DGRA Jahreskongress

14. September 2021

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Bundesverband der
Arzneimittel-Hersteller e.V.

Digitalisation of the Healthcare System

Electronic Product Information (e-PI)

- Projects on national/European/international level
- Key Principles for access and dissemination
- Electronic Paper or Structured information approach

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Incredible amount of paper

All leaflets produced worldwide in 1 year, laid flat and stapled on top of each other would be well over **500 km high.**

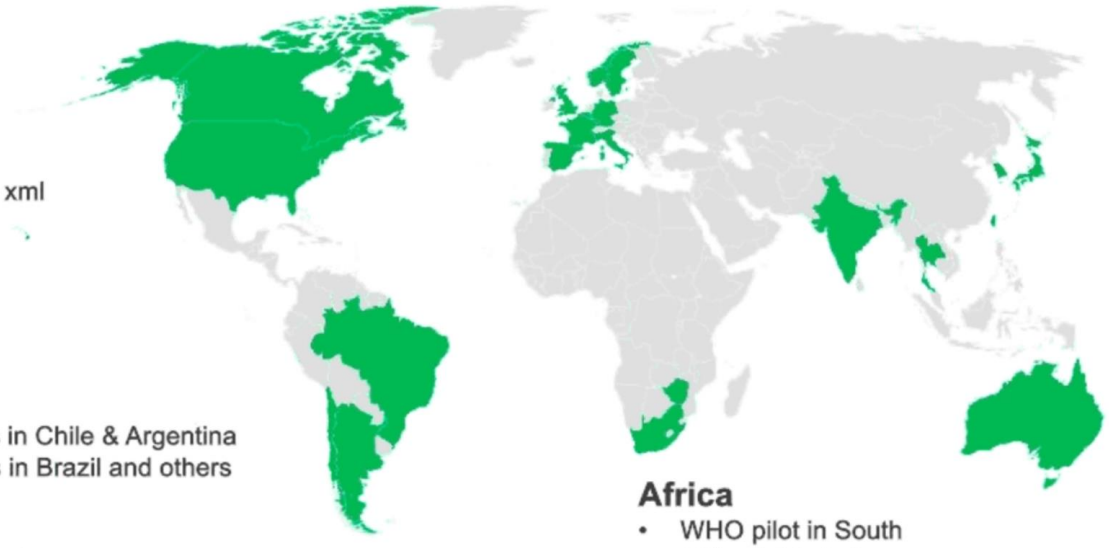
The idea of digital leaflets have been around **for more then 10 years** (20 years, remembering the PIM project) but unfortunately stayed “in the box”, like paper leaflets do.

ePI

Global landscape
Activities are ongoing across all regions

Global
- COVID-19
- Serialisation
- Transcelerate – clinical labeling

Europe
- EU ePI
- Many NCAs/TA/Industry websites
- Bel/Lux hospital pilot
- IMI projects
- EU MDR
- IDMP
- Italy – print at pharmacy



North America
- US - AMPI
- Canada – move to xml

Asia Pacific
- Australia & NZ
- Japan move to xml & regulation changes
- Pilots in:
  - Singapore
  - Taiwan
  - Thailand
  - South Korea
  - India

LATAM
- QR code pilots in Chile & Argentina
- TA discussions in Brazil and others

Africa
- WHO pilot in South Africa & Zimbabwe

DIA

ePI is more…

- Going towards Electronic Product Information is more then replacing a sheet of paper.
- Electronic PI supports increased interaction with other eHealth solutions
  - Medication Plan
  - Health records
  - Reporting of Side effects => www.Web-radr.eu
  - Recalls
- ePI will be beneficial for all stakeholders involved
  - Patients
  - HCP (Healthcare Providers)
  - Authorities
  - Industry

National Level

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Swiss GS1 Project

SAI - Individual search (refdata.ch)

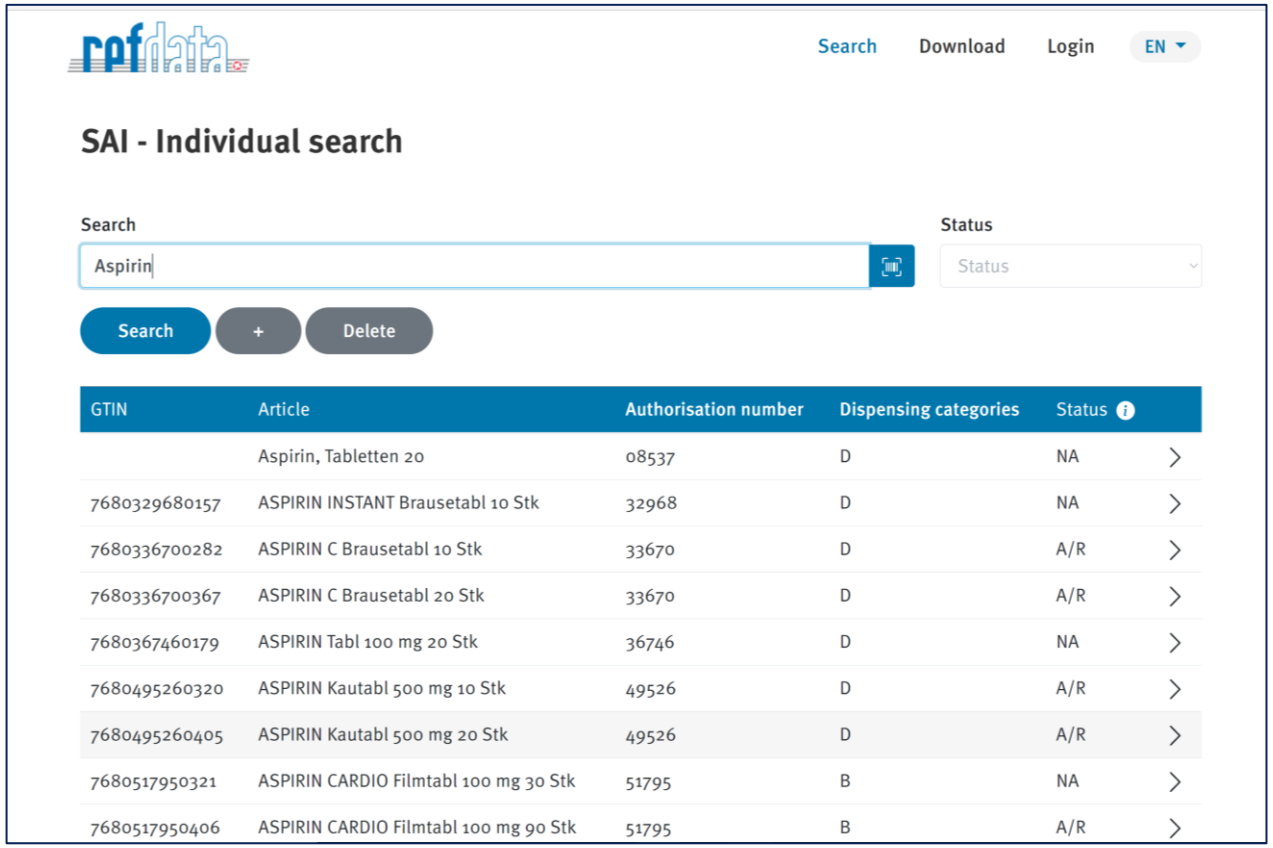
Artikel-refdatabase for medicinal products and medical devices

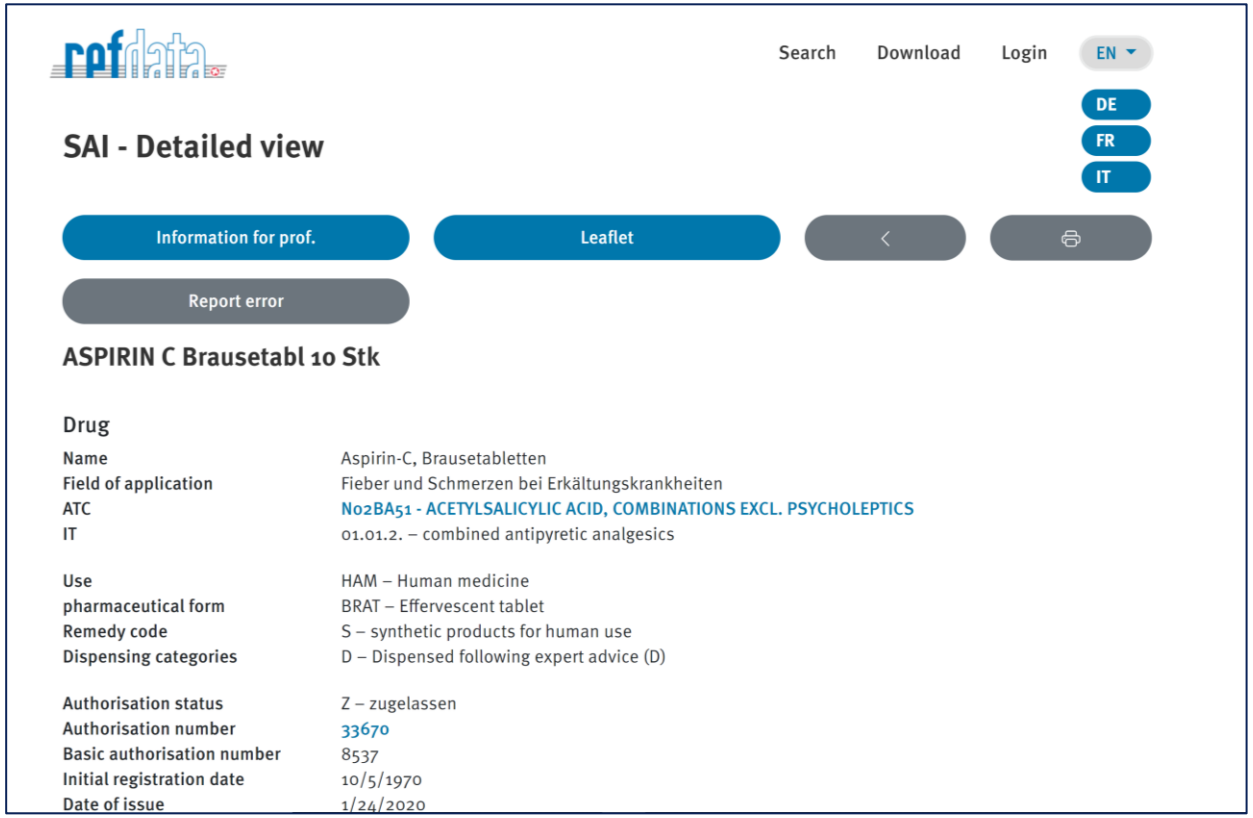
Drugs and medical devices approved in Switzerland can be referenced in the Artikel-refdatabase, provided that the articles are clearly identified by GS1 with a GTIN (Global Trade Item Number). By referencing their articles in the refdatabase, manufacturers increase visibility and improve the quality of the data in private and public electronic article catalogs and directories.

Structured Product Information (SPI; SAI in German)

In addition to the AIPS platform, the SAI-Plattform enables the research of human medicinal products approved by Swissmedic for structured characteristics and displayed for each product.

Swiss GS1 Project





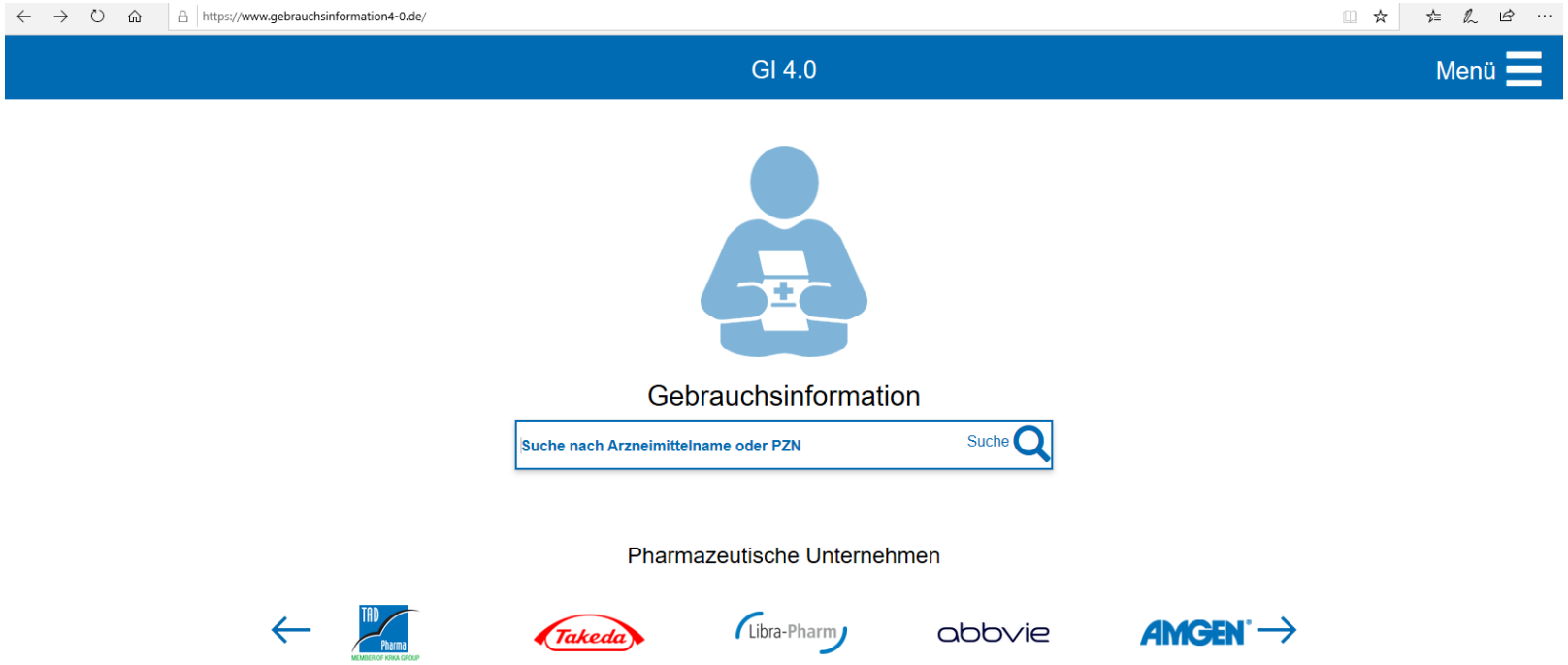
Project in Norway

The official system for electronic information on medicinal products in Norway - www.Felleskatalogen.no

Norway

- Owned by LMI (local trade association)
- LMI administers the companies' abbreviated SPC texts
- A printed version (booklet) of the abbreviated texts was available for HCPs 1958 – 2018 (last paper edition)
- Electronic versions available on www.Felleskatalogen.no since 2001
- APP for smartphones since 2010
- E-PIL structured as XML since 2013
- «My FK» - APP for PIL launched 2015
- Electronic PILs, print possibility, Braille version can be ordered, audio version available for visually impaired people
- Automatic harvesting from EMA (CP) and daily transfer from NoMA (NP, MRP/DCP)

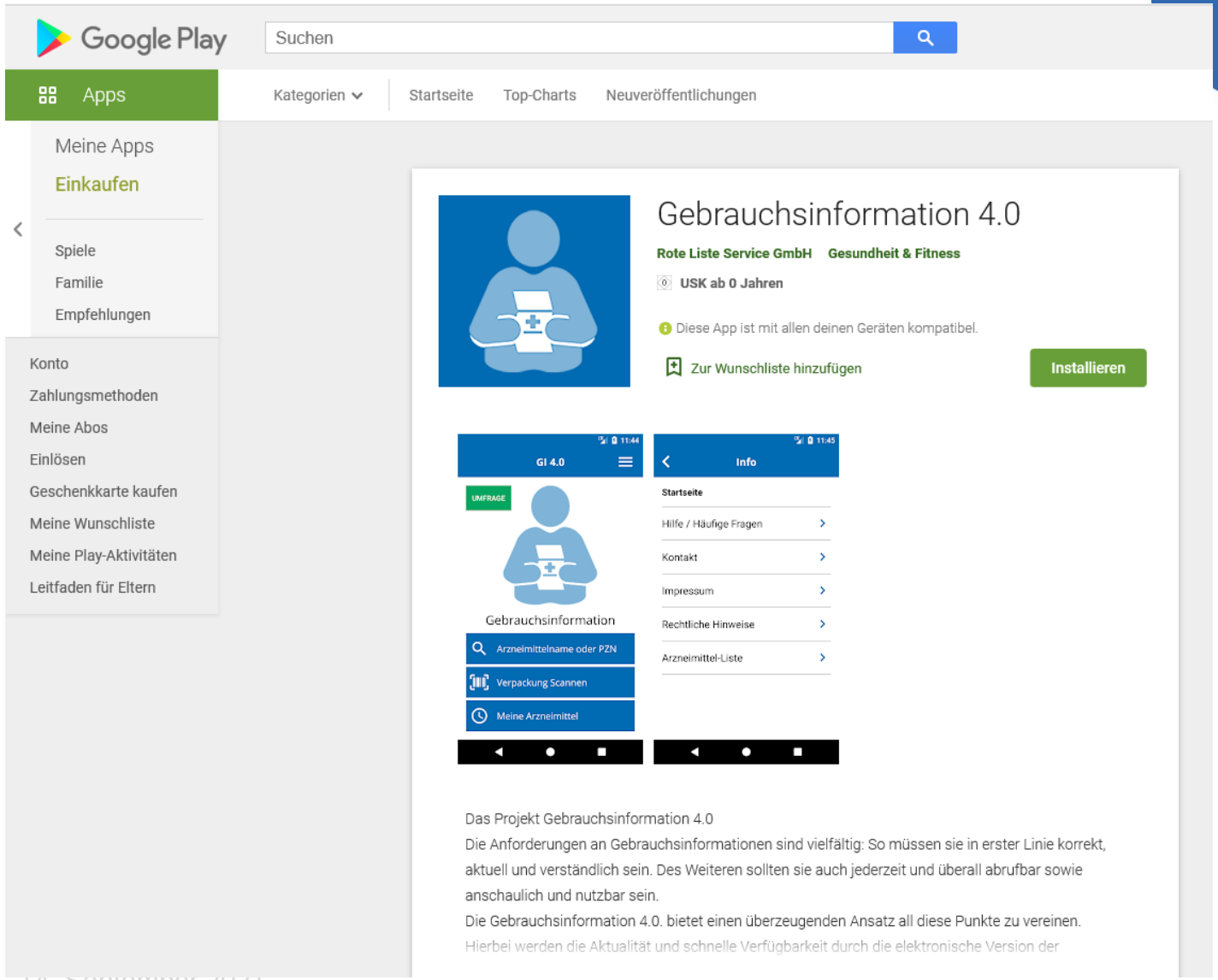
Germany



https://www.gebrauchsinformation4-0.de/

Germany

- Searchable Database
- Rx and OTC Leaflets
- XML and PDF output
- QRD structured
- Scanning PZN or Data Matrix



EU Level

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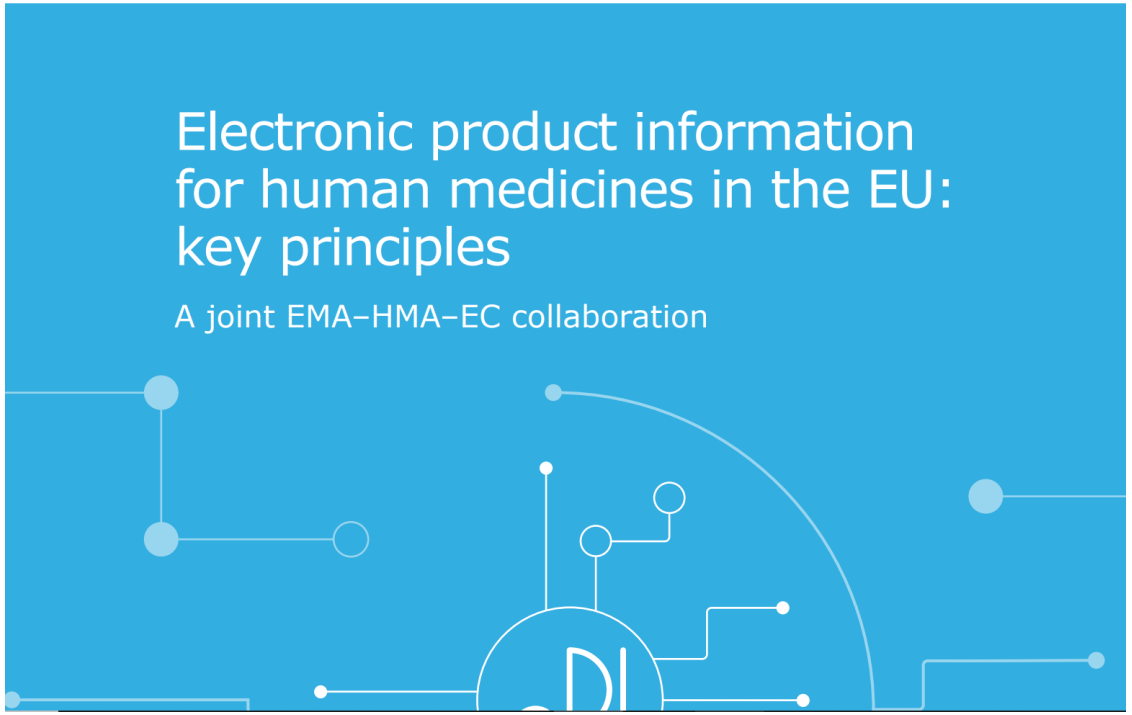
EMA Key Principles



[Electronic product information for human medicines in the EU: key principles (europa.eu)]

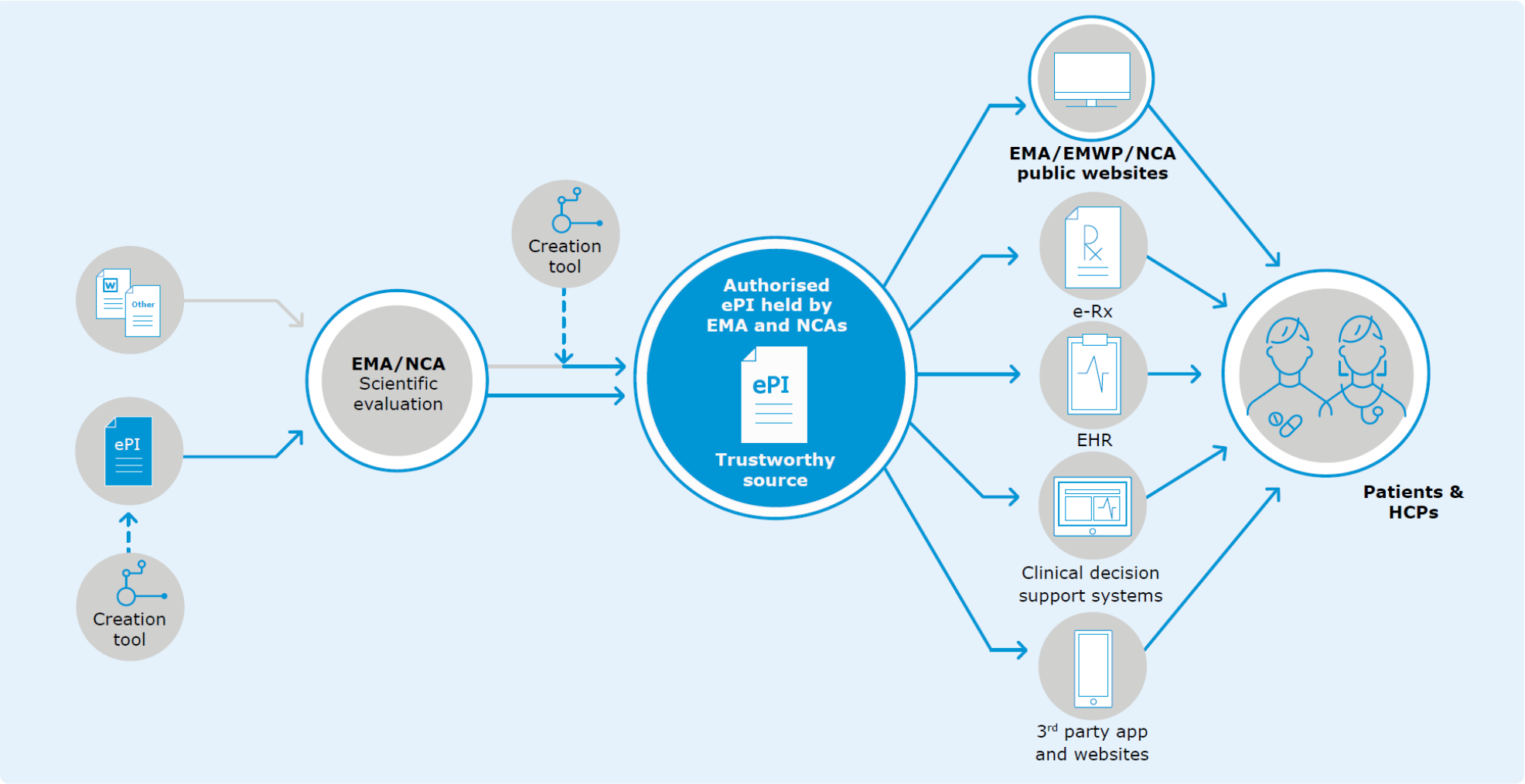
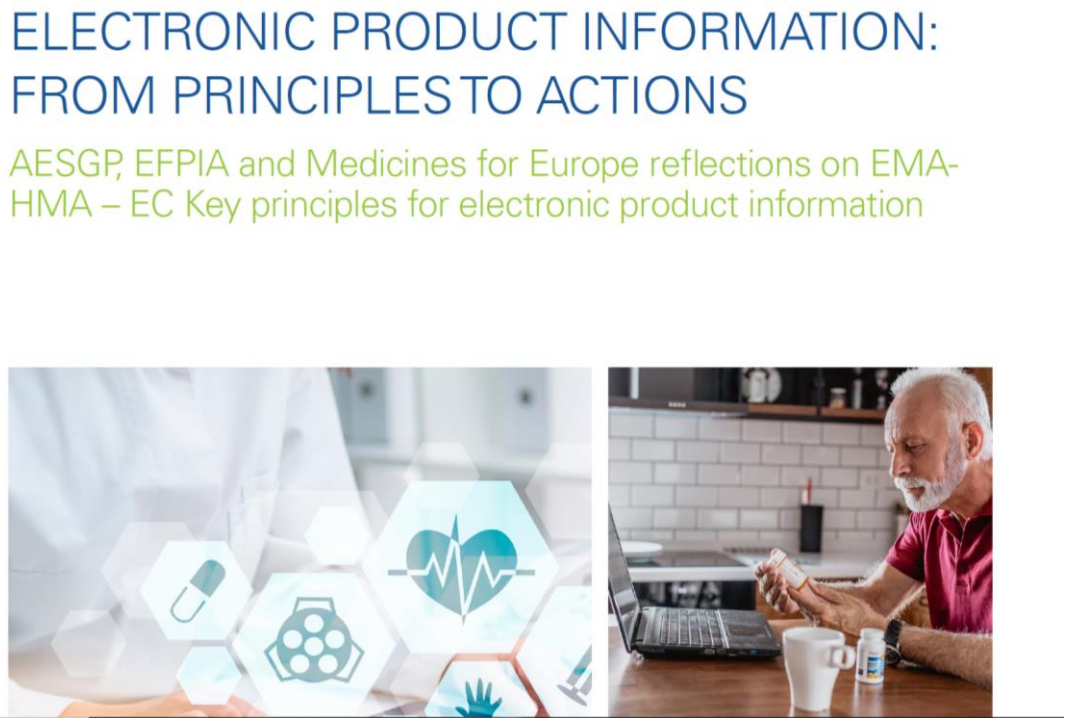


Figure 1. Proposed model for ePI process (subject to change following feasibility analysis once ePI project is started). A free, validated ePI creation tool is provided by the regulator. The tool could be used by the MAH to create ePI for submission in an application or to create ePI once an evaluation is complete. ePI for both nationally and centrally authorised products can be accessed from the European medicines web portal (EMWP) and NCA public websites. ePI can be used with systems for e-prescribing (e-Rx) and electronic health records (EHR). Data can be accessed by third-parties for example, for use in websites and patient / consumer apps.

EU Associations

AESGP, EFPIA and Medicines for Europe reflections on EMA – HMA – EC Key principles for electronic product information | AESGP



EMA ePI workshops

The following slides are taken from the published EMA presentations:
https://www.ema.europa.eu/en/events/epi-information-workshop-exploratory-workshop

Workshop 1 – 5th July 2021
Information workshop for stakeholders and partners

Agenda

- Introduction
- Electronic Product Information (ePI)
  - Background of ePI initiative
- ePI set-up project
  - FHIR and the EU common standard for ePI
  - ePI proof of concept prototype
  - Next steps for ePI and roadmap development
- Q&A

Workshop 2 – 6-8th July 2021
Exploratory workshop for technical specialists with a knowledge of development languages and REST API (hands-on exercises

Agenda

- Introduction
- Electronic Product Information (ePI)
  - Description and demonstration of use of ePI API
- Breakout sessions
  - Groups work on tasks using the ePI API
  - Groups discuss their use cases for the ePI API and the EU common standard
- Conclusion

EU context

- Complementing paper leaflet
- Multilingual
- Open access
- Flexible implementation
- Interoperability with ongoing EU eHealth initiatives

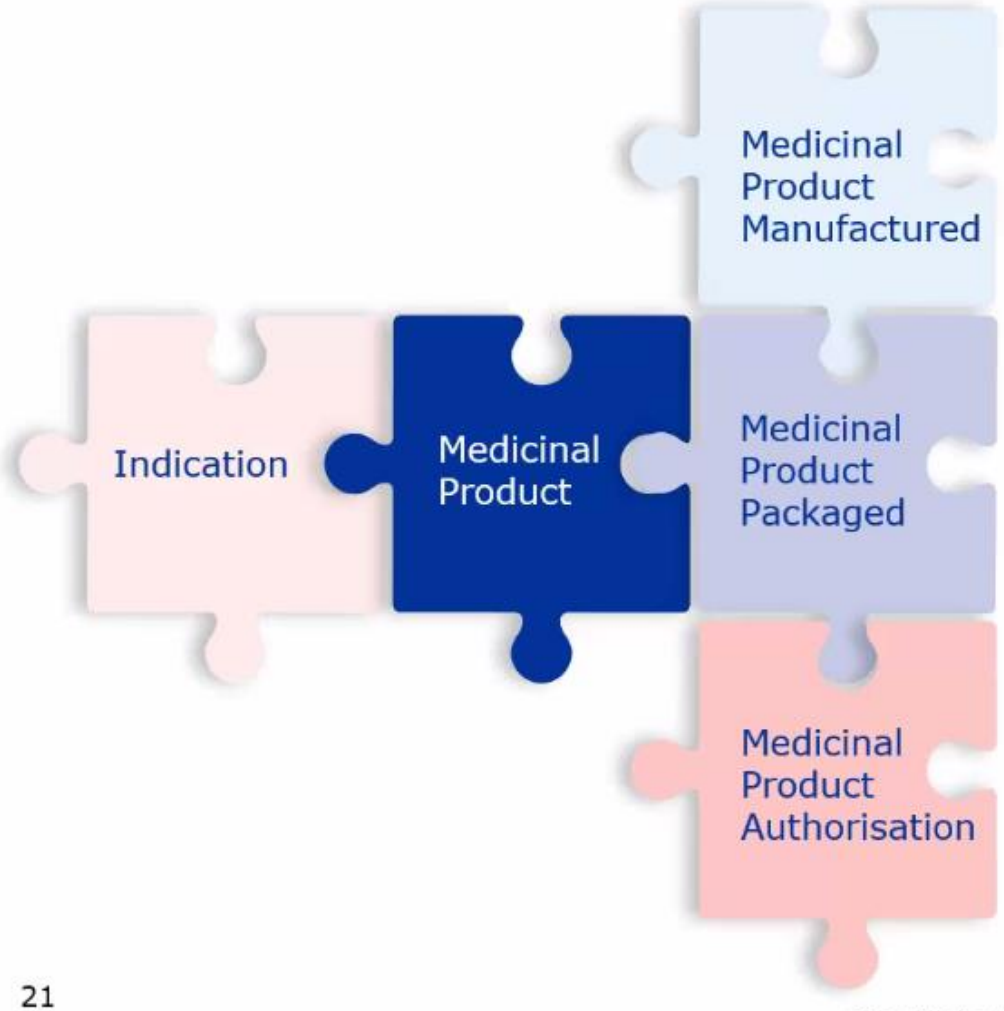
FHIR in one slide

Fast
Healthcare
Interoperability
Resources

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

- New free and open healthcare data API
- Builds on simplicity of HL7 V2
- With modern (web) standards
  - XML, JSON, HTTP, REST, UML
  - Familiar to new generation of developers
- Easy to implement the basics
- Getting very rapid take up

FHIR Resources



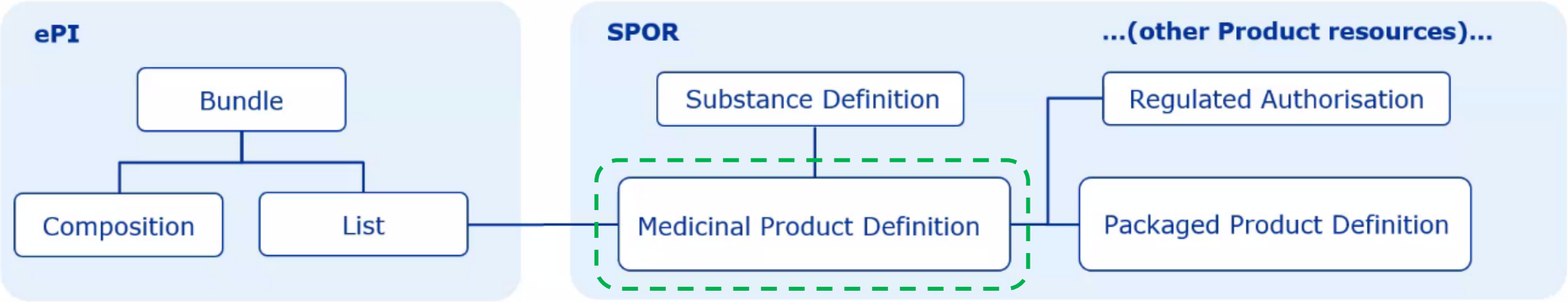
Resources are:

- Small, logically discrete units of exchanged data
- Defined behaviour and meaning
- Known identity/ location
- Smallest unit of transaction
- Connected by "references"

FHIR in ePI and SPOR master data

Alignment still TBD between FHIR and eCTD standards

- SPOR 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
- Both systems share data interoperability principles, standard, conventions and best practices
- The same FHIR tools and expertise can be leveraged by both systems



International Level

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ISO TS 16791

ISO/TS 16791:2020 HEALTH INFORMATICS — REQUIREMENTS FOR INTERNATIONAL MACHINE-READABLE CODING OF MEDICINAL PRODUCT PACKAGE IDENTIFIERS

This document outlines the requirements to implement international machine-readable coding on medicinal product packages in the healthcare supply chain; this process cannot be isolated from more general identification practice with medical devices or other categories of products. It assists all stakeholders implement, use, and optimize Automatic Identification and Data Capture (AIDC) technologies in their respective enterprises with a particular attention to Health Informatics. In that respect, this document complements ISO 11615.

ISO NP TS 23261

Requirements for accessing digital medicinal products information by using the existing data carrier

UNDER DEVELOPMENT

ISO TC215 WG6 (IDMP Group)

ISO/IEC DIS 22603-1

Information technology — Digital representation of product information — Part 1: General requirements

JTC 1

Datum des Dokumentes 2020-12-07

This standard establishes requirements for Electronic Product Labelling to provide electronically accessible product compliance markings and statements attesting to the product's compliance to standards, technical specifications, codes and regulations. A Machine-Readable symbol (e.g. a bar code or other scannable symbol) allowing a scanning device, such as a smartphone, barcode scanner, webcam or other similarly functional device to view and retrieve the product markings and technical statements on demand.
The scope of this standard (Part 1) addresses the general requirements which would be applicable to all types of products regardless of industry. Subsequent Parts address specific requirements for unique types of products.
Works on the system framework and overall technical requirements for Electronic Label Systems (ELS)

https://www.iso.org/standard/73561.html

New Opportunity Identification: Electronic standard for transfer of Regulatory label information

DRAFT FOR DISCUSSION ONLY

Proposed Solution : Use HL7 standards and CV's to standardise labelling information

CURRENT STATE: regulatory documents are designed for paper; non harmonized data standards (regional/international) with limited controlled vocabularies

FUTURE STATE: regulatory documents are machine readable; indexed; structured text using XML, international data standard and controlled vocabularies

PDF

SUMMARY PRODUCT INFORMATION

Route of Administration	Dosage Form / Strength	Nonmedicinal Ingredients
Oral	Controlled Release Tablets 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg and 80 mg	Butylated hydroxytoluene (BHT), hypromellose, polyethylene glycol, polyethylene oxide, magnesium stearate, titanium dioxide and hydroxypropyl cellulose (10 mg), iron oxide (15 mg, 20 mg, 30 mg, 40 mg, 60 mg, 80 mg), polysorbate 80 (10 mg, 30 mg, 40 mg, 60 mg), silicon dioxide and FD&C Blue No. 2 (80 mg)

DOSAGE FORMS, COMPOSITION AND PACKAGING

Dosage Forms: OxyNEO® tablets consist of a matrix with hydrogelling properties or whole tablets become highly viscous (gel-like) in water). The tablets have a hardened through a unique recrystallization process, HTR Technology™, and are designed to be resistant to crushing. Testing over the range of **OxyNEO** tablet fragment sizes showed that most of the controlled release properties were still retained (see **Drug Abuse Studies**).

OxyNEO® (oxycodone hydrochloride controlled release tablets) 10 mg are round, unscored, white, biconvex tablets imprinted with 'ON' on one side and 10 on the other.

OxyNEO® (oxycodone hydrochloride controlled release tablets) 15 mg are round, unscored, grey, biconvex tablets imprinted with 'ON' on one side and 15 on the other.

XML

PRODUCT INFORMATION

Product Type	PRESCRIPTION DRUG	Item Code (Source)	NDC:49999-899(NDC:10702-018)
Route of Administration	ORAL	DEA Schedule	CII

ACTIVE MOIETY

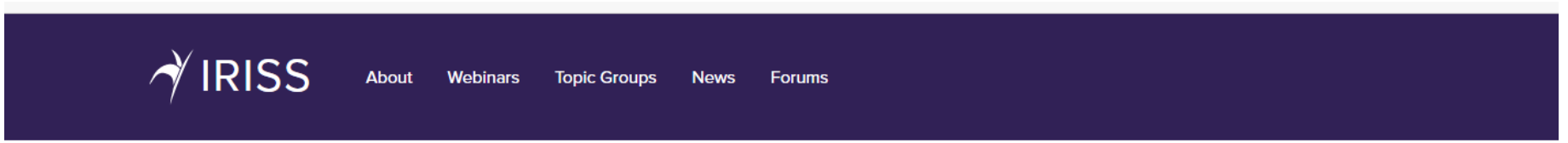
Active Moiety Name	Basis of Strength	Strength
OXYCODONE HYDROCHLORIDE (UNII: C1ENJ2TE6C) (OXYCODONE - UNII:CD35PMG570)	OXYCODONE HYDROCHLORIDE	5 mg

INACTIVE INGREDIENTS

Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

PACKAGING

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49999-899-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	12/20/2011	
2	NDC:49999-899-40	40 in 1 BOTTLE; Type 0: Not a Combination Product	12/20/2011	
3	NDC:49999-899-60	60 in 1 BOTTLE; Type 0: Not a Combination Product	12/20/2011	
4	NDC:49999-899-90	90 in 1 BOTTLE; Type 0: Not a Combination Product	12/20/2011	
5	NDC:49999-899-00	100 in 1 BOTTLE; Type 0: Not a Combination Product	12/20/2011	06/01/2014



Electronic Product Information

UPCOMING EVENTS

Sep 14 — 14:00–15:00 GMT+2 / 12:00–13:00 UTC
Electronic Product Information September 2021

Oct 12 — 14:00–15:00 GMT+2 / 12:00–13:00 UTC
Electronic Product Information October 2021

Nov 9 — 14:00–15:00 GMT+1 / 13:00–14:00 UTC
Electronic Product Information November 2021

Add to Outlook or Calendar Add to Google Calendar

Objectives

The need to provide enhanced product information to prescribers, product users and regulators, combined with a recognition of our increasing connectedness through technology enablement, opens up new pathways to deliver approved, high quality product information through electronic means. We see health authorities preparing to request more and more structured information, recently witnessed by the ePI (electronic Product Information) initiatives by EU EMA and Singapore HAS.

We envision a coalition across industry, regulators, health care professionals, vendors and product users, gathered together in the IRISS ePI topic group. This gives us all the opportunity to ensure that product information is delivered in line current regulatory standards. We can also identify early adopter countries for pilots, and streamline comments on evolving standards to best meet the needs of all end users of product information.

This group aims to:
- Define the full business case for moving to ePI and understand the conditions for

ePI Links

Electronic Product Information Home

Meeting Details

Summary and Conclusions

- **(Electronic) Product Information must:**
- be electronically available via a trusted source
- be user-friendly and easily accessible
- show the most recently regulator-approved product information (real time information)
- follow general health literacy principles
- allow the citizens and users to obtain, identify and use the information necessary to meet their individual needs;
- take into account the evolving environment including
  - the increasing use of mobile devices
  - eHealth initiatives such as eHealth Records, ePrescriptions, etc.
- Not leaving behind people and user groups with no access to internet or electronic media

Citizens means e.g. patients, etc

Summary and Conclusions

(Electronic) Product Information <u>should</u>:

- give better accessibility to materials which enhance citizens adherence to their medication (all in one place), e.g. risk minimization material, lay summaries of clinical trials
- encompass a step-wise approach to facilitate immediate implementation
- provide batch specific information when needed
- be set up in a reasonable and transparent time frame

Summary and Conclusions

(Electronic) Product Information Nice to have:

- Expandable for existing and future regulatory requirements such as eSmPC and educational material
- allow personalised views to enhance the user experience and understanding of the content, e.g.
  - deliver the citizens' preferred official EU/EEA language if available
  - deliver a navigation & search functionality
  - deliver a functionality to save locally own preferences, e.g. previous searches, „my own medication"
  - support citizens ability to electronically report adverse events
  - deliver a functionality for setting up alerts in case of updated product information, e.g. in case of new safety warning
  - be capable of delivering audible versions
  - allow for making additional use of video to aide training citizens/HCPs on the right use of the medication

Vision

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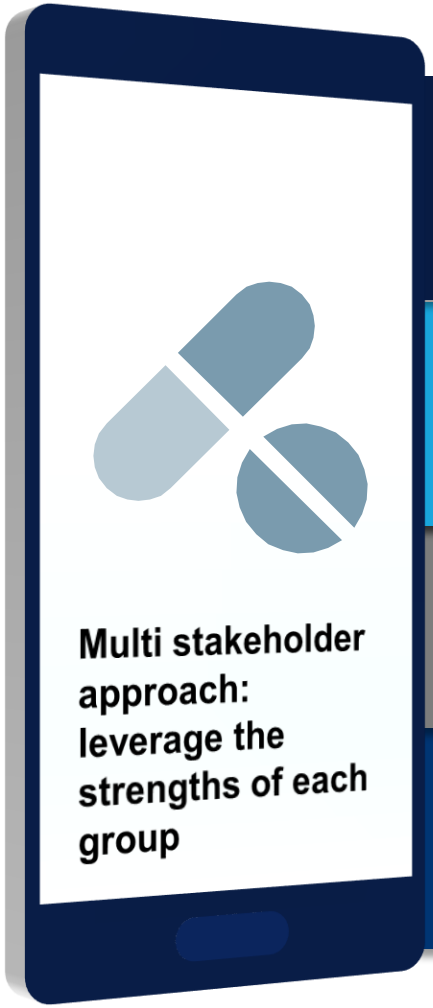
Working together to enhance health literacy and deliver eProduct Information to EU citizens



Electronic PI supports increased **interaction with eHealth solutions**

Continuous advanced tech. solutions needed for adequate standard of technology in a **rapidly transforming environment**

See ePI as a telematics priority and shape regulatory framework to enable digital innovations

Involvement of stakeholders in **development** – for flexible, harmonised and trusted approaches throughout Europe

Objectives

- Improved access along with content, readability and layout of product information, are considered key pillars for correct and appropriate use
- **Patients' role** in their own health care is changing from compliance to engagement:
  - Better understanding current needs and **future needs** of patients in 10-20 years
- (electronic) **Product Information content, readability and lay out**:
  - Comprehensive
  - Accurate
  - Up-to-date
  - Trusted
- Ensuring **improved access**
  - Regulator-approved and non-commercial
  - Easily accessible
  - Understandable and relevant
  - Enabling patients/HCPs to obtain, identify and use the information necessary to meet their individual needs

Some considerations for the future

Existing infrastructure
at local and regional level in the EEA should be used to the greatest extent possible (considering cost effectiveness)

Ensuring interoperability
by using open and international standards when available

Appropriately formatted content established authoring principles needed (e.g. electronic QRD-template)

Modern technologies (future changes)
Consider evolving environment incl. increasing use of mobile devices and electronic assistants and changing habits; eHealth initiatives such as eHealth Records, ePrescriptions, etc.

Interoperable links such as unique IDs
(product's master data) currently implemented in the EEA, e.g. EMA SPOR project, ISO IDMP, SNOMED CT or others

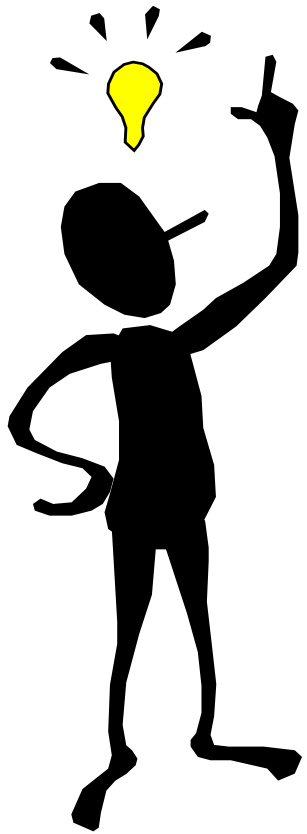
Well-accepted data carriers
on the package (such as linear barcodes, 2D DataMatrix codes or others) for scanning purposes

Secure access (data input)
improved privacy and prevention of source interference

Data privacy (citizens)
Support up-to-date data safety standards

No additional packaging requirements

No additional regulatory burdens
e.g. readability requirements for ePI



The End (of my slides)

Still confused ??

But I hope, on a higher level !

franken@bah-bonn.de