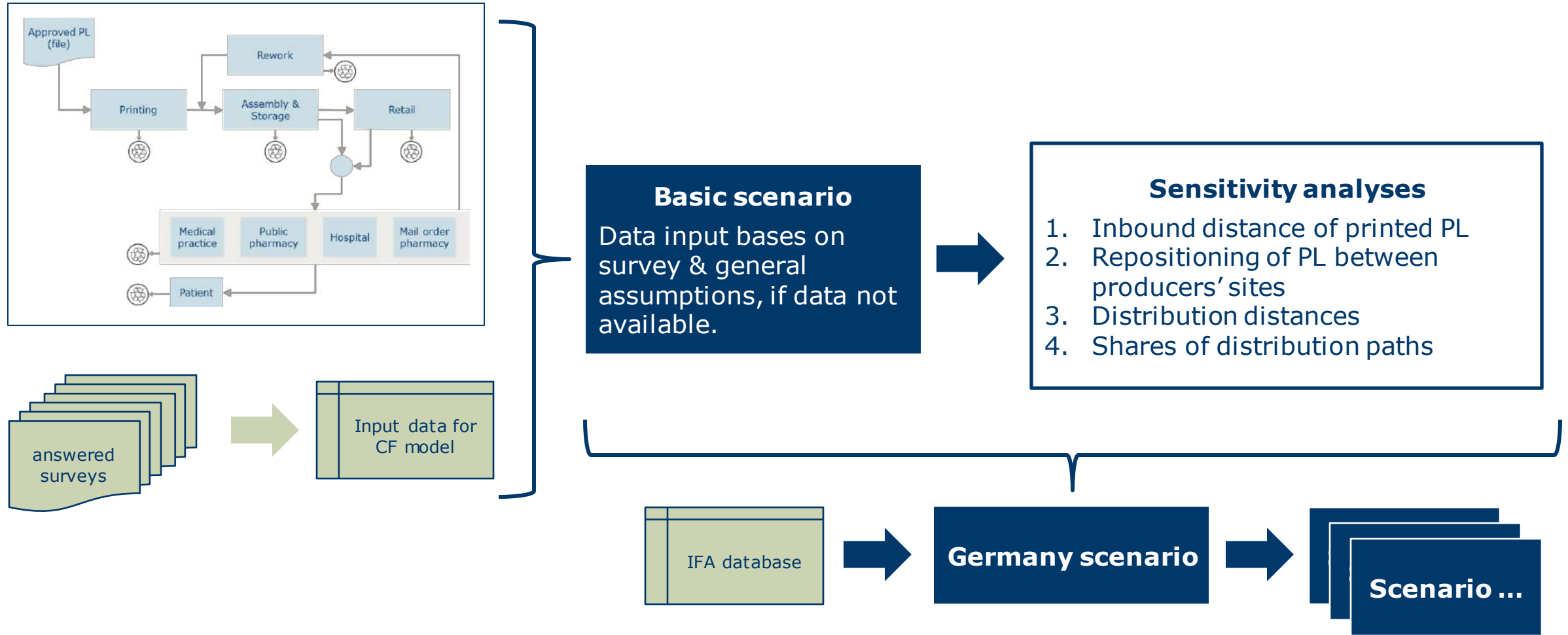
- one refusal to participate
- four assessed participation but could not participate
- 29 provided data in 35 datasets (some provided additional data later)  
evenly distributed between associations, all types and sizes of pharmaceutical companies

# Results from data evaluation

- **Calculation and analysis of 45 reference values plus individual value ranges and number of input values for**
  - General company information (e.g. share of addressed markets)
  - Printing, assembly and distribution
- **Values are mostly based on 1 to 20 survey values (except leaflet size and weight (69 values\*))**
- **Especially for distribution-related values only few input data from the survey (1-7 input values)**
- **We consider the input data as the best available data set for the project**
- Validation of calculated values based on experience from previous projects
  - Partial identification and exclusion of outliers
  - Further research and discussion with experts (e.g. share of distribution channels)

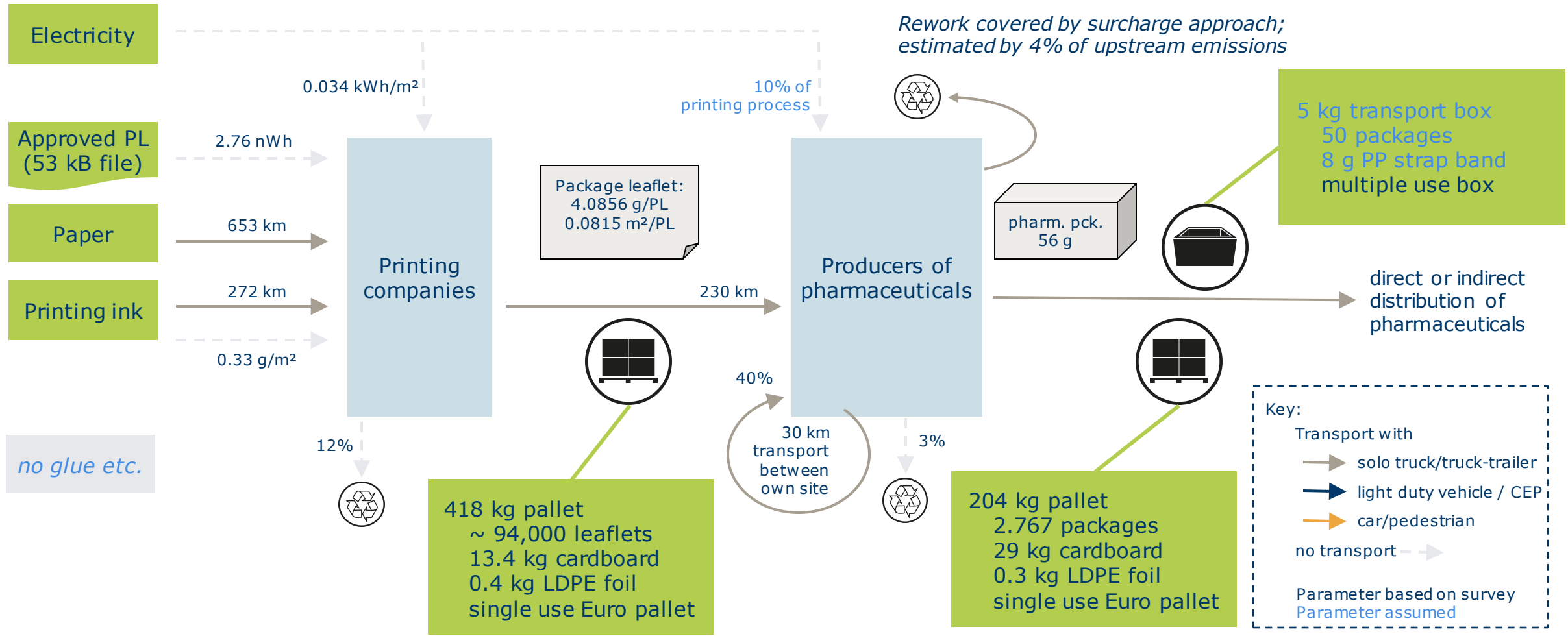
\* Larger Dataset of 324 values for Calculation of average size and weight including own measurements

# Calculation of GHG emissions: Basic scenario & sensitivity analyses



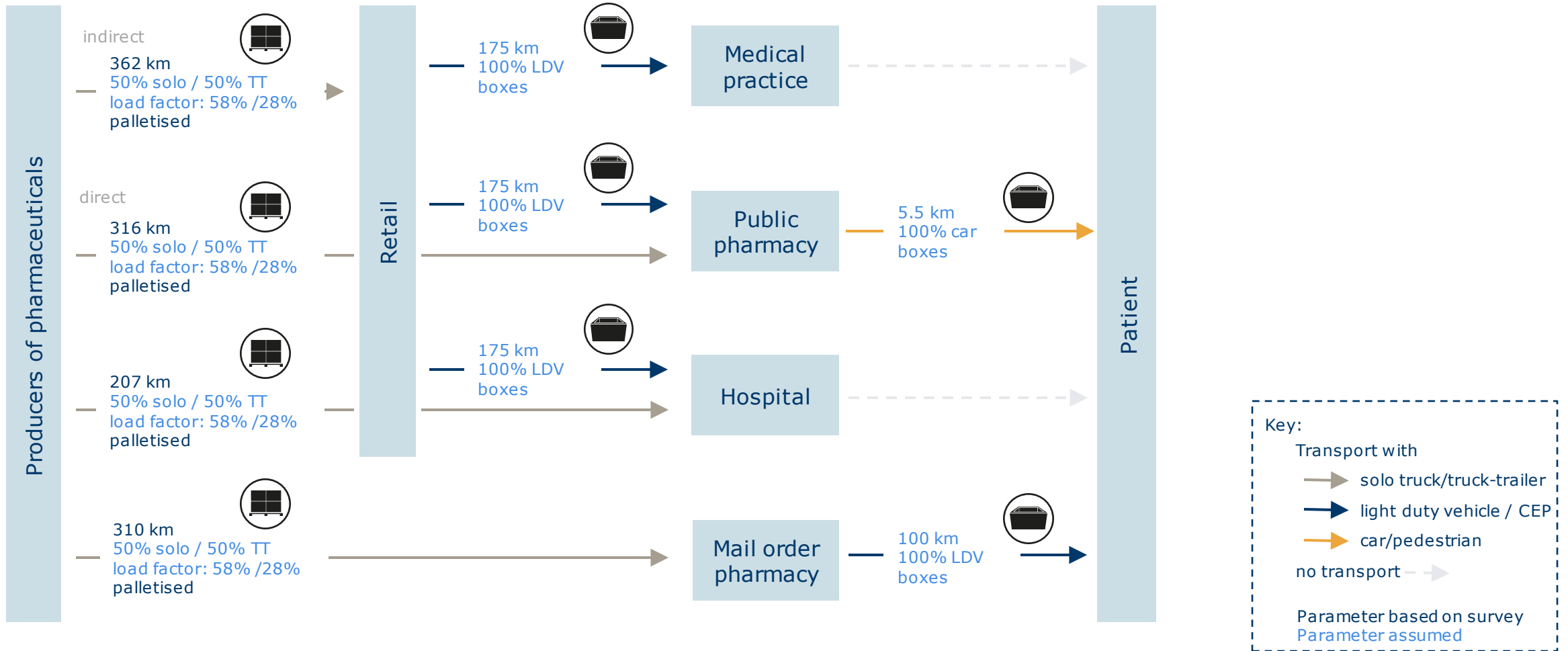


# Basic scenario: Printing and supply of printed leaflets



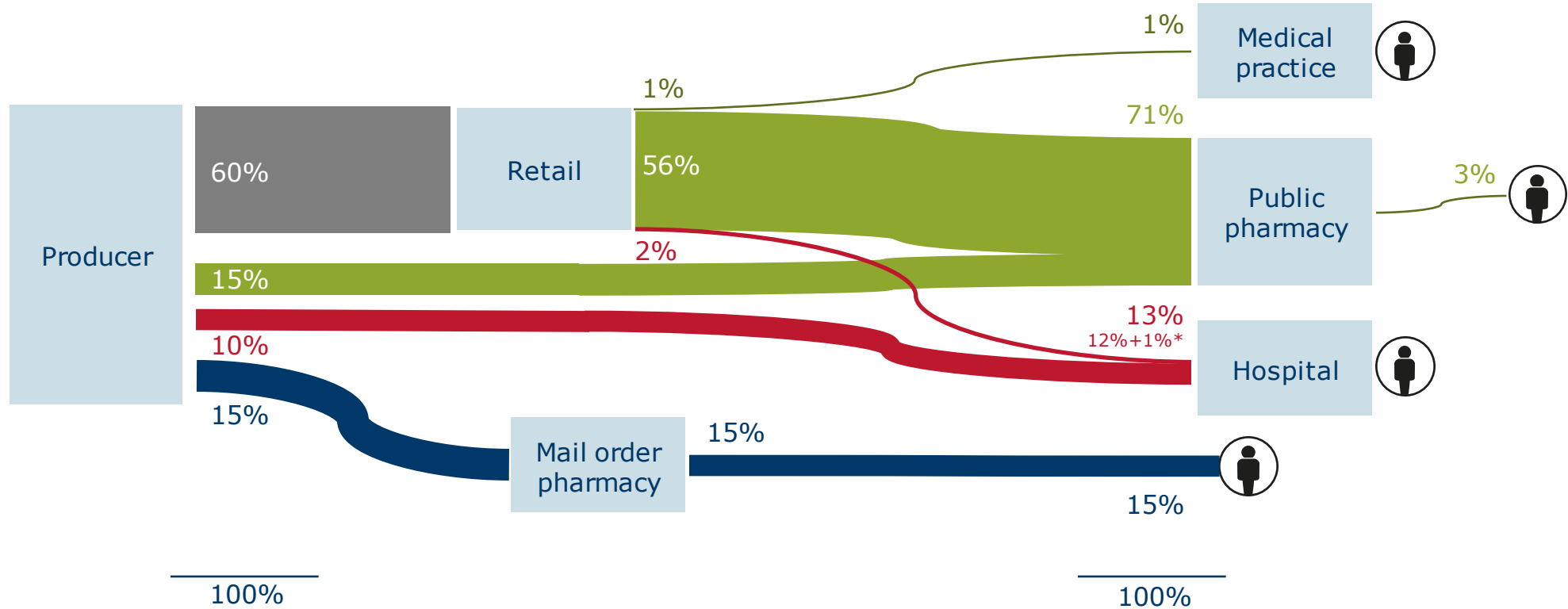
1-S-002w1

# Basic scenario: Distribution distances of pharmaceuticals



1-S.002w1

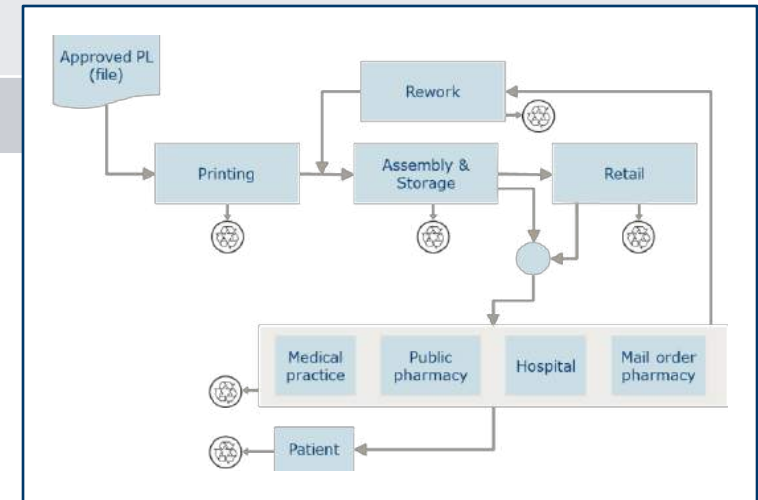
# Basic scenario: Share of distribution paths



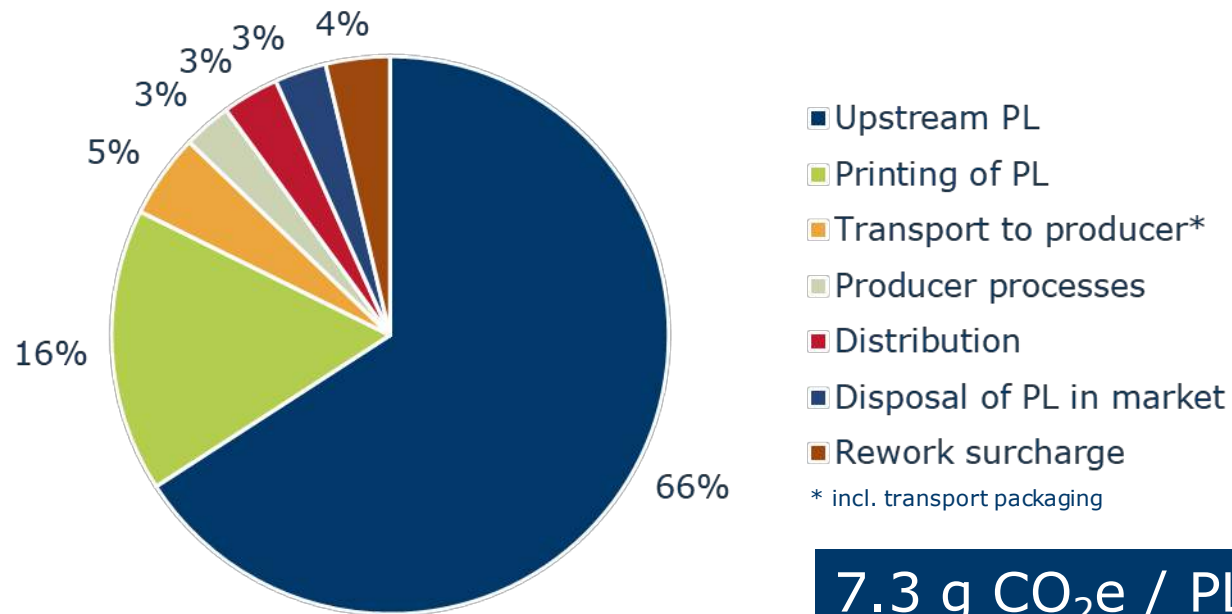
\*due to non-matching shares, manual correction by 1%

# Grouping of results for the carbon footprint

Cluster	Processes
Upstream PL	File transfer, paper for PL: production, inbound transport
Printing of PL	Production, inbound transport of ink, electricity use, waste paper
Transport to producer*	Transport from printing company to producer, *production and eoL of transport packaging
Producer processes	Repositioning between sites, surcharge for wasted PL
Distribution	Transport direct or indirect from producer to patient
Disposal of PL in market	End-of-life (eoL) of PL
Rework surcharge	Share of reworked PL



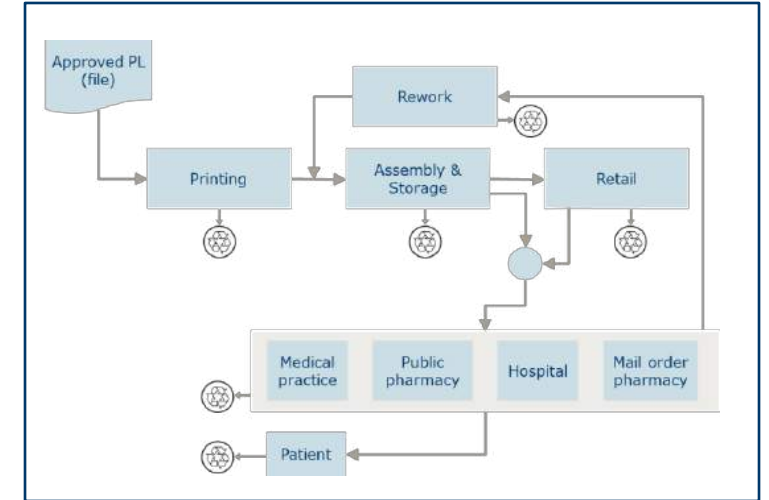
# Basic scenario: Results for the carbon footprint



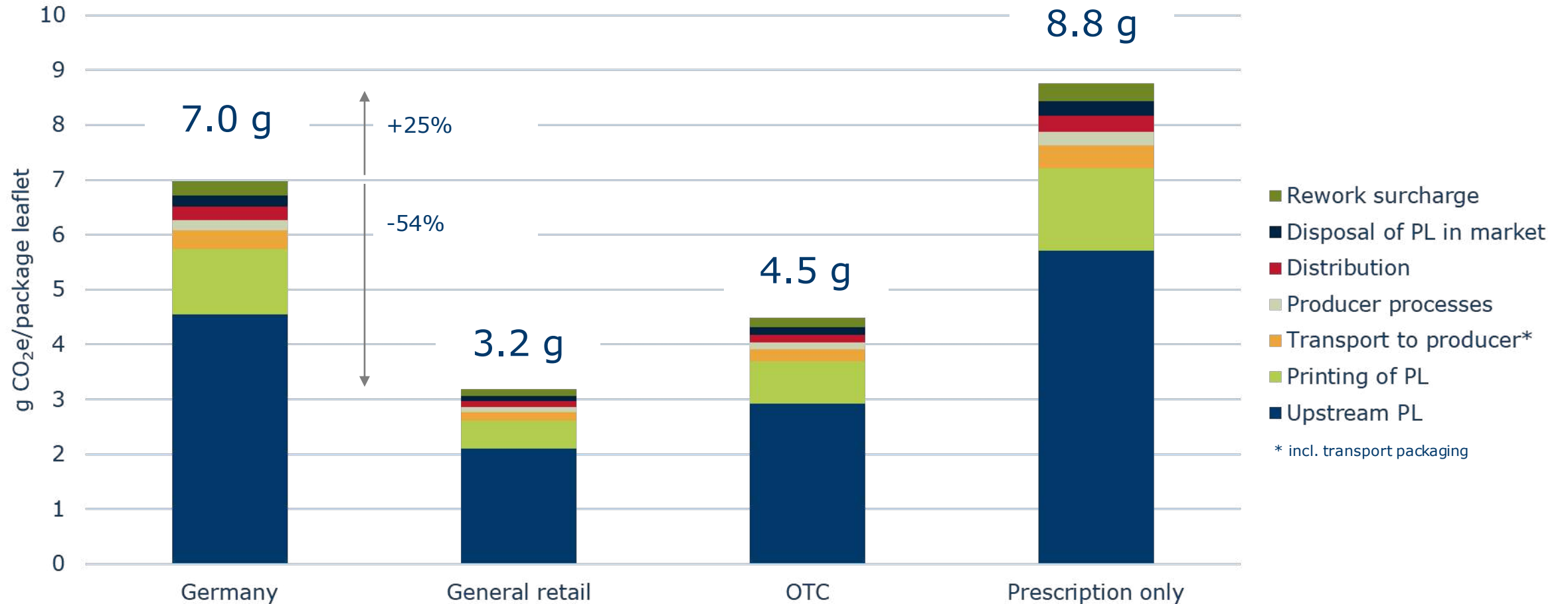
- Upstream PL
  - Printing of PL
  - Transport to producer\*
  - Producer processes
  - Distribution
  - Disposal of PL in market
  - Rework surcharge
- \* incl. transport packaging

**7.3 g CO<sub>2</sub>e / PL**

ca. ± 3.7% estimated in sensitivity analyses  
+ 3.8% // -3.6%

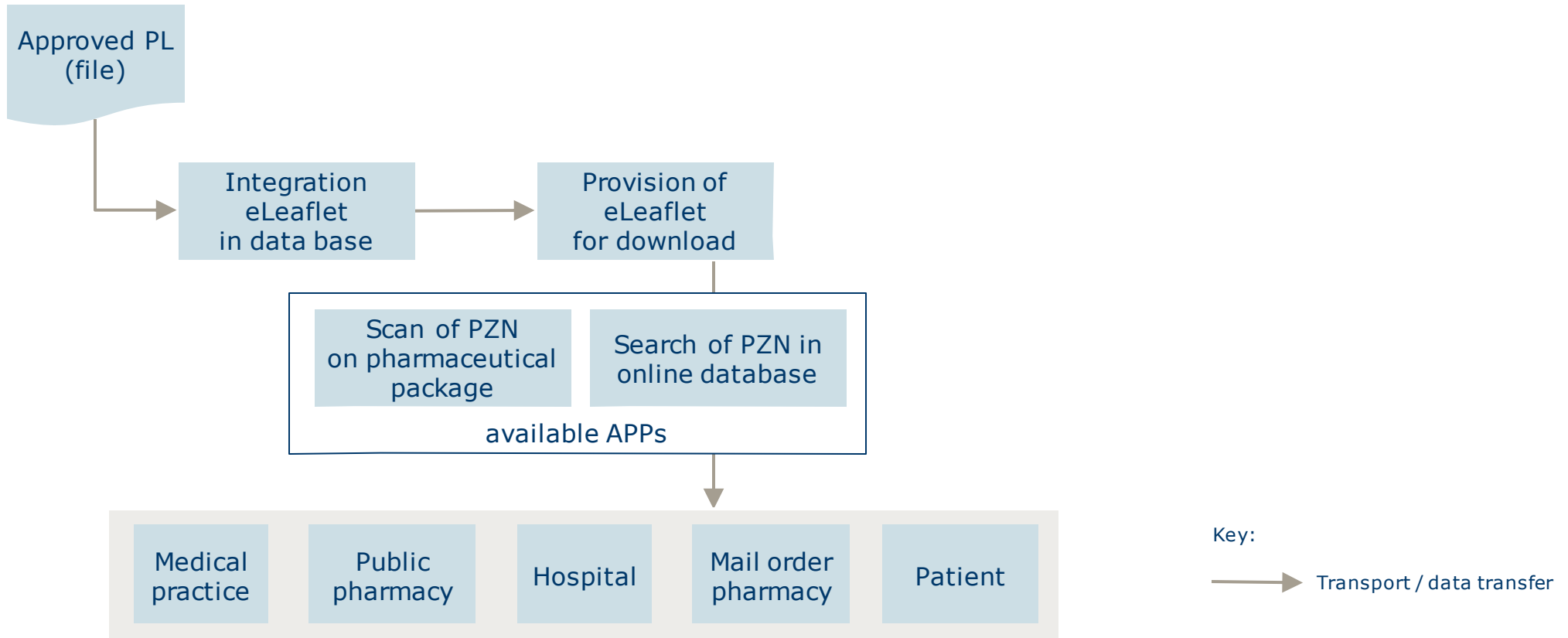


# Scenarios for paper-based leaflet





# Life cycle of package leaflets (digital)



# Underlying data for calculating GHG emissions

Process	energy consumption	unit
<b>data transfer</b>		
mobile internet	2.52E-10	Wh/kB
wired internet	5.2E-11	Wh/kB
<b>data storage</b>		
server / private cloud storage	0.00000003	Wh/kB
<b>data base / ePL access</b>		
Google search request	0.3**	Wh/request
scan code on pharma packaging	n/a	
<b>reading ePL / using personal devices</b>		
smartphone	1.3	Wh
tablet	4	Wh
laptop	13	Wh
desktop PC with monitor	87	Wh

- Main data basis is a study by Öko-Institut e.V. ordered by BUND (2020)\*
  - Summary and calculation of energy consumption values based on literature from the years 2009 and 2020
- Emissions calculated based on German electricity mix (2020) with reference to UBA 2022
- **It is possible, that due to technological advances energy consumption values might have decreased until today**

\*Gröger, Jens, Öko-Institut e.V. (2020): Digitaler CO2-Fußabdruck - Datensammlung zur Abschätzung von Herstellungsaufwand, Energieverbrauch und Nutzung digitaler Endgeräte und Dienste; online available: <https://www.oeko.de/fileadmin/oekodoc/Digitaler-CO2-Fussabdruck.pdf>

\*\*Google (2009): Powering a Google search, <https://googleblog.blogspot.com/2009/01/powering-google-search.html>

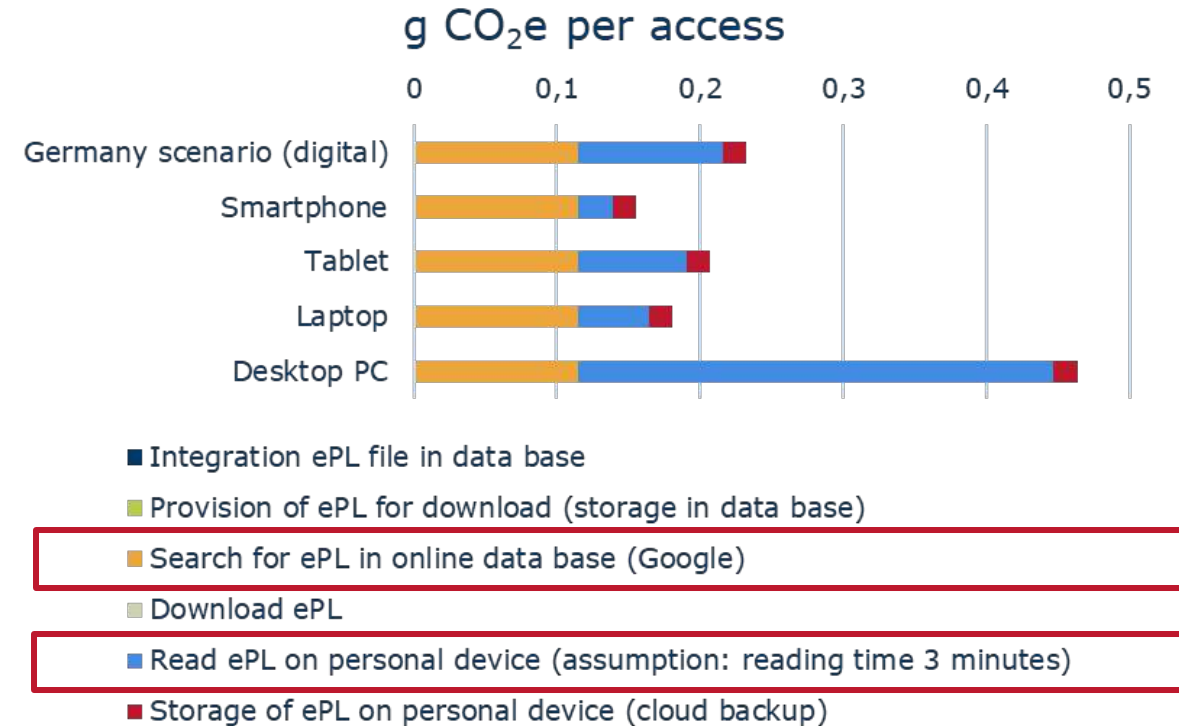
# Assumptions and scenarios for calculation

## Assumptions

- 50% pdf-files (320kB), 50% xml-files (5 kB)
- Duration of storage in central data base: 15 years
- Duration of storage in private cloud: 1 year
- Total storage cap. for ePLs: 47.55 GB
- Total accesses per ePL from central data base: 650,400,000
- Reading time 3 minutes

## Scenarios

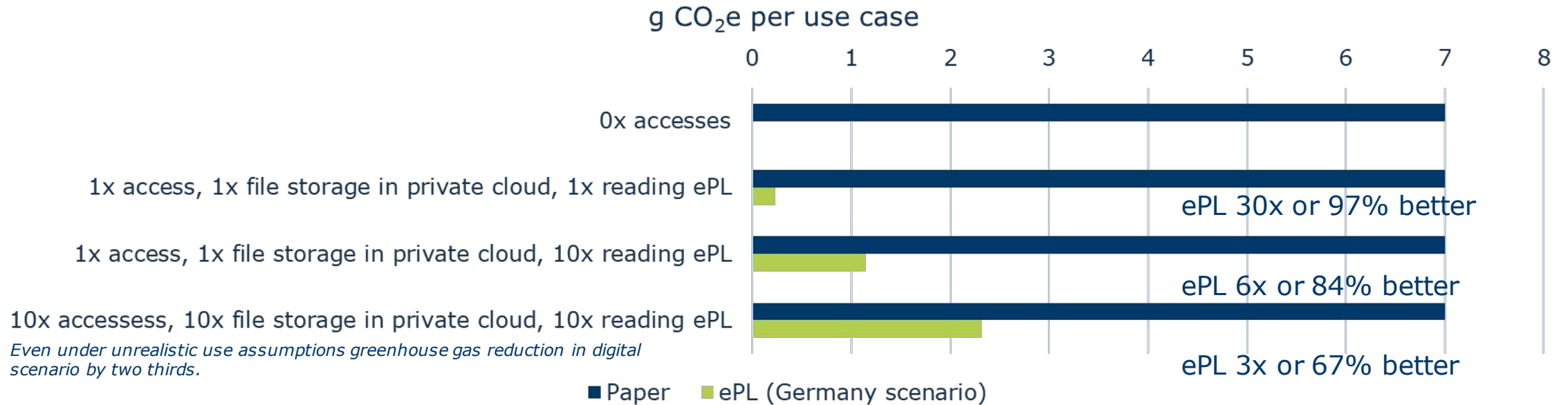
- S1: Germany scenario (digital)\*
- S2: Smartphone, mobile internet
- S3: Tablet, mobile internet
- S4: Laptop, wired internet\*\*
- S5: desktop PC, wired internet\*\*



\*37% access ePL via smartphone, 15% via tablet, 28% via laptop, 20% via Desktop PC

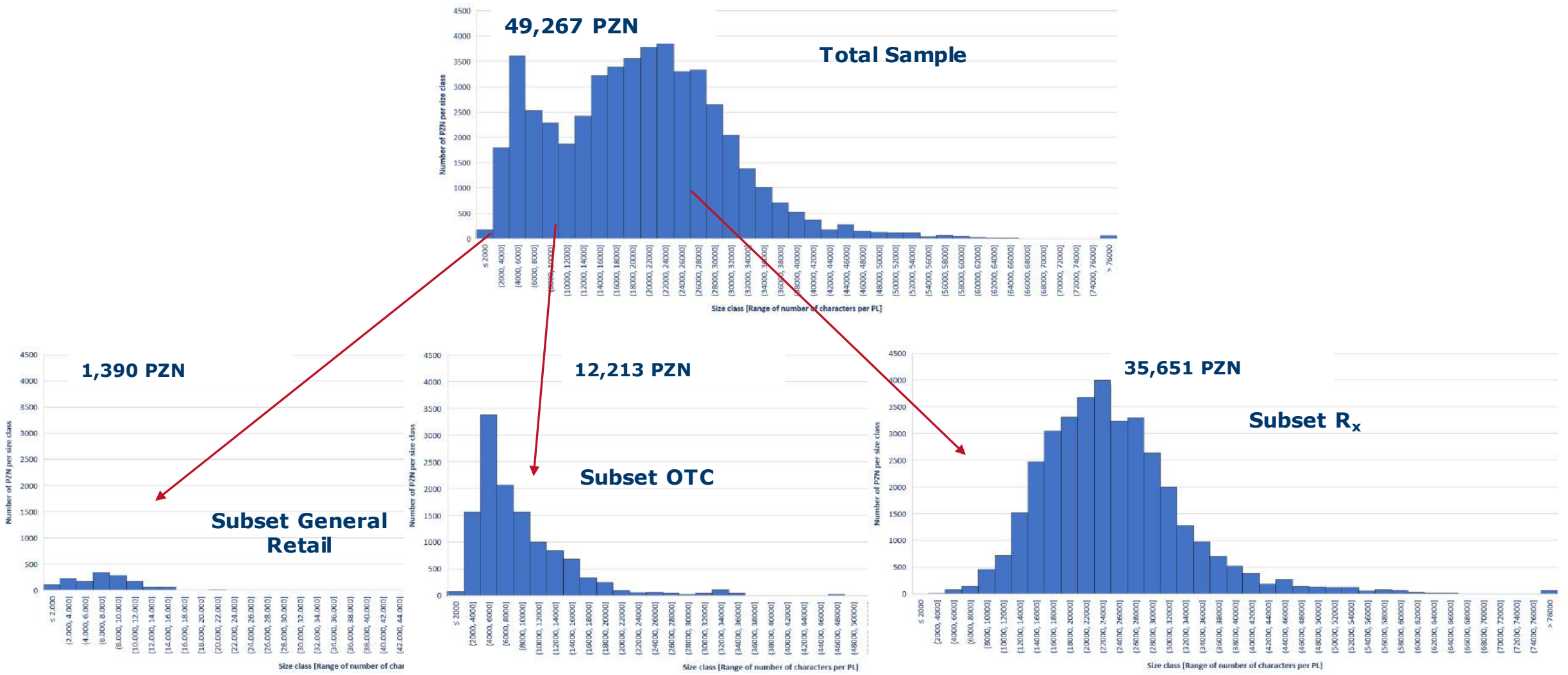
\*\*assumption: Reading ePL claims only 20% of total device performance

# Paper PL vs. ePL



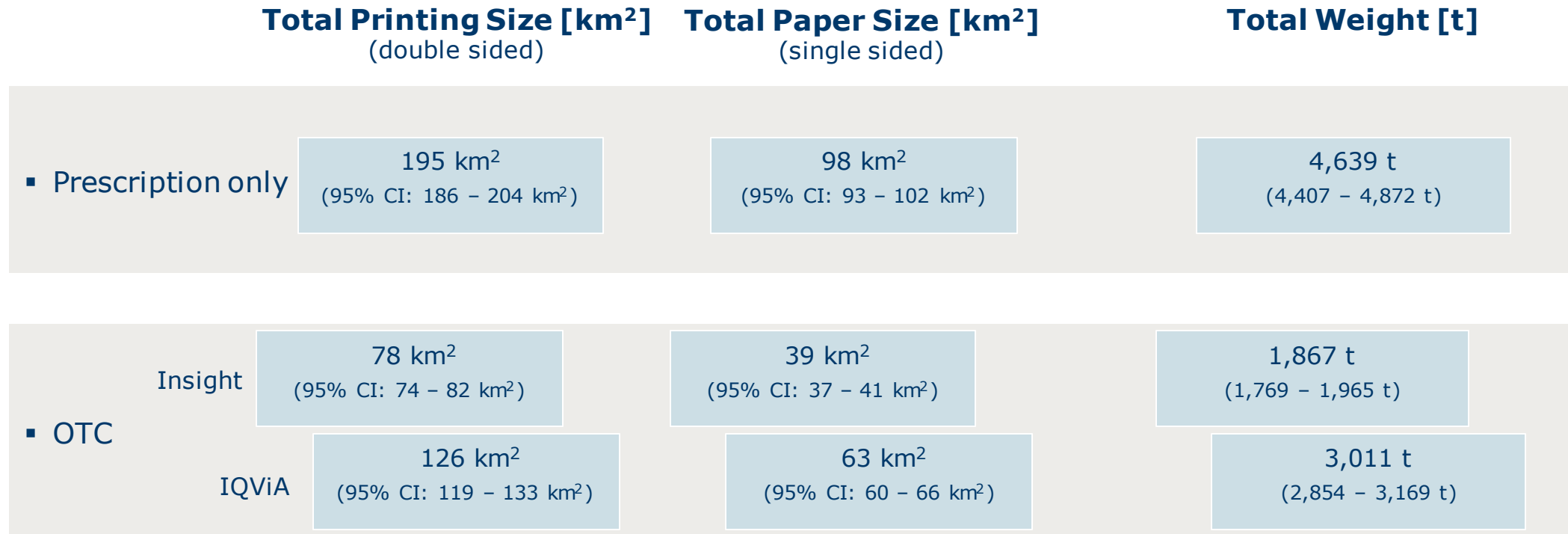
**Digital version (ePL) can be kept up to date while paper versions may be outdated when used.**

# Analysis of size distributions: Characters per PL Total Sample and Subsets pdf Analysis



1.-S.002w1

# Estimation of Total PL Size and Weight, Germany 2022



Margin of error as 95% CI derived from unit sizes as main error source



# Estimation of Total PL Size and Weight, Germany 2022: Extrapolation Production Waste

**Total Printing Size [km<sup>2</sup>]**  
(double sided)

**Total Paper Size [km<sup>2</sup>]**  
(single sided)

**Total Weight [t]**

**Dispensed/  
Sold**  
(repeated  
prev. Slide)

		Total Printing Size [km <sup>2</sup> ] (double sided)	Total Paper Size [km <sup>2</sup> ] (single sided)	Total Weight [t]
▪ <b>Total</b>	Insight	<b>273 km<sup>2</sup></b> (95% CI: 260 – 286 km <sup>2</sup> )	<b>137 km<sup>2</sup></b> (95% CI: 130 – 143 km <sup>2</sup> )	<b>6,507 t</b> (95% CI: 6,176 – 6,837 t)
	IQViA	<b>321 km<sup>2</sup></b> (95% CI: 305 – 337 km <sup>2</sup> )	<b>161 km<sup>2</sup></b> (95% CI: 153 – 168 km <sup>2</sup> )	<b>7,651 t</b> (95% CI: 7,260 – 8,041 t)

**Dispensed/  
Sold and  
Production  
Waste**

		Total Printing Size [km <sup>2</sup> ]	Total Paper Size [km <sup>2</sup> ]	Total Weight [t]
▪ <b>Total</b>	Insight	<b>320 km<sup>2</sup></b> (95% CI: 305 – 336 km <sup>2</sup> )	<b>160 km<sup>2</sup></b> (95% CI: 152– 168 km <sup>2</sup> )	<b>7,622 t</b> (95% CI: 7,235 – 8,010 t)
	IQViA	<b>376 km<sup>2</sup></b> (95% CI: 358 – 395 km <sup>2</sup> )	<b>188 km<sup>2</sup></b> (95% CI: 179 – 197 km <sup>2</sup> )	<b>8,963 t</b> (95% CI: 8,506 – 9,420 t)

Waste on level pharmaceutical entrepreneur: 3%, data from surveys

Waste on level printing house: 12%, data from surveys

Margin of error as 95% CI derived from unit sizes as main error source

# Results in a Nutshell: Package Leaflets 2022, Germany

## Dispensed PL 2022: 1.5 (1.9) bn

Due to the absolute amount of emissions carbon footprint reduction alone is probably no isolated reason to replace printed PL.

**But:**

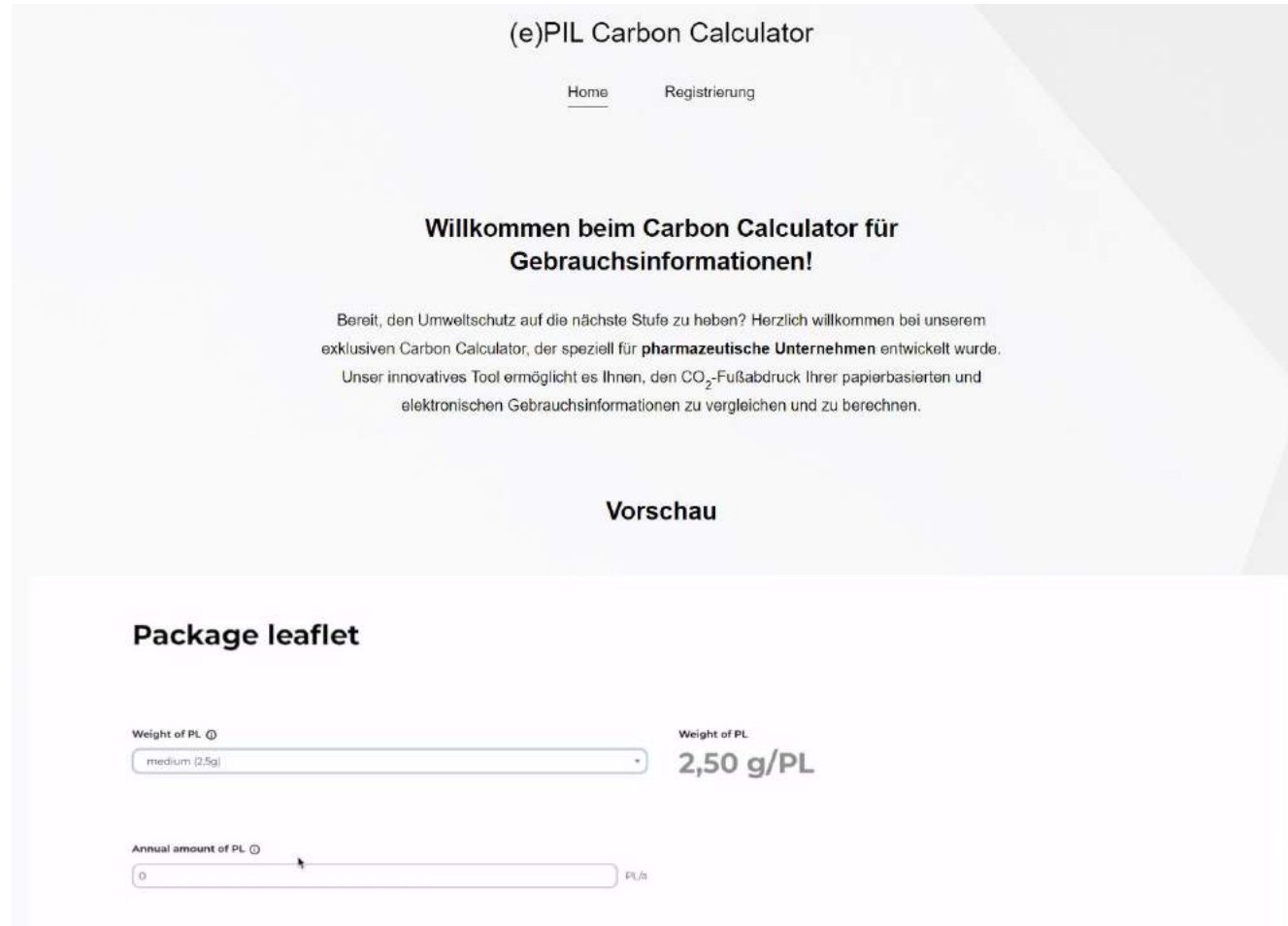
**Better patient information by ePI combined with replacing printed package leaflets additionally to improved information is rewarded by a Carbon FootPRINT reduction of > 90%!**

**11,600 (13,700) t CO<sub>2</sub>e**    **10.8 t CO<sub>2</sub>e** = average annual GHG emissions of German inhabitant<sup>(1)</sup>  
3,100 (3,663) Circumnavigations by Mid-Range Car

## Potential Reduction by using ePL (only) > 90%

(1) BMUV: <https://www.bmuv.de/media/kohlenstoffdioxid-fussabdruck-pro-kopf-in-deutschland>, status 2/2022





<https://www.epilcarboncalculator.com>

IGES Institut

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**[www.iges.com](http://www.iges.com)**

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Anna Preut [anna.preut@iml.fraunhofer.de](mailto:anna.preut@iml.fraunhofer.de) +49 231 / 97 43-377

**[www.iml.fraunhofer.de](http://www.iml.fraunhofer.de)**



digital

PILOTPROJEKT

# ePIL Pilot Germany: State of Preparations

Berlin, 5th March 2024 – DRAFT

VERTRAULICH/ CONFIDENTIAL





**The following presentation gives insights into the current state of preparations of diGital pilot project.**



**Therefore the presentation includes forward looking statements which are subject to future decisions by the legal entities which commissioned the initialization phase and in certain aspects to decisions by state authorities.**

**The following contents are therefore - if needed - subject to future change.**

# diGital pilot project

## Wording

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**diGital** - a play on words:

Package leaflet or patient information leaflet is translated by the regulatory term "**Gebrauchsinformation**" or "**GI**" in to German language.

As "**GI**" is part of the word "di**g**ital" and the project is planned with a focus on Germany, it was decided to call it:

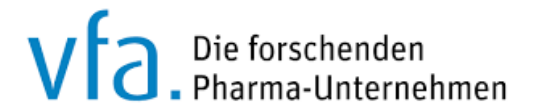
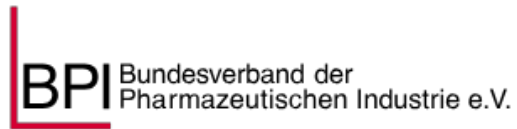
**diGital** pilot project

# diGital pilot project

## Initiators and project office

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The **diGital pilot project** is an initiative by Germany's four leading industry associations of the pharmaceutical industry:



Conceptualization and planning is supported by:



**Dr. Norbert Gerbsch**  
*IGES Institut*



**Paul Kamm**  
*Rote Liste*

# diGital pilot project

## Background, digitization of patient leaflets

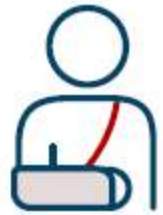
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With ePIL, the benefits are many...



... let's seize the opportunity together!

## Progress and advantages for all stakeholders



Patients



Doctors



Hospitals



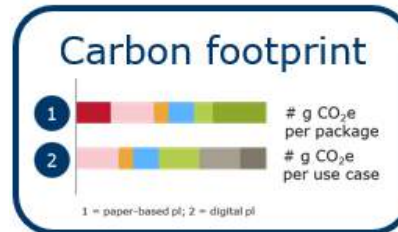
Regulators & Authorities



Industry



Payors



**Technological change is reflected in legislative initiatives and discussions at national and EU level and pilot projects in a number of European countries**

### EU pharma package under discussion

- Currently legal obligation to provide printed package leaflets, art. 58 Dir. 2001/83/EC, "The inclusion in the packaging of all medicinal products of a package leaflet shall be obligatory unless all the information required by [...] is directly conveyed on the outer packaging or on the immediate packaging."
- Digital package leaflets with no formal status in pharma legislation so far.
- Nevertheless advancing in everyday life (pdf).
- Therefore the draft commission proposal and amendments in the EU parliament discuss mandatory or optional availability in paper and/or electronic format.
- In any case: Digital formats will gain in importance, availability and will provide additional functionalities.

### Healthcare system digitization in Germany (selection)

- DigiG, Digital-Gesetz, digital law, adopted, 14 Dec. 2023, i.e. obligatory electronic patient record with opt-out option
- GDNG, Gesundheitsdatennutzungsgesetz, Law on use of health data, adopted, 14 Dec. 2023, use of electronic health data, i.e. for research
- PDSG, Patientendatenschutzgesetz, law on protection for patient data, adopted 3 July, 2020
- Digitale Versorgung und Pflege Modernisierungsgesetz (DVPMG), adopted 6 May, 2020
- DVG, Digitale-Versorgung-Gesetz, law on digital healthcare, adopted 7 Nov. 2019, i.e. DiGA
- European Medicines Agency pilot project to test ePI
- Gebrauchsinformation 4.0<sup>®</sup> developed as patient-focused solution

**Pilot projects in: Belgium, Luxemburg, the Baltic States, Portugal, Spain, France (2024),...**



**The diGital pilot project aims to advance  
electronic package information leaflets.**

**It serves as an important step in anticipating forthcoming developments  
and legislation, enabling us to gather more experiences, data,  
and solutions for future implementation.**

# diGital pilot project – main pillars

The diGital pilot project addresses acute and long-term challenges

## diGital pilot project



### Overcoming supply shortages - diGital leaflets provide concrete help

- Mitigate supply shortages with packs in other languages and make German package leaflets quickly available digitally for greater availability of information.



### Package leaflets in hospitals - diGital better than printed

- Remove printed package leaflets for use in defined pilot products.
- Improve information flow and handling in everyday clinical settings; improve carbon footprint.



### Integrate ePILs into health insurance apps - facilitate availability for patients

- ePILs can be called up in health insurance apps based on received prescription informations (PZN/batch).
- Current ePILs are provided for each prescribed medication.



### Promote the regular use of ePIL

- Digital patient information leaflets offer patients many advantages.
- The advantages of ePILs should be promoted with the help of various measures.

# diGital pilot project – Goals

The pilot project is examining the practicality of digital patient information leaflets



## Goals of the diGital pilot project



### ... for supply shortages

Demonstrate that digital patient information leaflets facilitate access to product information for patients.



### ... for hospitals

Demonstrate that the printed patient information leaflet (PIL) can be fully replaced by an electronic PIL in clinical practice for medicinal products that are only intended for inpatient use.



### ... for patients

Demonstrate that simplified access to digital patient information leaflets can increase patient usage.

# Pilot pillar I: overcoming supply shortages (1/2)

ePILs can help mitigate supply shortages and provide easy access for patients



## Overview



Digital package leaflets can alleviate supply bottlenecks and make it easier for patients to access information.



Current shortage situations mitigated by approval of foreign imports in another language by the authorities.



Packs are delivered unchanged with foreign package leaflet. DMC is used to access ePIL in national language.



Data collection of the number of accesses to digital GIs of imported products.

This operational pillar aims  
**to gain insights into facilitating patient access  
to products and product information in the context of supply  
shortages.**

# Pilot pillar I: overcoming supply shortages (2/2)

ePILs can help mitigate supply shortages and provide easy access for patients



## High-Level process



*Please note: The process steps listed are a simplified summary for illustrative purposes and include many other intermediate steps*

# Pilot pillar II: hospital pilot (1/2)

## Digital package leaflets can adequately replace paper versions



### Overview



The printed package leaflet for medicinal products can be fully replaced by an ePIL in clinical practice.



Approval of the pilot products by the authorities is required.



Packages are delivered without package leaflets and hospitals are informed i.e. via delivery notes.



Data collection of the number of accesses to ePILs and survey of hospital staff by questionnaires in regard to practicability.

This operational pillar aims **to demonstrate that packages with ePIL only are equivalent or even superior in everyday healthcare life in hospital settings.**



# Pilot pillar II: hospital pilot (2/2)

## Digital package leaflets can adequately replace paper versions



### High-Level process

1



Registration of pilot products based on defined criteria

2



Approval of exemption from §11 AMG by authorities for pilot products to participate

3



Upload the digital package leaflet to the platform and assign the relevant NTIN

4



Delivery of pilot products with reference on delivery note

5



Scan of the pilot packs by HCP with app and display of the ePIL. Questionnaire to gather information about use.

*Please note: The process steps listed are a simplified summary for illustrative purposes and include many other intermediate steps*

# Pilot pillar III: integration in further apps (1/2)

## Fostering patient acceptance through easy access to ePILs



### Overview



Easy access to ePIL by storing it in SHI<sup>1</sup> apps can increase access and thus acceptance and use.



SHI apps and related applications (e.g. ePA) are important drivers of the digital transformation in the German healthcare system.



As many digital package leaflets as possible should be integrated into SHI apps in a structured format.



Data collection of access figures to ePILs through SHI apps and optional surveys of insured persons

This operational pillar aims to **increase the availability of ePILs and investigate whether patients make greater use of digital patient information leaflets when access is made easier.**

# Pilot pillar III: integration in further apps (2/2)

## Creating patient acceptance through easy access to ePILs



### High-Level process

1



Pilot participants provide digital package leaflets for their products.

2



Upload and conversion of the package leaflets to the corresponding infrastructure

3



Provision of ePILs to health insurance apps via dedicated interfaces.

4



Storage of the digital package leaflet for medication overviews.

5



Insured persons receive the latest and if applicable batch-related ePIL by clicking on medication

*Please note: The process steps listed are a simplified summary for illustrative purposes and include many other intermediate steps*

# Pilot pillar IV: Promote the regular use of ePIL

Increasing patient acceptance and use by communicating advantages



## Overview



Patients need more information about the many advantages of digital package leaflets to increase the overall use of ePIL solutions.



Promoting communication by operators of apps with ePIL such as payor apps, communicating using social media,...



Exploring possibilities for push messages



Engagement with different user groups to generate further insights on user needs and wishes.

This operational pillar aims to **increase knowledge about ePILs, increase acceptance and use of ePILs by patients.**

# diGital pilot project

Making efficient use of existing technologies

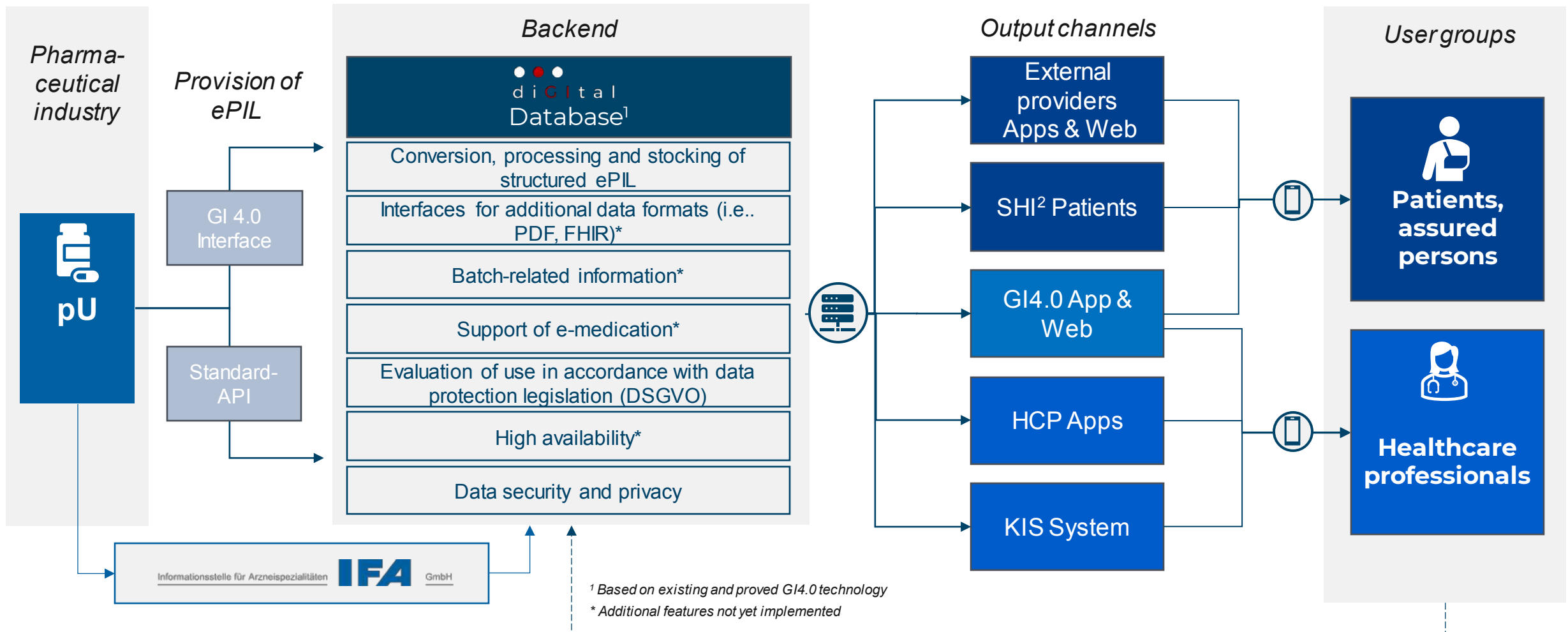
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**The pilot project uses existing technologies, databases, apps and user channels to maximise speed and results**



# diGital pilot project

## General outline of system architecture





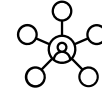
# Involved stakeholders

A large number of stakeholders are necessary for successful implementation



## Associations (BAH, BPI, ProGenerika & vfa)

Act as initiators and representatives for the interests of pharmaceutical companies.



## diGItal Pilot PMO

Responsible for the conceptualisation, coordination and implementation of the project.



## Pharmaceutical companies

Participate in the pilot, receive regular updates and can provide feedback for optimization.



## Patients

Users of the ePILs, which can provide valuable feedback.



## Authorities

Responsible for the exemption authorization as well as permits for delivery shortage products.



## Hospitals

For hospital pilot, support of hospitals especially a sample for questionnaires is necessary to collect data.



## Technology partner

Possible partners for the integration of ePILs in other applications in order to reach as many users as possible.



## Further stakeholders

Other associations and interest groups are important multipliers (e.g. ADKA, ABDA, payors, etc.)

# diGital pilot project – Differentiation factors (1/2)

The project pursues an extended and differentiated approach compared to existing pilots

1

## Supply shortages Better provision of information

2

## Batch Actuality of ePIL

3

## Extended data collection Involvement of other stakeholders

### Pilot projects in other European countries

- Addressing supply shortages is not part of the existing pilots.

- There is no batch reference to ePILs today.

- Rudimentary data collection focusing on hospital pharmacists.

### diGital pilot project

#### Outpatient context

- ePILs can fulfil the requirements of AMG §§ 10 and 11 for access to product information in German language for packages in other languages than German
- If the company is interested, a demonstration can be carried out using further case studies.

#### Hospital context

- Easier handling in everyday clinical practice thanks to ePILs.
- A translation needs to be provided.

- The authority and the MAH can coordinate the timing of changes in the event of adjustments.
- Always current / correct ePIL available for batch.

- Expanded data collection from various stakeholders to gather evidence for legislation.
- When using the G4.0 app and website, access figures can be recorded anonymously in accordance with data protection laws (DSGVO).

# diGital pilot project – differentiation factors (2/2)

The project pursues an extended and differentiated approach compared to existing pilots

	<b>4</b> <b>App usage</b> <b>Maximum user-friendliness</b>	<b>5</b> <b>Extended user group</b> <b>Germany &amp; other pilot countries</b>	<b>6</b> <b>International cooperation</b> <b>Optional</b>
<b>Pilot projects in other European countries</b>	<ul style="list-style-type: none"> <li>Previous pilots only use websites to display the ePIL and usually refer to static PDFs.</li> </ul>	<ul style="list-style-type: none"> <li>Addition of a further large market to existing and planned pilots in other European countries (Belgium, Luxemburg, Baltic states, Portugal, Spain, France, etc.).</li> </ul>	<ul style="list-style-type: none"> <li>Pilot projects have so far been primarily national in scope and multi-market packs are not taken into account.</li> </ul>
<b>diGital pilot project</b>	<ul style="list-style-type: none"> <li>Use of an app to improve the availability of information and thus improve handling in everyday clinical practice.</li> <li>Integration of ePILs in other applications, e.g. ePA, is conceivable.</li> </ul>	<ul style="list-style-type: none"> <li>In addition: More efficient use of packaging lines may increase efficiency and availability of products participating in pilot projects</li> </ul>	<ul style="list-style-type: none"> <li>Possible cross-border cooperation offers a new, relevant approach for pilot projects.</li> <li>The use of multi-market packs without package inserts can be tested.</li> </ul>

# Declaration of interest

## Survey indicates high interest in the pilot project across all topics

From mid-December 2023 until end of January 2024, German pharmaceutical companies were **able to express a non-binding general interest for participation.**

**+60 companies** across the entire spectrum of the pharmaceutical industry responded positively to the survey!

**67%**

*...indicated interest for the supply shortage topics*

**68%**

*... indicated interest for the hospital pilot topic.*

**72%**

*... indicated interest for the health insurance integration topic.*

The pharmaceutical companies that expressed their interest in participation make up **2/3 of the entire RX-pharmaceutical** market by package numbers in Germany!

## Next steps

Operational start of most of the project's pillars can start soon



ePILs for supply shortages



ePIL integration in health insurance apps



General promotion of ePIL



No further special regulatory approvals needed, processes and general framework are defined.

As a result, these project pillars can start soon, depending on finalization of planning process.



ePIL hospital pilot



Regulatory approval and discussions are pending.

More detailed information for involved stakeholders planned soon according to project progress

# Contact

Please contact us:

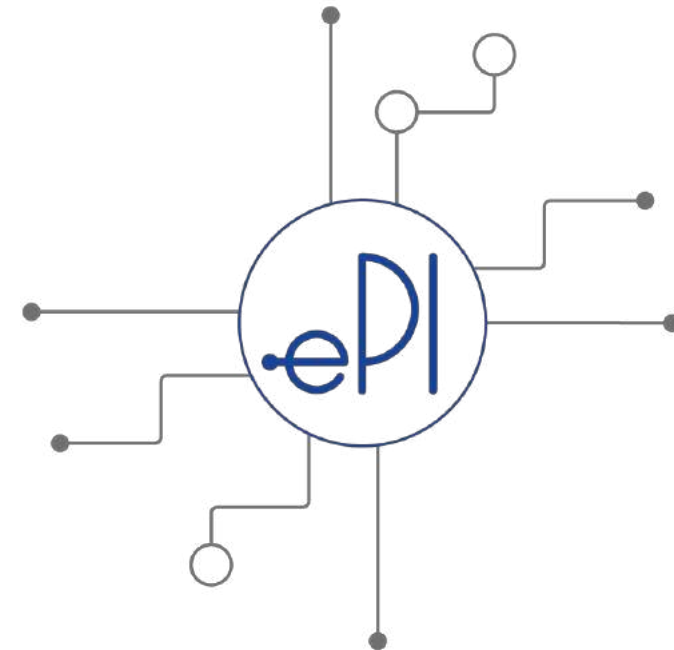
- [info@di-gi-pilot.de](mailto:info@di-gi-pilot.de)
- At our roll-up in the lobby
- <https://www.di-gi-pilot.de>



# Inter-Association Task Force ePI (IATF)

5 March 2024

Britt Vermeij, Chair of the Inter-Association Task Force





# Background

2015) [Nivel](#) report

2016) [response](#) from Industry working group of Medicines for Europe, EFPIA and AESGP: Inter-association taskforce

2017) [EMA](#) response to Nivel report



EMA, HMA and CMDh worked together on preparation of a roadmap and defining the key principles

# Inter-association taskforce (IATF)

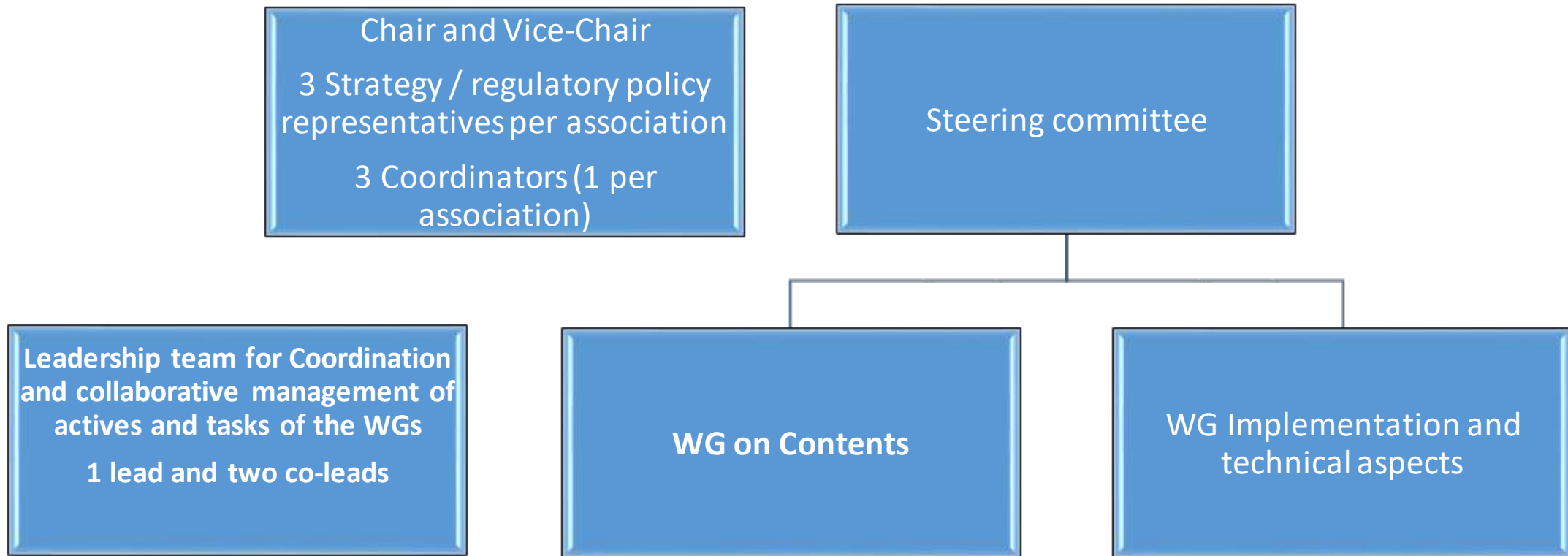
Medicines for Europe, EFPIA, AESGP

Pharmaceutical Industry aims to partner with stakeholders to identify solutions, focussing on:

- Develop improved product information content, layout and readability within current and future legislation and guidance.
- Support development of a standardized ePI structure and common portal as a single source of truth to facilitate data upload and dissemination of electronic product information, as well as create regulatory efficiency.
- Stimulate the transition from paper to electronic product information to unlock value for Patients, HCPs, Consumers, Health Authorities, Industry and the Environment.
- Leverage ePI to increase the impact and the use of the information available in the PI to drive better health literacy.



# Composition of the IATF

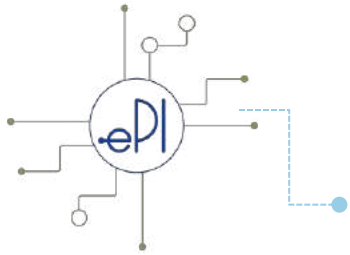


# Initial activities

## Different working groups:

- SWOT analysis
- Content improvement
- User testing
- Readability guidelines
- Technical aspects and requirements

# 2019/2020 EMA – HMA Key principles for ePI



Consultation on the draft of the EMA – HMA Key principles for ePI January – July 2019



EMA – HMA Key principles for ePI published on 29 January 2020



Extended IATF position paper published in October 2020

# 2021-2023 activities

Proposals for improvement of content of the leaflet

Collaboration and discussions with various regulators

Support of industry SME's in EMA/HMA pilot

Legal proposal for Draft Pharmaceutical Legislation

Outreach to external stakeholders

# Activities moving forward

Continue to share Industry position and drafting of proposals for the Pharma Review

Continue support EMA/HMA ePI pilot

- Support to industry SMEs and questions raised
- Future roadmap for ePI implementation

Continue work with regulators on improvement of the content

- Improvement of the QRD template
- Position on implementation of QRD update
- Response QRD/Authorities proposals
- PV aspect of the PL

External outreach to stakeholders

- Hospital/Retail Pharmacists
- Regulatory bodies (QRD, EMA, CMDh)
- Patient/consumer organisations
- Others

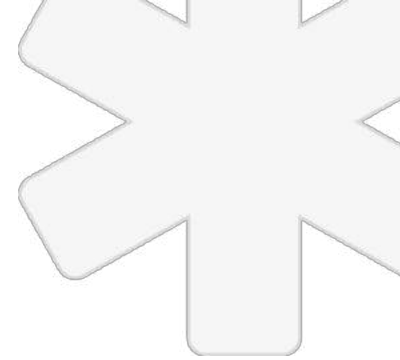
Prepare several position papers to support discussions with stakeholders:

- Dissemination of ePI (“downstream”)
- National pilots
- Access to the leaflet
- Key Information Section





European Federation of Pharmaceutical  
Industries and Associations



## Making ePI accessible to everyone

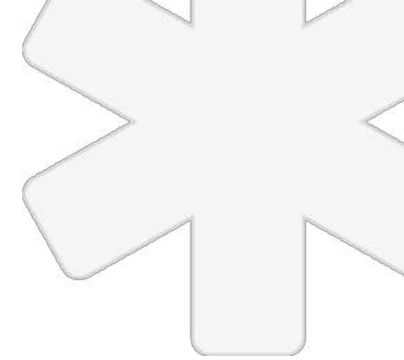
Author: Laura Bacci Garriga - on behalf of EFPIA

Date: 05/March/2024



ROTE Liste Summit, Berlin 2024





# Contents

The Context : Draft EU General Pharmaceutical Legislation

- Electronic Product Information in the Directive (ePI)
- Opportunities and Challenges
- Stakeholders' Concerns

Who might be left behind by ePI?

- EUROSTAT Data

Exploring Solutions

- EFPIA
- ePI: Drivers and benefits for all stakeholders
- Criteria for Success

Next Steps in the EU Legislative Process

# THE CONTEXT- THE DRAFT EU GENERAL PHARMACEUTICAL LEGISLATION (GPL)

## Electronic Product Information in the Directive

Draft Directive, Chapter VI, Article 63.3,  
European Commission original draft version

3. Member States may decide that the package leaflet shall be made available in paper format or electronically, or both. In the absence of such specific rules in a Member State, a package leaflet in paper format shall be included in the packaging of a medicinal product. If the package leaflet is only made available electronically, the patient's right to a printed copy of the package leaflet should be guaranteed upon request and free of charge and it should be ensured that the information in digital format is easily accessible to all patients.

## Opportunities, Challenges and Objective

### Opportunities

The Introduction of ePI in EU legislation for the first time.

Paper leaflets and electronic versions can be in a common language, e.g. English. i.e. No need to be in the national language.

Can introduce electronic package leaflets in every EU language (like currently in the packs).

### Challenges

Each MS can decide to use either only the paper leaflet, only the electronic product information or both at the same time.

Each MS can decide the timeline for implementation.

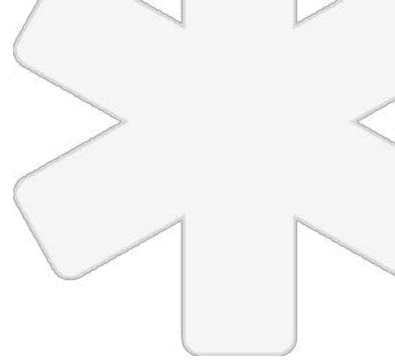
Possibility of the co-existence of the paper leaflet and the electronic leaflet.

If a MS takes no decision, then the paper leaflet will be used per default.

After five years following 18 months following the date of entering into force of the Directive (publication in EU OJ + 20 days), the EC can issue an act on a pan-European approach for ePI.

**Objective:** Find a system whereby a printed version of the paper leaflet can be provided to the patient upon request and free of charge.

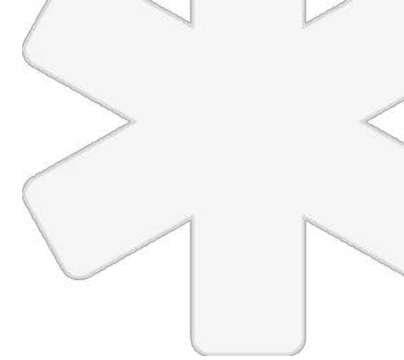
## Stakeholders' Concerns



The main concern of stakeholders such as patient organisations, the European Commission, MEPs and MS is that no patient is left out due to poor internet access or no internet skills.

Points to consider:

- How big is the problem? How many requests for a printed copy are expected?
- What technology solutions need to be developed to make this possible?
- Who will fund the final solution and how will it be managed/ organized?



## WHO MIGHT BE LEFT BEHIND WITH EPI?

### EUROSTAT DATA

#### Internet access of households, 2010 and 2023

In 2023, internet access in EU households was 93%. The lowest rates of household internet access among the EU Member States were reported by Greece (87%), Bulgaria and Lithuania (both 89%)

#### Use of internet

The share of EU internet users was 92% in 2023, up from 67% in 2010.

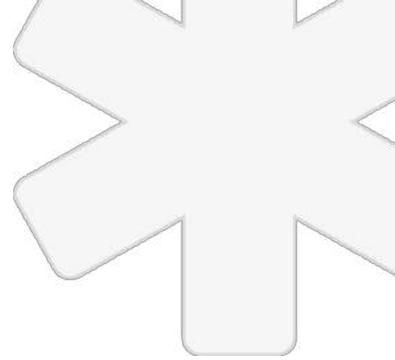
In 2023, 92% of the individuals between 16 and 74 years used the internet at least once within the three months prior to the survey date.

#### Devices used to connect to the internet

Mobile devices were used to connect to the internet by 9 out of 10 EU internet users in 2023. The connection through a laptop or a tablet was opted for by 63% while 31% of EU internet users connected via a desktop computer in 2023.

## EXPLORING SOLUTIONS

### EFPIA engagement



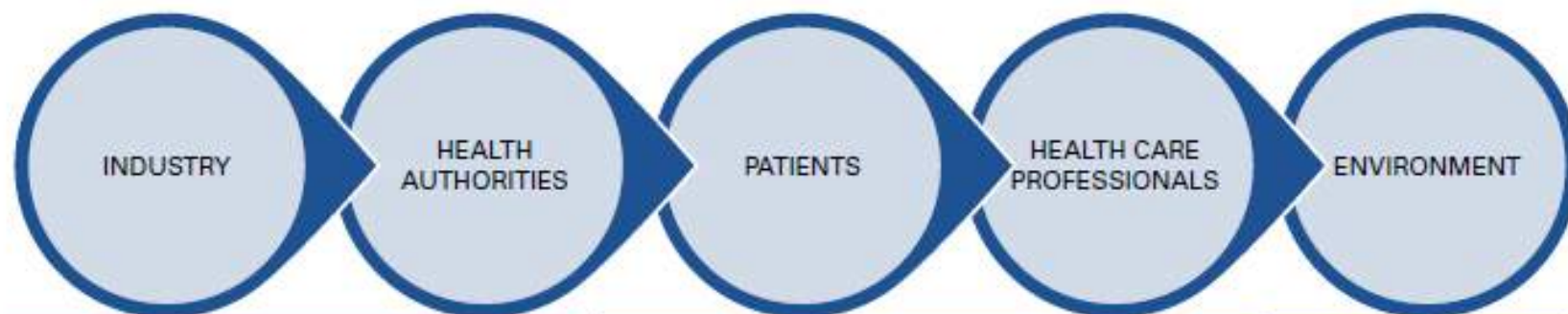
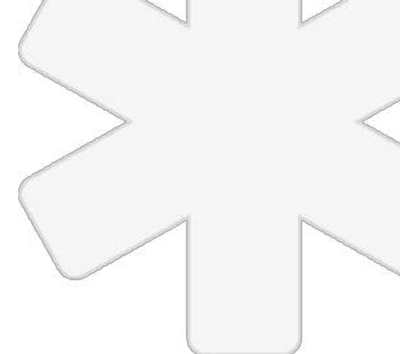
**“EFPIA, the European Federation of Pharmaceutical Industries and Associations, is actively exploring solutions to ensure that no patient is left behind in the transition from the paper leaflet to electronic product information. We are open to engaging in constructive discussions with stakeholders on the provision of package leaflets, recognizing the importance of balancing digital innovation with the needs of those requiring traditional formats.”**

EFPIA wants to show its readiness to go into a closer dialogue with stakeholders regarding the provision of a paper version of the ePI (electronic product information).



## EXPLORING SOLUTIONS

### ePI: Drivers and benefits for all stakeholders



- Mitigation of shortages
- Efficiency gains for regulatory systems and facilitating decision-making
- Enhancing knowledge of trends in medicines and their evolution

- Improved access to tailored information on end-user needs
- Accessibility to user with diverse abilities
- Advance health literacy
- Provision of the latest information on a medicine's safety, benefits and conditions of use
- Informed decision-making by patient/consumer and HCPs
- Multi-linguale ePI

- Less waste of paper leaflet



## EXPLORING SOLUTIONS

### CRITERIA FOR SUCCESS

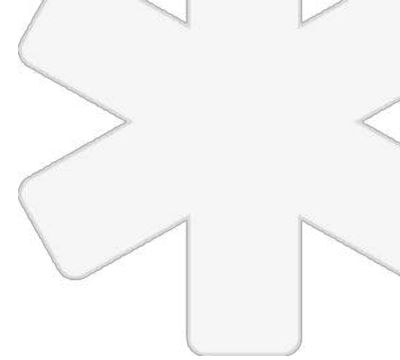
The solution developed to provide patients with a paper version of the leaflet for free will need to fulfil the 3 criteria below to ensure success:

- Meet the needs of patients, be free for patients, and in the patient's language
- Be financially viable at point of sale or dispensation
- Still have environmental benefits

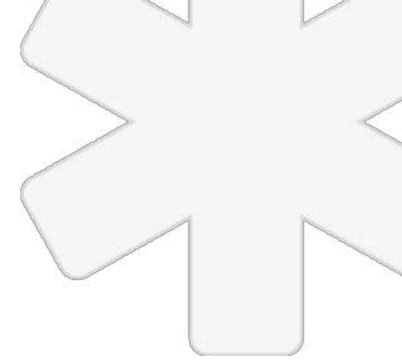
Fraunhofer IGES Study (published end 2023) Carbon Footprint of Package Leaflets:

- Switching to ePI has significant potential to reduce GHG emissions.
- Based on a detailed carbon footprint study and market analysis.
- Average CO<sub>2</sub> emission for paper leaflet is 7.0 g with a 90% reduction potential for ePI.
- This can be extrapolated to a carbon footprint reduction in the EU of 50 400 tons of CO<sub>2</sub> which is equivalent to the carbon footprint of :
  - 461 000 EU households
  - 31 500 transatlantic flights
  - 5 000 000 Stadion events

## NEXT STEPS IN THE EU LEGISLATIVE PROCESS



- 11/03: General Pharmaceutical Legislation: planned vote in European Parliament ENVI committee
- 10-11/04: General Pharmaceutical Legislation: possible date for vote in European Parliament plenary
- 06-09/06: European Parliament elections
  
- The draft document approved by the European Parliament will then go to the Council for the first round of discussions, amendments and voting. This debate will first take place during the Hungarian Presidency.



## Q&A

**Thank you for your attention.**