EMA-HMA-EC ePI pilot & beyond

RoteListe ePI Summit 2024

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

- **Fast**
- **Healthcare**
- **Interoperability**
- **Resources**

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
ePI at Product Lifecycle Management Portal


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
ePI pilot objectives

- 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
Pilot participants and procedures

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

**Phase**
- **ePI Creation**
  - Applicant creates ePI EN
- **ePI ID in cover letter**
  - Applicant informs of ePI ID in cover letter
- **Validation check**
  - Validation check ePI present
- **Evaluation**
  - Start of the evaluation
- **PI changes if required**
  - Applicant reverts ePI to draft, makes changes and finalises
- **Evaluation ends**
  - Notification/Approval/CD
- **Approval**
  - Approver approves ePI in portal
- **Publishing**
  - Publisher publishes ePI

**Activities**
- **Owner**
  - Applicant
  - EMA
  - Applicant
  - EMA

**Timing**
- **Before Day 1**
- **Day 1**
- **End of procedure**
  - Time of EPAR publication

**Owner**
- **Applicant**
- **EMA**
- **Applicant**
- **EMA**

**Time of EPAR publication**

**ePI pilot planning**
ePI pilot duration

- Duration: July 2023 – July 2024
- First ePIs published: https://plm-portal.ema.europa.eu/ePIAll/
Interoperability and Product Lifecycle Management

A smoother and more coherent user journey

1. Capture data for regulatory processes
2. Validate, assess and analyse data
3. Store data using agreed standards
4. Share data & information across the lifecycle for customer value

SPOR Master Data Management & FHIR Data Exchange

Web-based electronic Application Form (eAF)
Product Data Management User Interface (UI)
ePI authoring and publication
PMS
ePI repository

Data from
Developers
of medicines

Industry
Patients & Citizens
Academia
Healthcare Professionals & Veterinarians
EMA & National Regulators
FHIR in European Medicines Regulatory Network

**eAF**

- **Task**: Procedural Information ...
  - Medicinal Product 1
  - Medicinal Product 2
  - ...

- **(Sub)Task 1**
  - ...

- **(Sub)Task 2**
  - ...

- **Provenance A**

- **Provenance B**

- **eAF FIHR messages includes/overlaps with the PMS product data**

**ePI**

- **Bundle**
  - **List**
  - **Composition**

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

- **ePI and SPOR resources do not currently overlap, they interconnect**

**PMS**

- **Medicinal Product**
  - Medicinal Product Definition
    - Name
    - Authorised Pharmaceutical Form
    - ATC
    - Manufacturers
    - GMO
    - Indication
    - PHV Enquiry contact Info
    - QEPV
    - PSWF location
    - Clinical Trial
  - Administerable Product Definition
  - Pharmaceutical Products
  - Route of Administration
  - Manufactured Items Definition
    - Manufactured Items
  - Ingredient
    - Ingredients
    - Ingredient Documentation
  - Provenance
    - Last update Reason
  - Packaged Product Definition
    - Package
    - Shelf Life
    - Data carrier
    - Device Definition
    - Medical Device

- **PMS uses FHIR to represent IDMP-compatible Products and Substances**
## ePI roadmap

<table>
<thead>
<tr>
<th>2021</th>
<th>2022</th>
<th>2023-2024</th>
<th>2024-</th>
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</thead>
<tbody>
<tr>
<td>• EU ePI Common Standard developed &amp; adopted by EMRN</td>
<td>• MVP development</td>
<td>• MVP completed</td>
<td>• Pilot outcomes inform implementation strategy</td>
</tr>
<tr>
<td></td>
<td>• NCA product owner and NCA and pharma SMEs onboarded</td>
<td>• Pilot ongoing</td>
<td>• Feature development</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Pilot outcomes report</td>
<td>• Revision to the pharmaceutical legislation</td>
</tr>
</tbody>
</table>

Next **system demo** live on YouTube and EMA website on 26\textsuperscript{th} March
Thank you for your interest

Further information

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

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
This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 875299
Improving Patient Safety – a Never Ending Story
Barriers to the Free Flow of Safe Drug Information

► 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

► 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
Key Identification Challenges (I)

➢ 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)


➢ 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
Key Identification Challenges (II)

- 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
Defining Semantic Interoperability for Health

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.
Defining Semantic Interoperability for Health

► What is your role in the life-cycle of a medicinal product?
Towards a seamless MP Data Value Chain

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 ePrecription 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

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**

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

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

As an Innovation Action, UNICOM is focusing on implementation: its long-term goal is to realise a seamless, semantically interoperable Data Value Chain enabling data sharing across the full life cycle of medicines and across all actors involved in handling such information.

NCA/EMA, eHealth National Institutions / EC DG Santé & CNECT, SDOs and related projects co-operate to achieve it.

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 875299.
Submission of medicinal product information

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

EMA EU / National Medicinal Products Databases

Support for Prescribing

eDI is basic in these processes

Effective Clinical Use of Medicinal Products

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

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

More and more Member States going live with the services
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.**

<table>
<thead>
<tr>
<th>eHDSI data elements</th>
<th>Preferred coding system</th>
<th>Attributes from EMA IG version V2.1 (2021-02)</th>
<th>#</th>
<th>Attribute</th>
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<td>EDQM</td>
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<td>1.5. Authorised Pharmaceutical Form</td>
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<td>EDQM</td>
<td>4.10.1. Unit of presentation</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Obtain the coded data from NCAs/EMA

ePrescription and Patient Summary contain posology and instructions as coded data
Understanding how to use and report on Adverse Events

EMA EU / National Medicinal Products Databases

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

Effective Clinical Use of Medicinal Products

eDI: the basic tool for patients
Illustrating work in GRAVITATE HEALTH

Defining the G-lens design methodology - personas

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.
Gravitate-Health support Xborder health services

Multi-lingual focused information ePrescription – (e)Dispensation

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

FHIR ePI IG medicinal product info

Cross-border mobility - trust and safety -

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

Illustrations from helsenorge.no, 2023 and FHIR ePI IG
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
This project has received funding from the European Union’s Horizon 2020 research and innovation programme under grant agreement No 875299

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
Final considerations

- 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

...and many other colleagues 😊

- Dr Robert A. Stegwee
- Chair, CEN Technical Committee 251 Health Informatics
Further Information on UNICOM
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Twitter: @unicom_idmp
linkedin.com/company/unicom-idmp
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 Evangalist

Co-Architect of ISO 11615 (IDMP)
Member Municipal Parliament City of Emmen
Member Advisory Board Refdata-Stiftung Schweiz
Member IDMP Advisory Board of Swissmedic

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Datamodel > data structuring and data analysis
IDMP is also about Controlled Vocabularies

<table>
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https://spor.ema.europa.eu/
It is about Quick data exchange
ISO 11615 – Medicinal Product

Marketing Authorisation Holder

Regulatory Agency

Manufacturer

Packaging

Device

Manufactured Item

Ingredients

Pharmaceutical Product

Clinical Particulars

Marketing Authorisation

Approved

Medicinal Product
IDMP and the Medicines Regulatory Agencies

Implementation Started

Implementation Started

Implementation Started

In Preparation (Fast Follower)

In Preparation
Once-Only >> Single-Sourcing
### Monolytic & Prosa

<table>
<thead>
<tr>
<th>Strength</th>
<th>Pack Sizes</th>
<th>Indications</th>
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<td>Ind. C</td>
<td>CH / LI de, fr</td>
</tr>
</tbody>
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"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
The Old Way: Microsoft Word

Page 2

1. NAME OF THE MEDICINAL PRODUCT
   Insulin Rapid 10 IU/ml solution for injection in a vial

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
   Each vial contains 10 IU/ml of the medicinal product.

3. PHARMACEUTICAL FORM
   Solution for injection in a vial.

4. ADVERSE REACTIONS
   Infusion reactions are possible.

Page 11

1. NAME OF THE MEDICINAL PRODUCT
   Insulin Rapid 40 IU/ml solution for injection in a vial

2. PHARMACEUTICAL FORM
   Solution for injection in a vial.

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

Page 20

1. NAME OF THE MEDICINAL PRODUCT
   Insulin Rapid 100 IU/ml solution for injection in a cartridge

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
   Each cartridge contains 100 IU/ml of the medicinal product.

3. PHARMACEUTICAL FORM
   Solution for injection in a cartridge.

Page 3

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

4.4 Special warnings and precautions for use
   Patients with diabetes mellitus.

Page 12

1. NAME OF THE MEDICINAL PRODUCT
   Insulin Rapid 40 IU/ml solution for injection in a vial

2. PHARMACEUTICAL FORM
   Solution for injection in a vial.

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

Page 21

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

4.4 Special warnings and precautions for use
   Patients with diabetes mellitus.

60 % Match

100 % Match
Reusable Content

The Old Way: Microsoft Word

Monolytic documents

24 languages

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
IDMP and Controlled Vocabularies
"What does this look like in reality?"
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 candidal vaginitis.
"What does this look like in reality?"

**Software Vendors**
- IDMP Tools
- Master Data Management Systems
- eCTD Tools
- Structured Content Authoring Tools
From SmPC/PIL to IDMP

Controlled Vocabularies
- Authorities: EMA RMS
- EDQM
- UCUM
- MSSO
- WHO
- Snomed
- Etc.
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
"What does this look like in reality?"

Controlled Vocabularies

- Authorities: EMA RMS, Swissmedic, Anvisa, FDA
- EDQM
- UCUM
- MSSO
- WHO
- Snomed
- Etc.

Medical Writer Team

SmPC, PIL, Labeling

IDMP - FHIR - XML
"What does this look like in reality?"

IDMP - FHIR - XML

```
<name>
  <part value="Wonderdrug"/>
</name>
```

```
<strength>
  <numerator>
    <value value="20" unit value="mg"/>
  </numerator>
  <system value="http://units.of.measure.org"/>
  <code value="mg"/>
</strength>
```

**new paragraph**
User of Artificial Intelligence

IDMP - FHIR - XML

Controlled Vocabularies
- Authorities: EMA RMS, Swissmedic, Anvisa, FDA
- EDQM
- UCUM
- MSSO
- WHO
- Snomed
- Etc.

SmPC, PIL, Labeling
"What does this look like in reality?"
User of Artificial Intelligence

IDMP - FHIR - XML

Controlled Vocabularies
- Authorities: EMA RMS, Swissmedic, Anvisa, FDA
- EDQM
- UCUM
- MSSO
- WHO
- Snomed
- Etc.

Medical Writer Team
SmPC, PIL, Labeling

Medical Writer Team
"What does this look like in reality?"

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:

1. **Name of the medicinal product**
   - Canesten 200mg Tablet.

2. **Qualitative and quantitative composition**
   - Each tablet contains Clotrimazole 200mg.
   - For the full list of excipients, see section 6.1.

3. **Pharmaceutical form**
   - Tablets.

4. **Clinical particulars**
   4.1 **Therapeutic indications**
   - Canesten 200mg Tablets are recommended for the treatment of candidal vaginitis.

4.2 **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.

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**
   - (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...

**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.

**Speed**
Increase speed for content creation and downstream processing

**Regulatory requirements**
Fulfil diverse and highly complex requirements around the world

**Quality/Compliance**
Avoid risks related to content propagation and increase oversight

**Integrations**
Connect Labeling data across systems and processes

**Key principles**
We manage content, not documents
We connect information items
We re-use content

A journey towards the future of Labeling | Niklas Jänich & Murali Menon
The challenges at the example of deviations

<table>
<thead>
<tr>
<th>Different meaning and emphasis</th>
</tr>
</thead>
<tbody>
<tr>
<td>• based on content</td>
</tr>
<tr>
<td>• based on position</td>
</tr>
<tr>
<td>• based on position and content</td>
</tr>
<tr>
<td>• based on structure and/or content</td>
</tr>
</tbody>
</table>

- Content not implemented (minus deviation)
- Additional content (plus deviation)
Rethinking the Labeling process
Labeling content implementation in the new world

Component-level Metadata, e.g.,
- MedDRA code
- Co-morbidity
- Intended effect

Change Control
- Trigger
- Urgency Level
- Safety Signal ID
- ...

Deviation

CCDS

SmPC

PIL

Indication 1
Warning 1
Warning 2
Interaction 1

Indication 1
Warning 1
Warning 2
Interaction 1

Indication 1
Warning 1
Warning 2
Interaction 1

Indication 1
Warning 1
Warning 2
Interaction 1

Indication 1
Warning 1
Warning 2
Interaction 1

A journey towards the future of Labeling | Niklas Jänich & Murali Menon
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 from travelling

**SmPC** = Summary of Product Characteristics
**PIL** = Patient Information Leaflet
Downstream integrations

- Master Data Management Referentials
- Submissions
- Translations
- TRAIL
- GxP-validated structured content management for Labeling content
- Change & Deviation Management
- Distribution internal & external
- BI Product Websites
- electronic Product Information
- Artworks
- IDMP

A journey towards the future of Labeling | Niklas Jänich & Murali Menon
OFEV is indicated in adults for the treatment of idiopathic pulmonary fibrosis (IPF).

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).

OFEV is indicated in adults for the treatment of systemic sclerosis associated interstitial lung disease (SSc-ILD).
The journey continues
TRAIL capabilities & collaboration on ePI

TRAIL
GxP-validated structured Labeling content

Interface

Go-to-Market & Operations

ePI via codes on packs

Go-to-Market

BI Product Websites

Regulators

EMA ePI pilot

Compendia

Internal Boehringer project

Boehringer Ingelheim

A journey towards the future of Labeling | Niklas Jänich & Murali Menon 12
Structured, connected, coded Labeling and the future of ePI

Do not take <X> • if you suffer from very low blood pressure

NEW! • if you suffer from severe liver problems

NEW! • Severe hypotension (< 90/50 mmHg)

NEW! • Severe hepatic insufficiency

NEW! • Resting heart rate below 70 beats per minute prior to treatment

NEW! • if you have heart failure which has recently become worse

Contraindications

- Contra-indications Text
- Contra-indications as “Disease / symptom / procedure”
- Disease status [0..1]
- Co-morbidity [0..1]
Questions & Discussion
A journey towards the future of Labelling
The Docuvera Journey...

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

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

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

IT | HighTech | Finance | Aviation | Defense | Government

23 YEARS EXPERTISE SINCE 2000

platform scale-up
2021 – 2024+

HighTech | Finance | Aviation | Defense | Government

BIOPHARMA SOLUTION
2017 LAUNCH

IT Software Corporation
The Solution

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

PRODUCT is indicated for...

Structured Content Authoring allows blocks of content to be reused in many documents.

Most common adverse reactions

Tissue Necrosis: necrosis of skin..

- Dosage and Administration
- Dosage Forms and Strengths
- Indications and Usage
- Contraindications
- Warnings and Precautions
- Adverse Reactions
- Use in Specific Populations
- Recent Major Changes
- Qualitative and Quantitative

Our customers love us.
Differentiation

Template guided
Review & Approval
Localization
Versioning & Archiving
Omni-channel Publishing
Task Notifications
RESTful API
Search
Auditing & Reporting
Content Migration
21 CFR Part11 Compliant
Permissions

Single Integrated Solution

Simple interface drives high level of user adoption.
Integrated platform lowers system integration risk.

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
<table>
<thead>
<tr>
<th>CO ID</th>
<th>Created date</th>
<th>Created by</th>
<th>Modified date</th>
<th>Modified by</th>
<th>Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>CO-158</td>
<td>Jan 24, 2024 4:33 AM</td>
<td>Susie Winn</td>
<td>Feb 13, 2024 11:50 AM</td>
<td>Susie Winn</td>
<td>New Indications – Bone Infections</td>
</tr>
<tr>
<td>CO-51</td>
<td>Oct 10, 2021 8:29 PM</td>
<td>Janet Schorr</td>
<td>Feb 01, 2024 2:13 AM</td>
<td>Susie Winn</td>
<td>Indications – Strained tendons</td>
</tr>
<tr>
<td>CO-154</td>
<td>Aug 17, 2023 10:08 AM</td>
<td>Susie Winn</td>
<td>Aug 17, 2023 10:23 AM</td>
<td>Susie Winn</td>
<td>New prescribing information</td>
</tr>
<tr>
<td>CO-153</td>
<td>Aug 17, 2023 1:00 AM</td>
<td>Susie Winn</td>
<td>Aug 17, 2023 2:55 AM</td>
<td>Susie Winn</td>
<td>Change to prescribing Age</td>
</tr>
<tr>
<td>CO-151</td>
<td>Aug 01, 2023 11:44 AM</td>
<td>Janet Schorr</td>
<td>Aug 15, 2023 11:31 AM</td>
<td>Susie Winn</td>
<td>Indication for bone infection</td>
</tr>
<tr>
<td>CO-150</td>
<td>Aug 01, 2023 11:41 AM</td>
<td>Janet Schorr</td>
<td>Aug 07, 2023 4:30 AM</td>
<td>Susie Winn</td>
<td>New AE for headaches</td>
</tr>
<tr>
<td>CO-149</td>
<td>Jul 07, 2023 2:57 PM</td>
<td>Susie Winn</td>
<td>Jul 07, 2023 2:57 PM</td>
<td>Susie Winn</td>
<td>New information – demo July ?</td>
</tr>
<tr>
<td>CO-145</td>
<td>Jun 27, 2023 2:44 PM</td>
<td>Susie Winn</td>
<td>Jun 27, 2023 2:45 PM</td>
<td>Susie Winn</td>
<td>Ppl need to know about this change</td>
</tr>
<tr>
<td>CO-144</td>
<td>Jun 27, 2023 10:19 AM</td>
<td>Susie Winn</td>
<td>Jun 27, 2023 10:21 AM</td>
<td>Susie Winn</td>
<td>German preferred center</td>
</tr>
</tbody>
</table>

**Details**

**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

**Notified by:**
Susie Winn
In collaboration with Boehringer

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
<table>
<thead>
<tr>
<th>Version</th>
<th>Branch name</th>
<th>Date</th>
<th>Versioning events</th>
<th>Approved by</th>
<th>Exported</th>
<th>Exported by</th>
<th>Reason(s) for change</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.0.1</td>
<td>SPMC-TM88-HY93</td>
<td>Apr 17, 2024</td>
<td>Minor approval</td>
<td>Alan Approver</td>
<td>Yes</td>
<td>Alice Author</td>
<td>New disclaimer</td>
</tr>
<tr>
<td>2.2</td>
<td>SPMC-Ao12-4433</td>
<td>Mar 3, 2024</td>
<td>Minor approval</td>
<td>Alan Approver</td>
<td>Yes</td>
<td>Alice Author</td>
<td>Positive opinion received</td>
</tr>
<tr>
<td>2.1+</td>
<td>SPMC-Ao12-4433</td>
<td>Dec 8, 2023</td>
<td>New version</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>New version created: General updates</td>
</tr>
<tr>
<td>2.1</td>
<td>SPMC-Ao12-4433</td>
<td>Nov 22, 2023</td>
<td>Minor approval</td>
<td>Sarah Approver</td>
<td>Yes</td>
<td>Dave Author</td>
<td>Ready for submission to HA</td>
</tr>
<tr>
<td>2.1+</td>
<td>SPMC-Bh99-171K</td>
<td>Nov 5, 2023</td>
<td>New branch</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>IDMP updates to SPMC required</td>
</tr>
<tr>
<td>2.1</td>
<td>SPMC-NP69-MNC9</td>
<td>Oct 18, 2023</td>
<td>Minor approval</td>
<td>Alan Approver</td>
<td>DMS</td>
<td>Alice Author</td>
<td>Updated template</td>
</tr>
<tr>
<td>2+</td>
<td>SPMC-NP69-MNC9</td>
<td>Jul 5, 2023</td>
<td>New branch</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>New version created: General updates</td>
</tr>
<tr>
<td>2</td>
<td>SPMC-Ao12-4433</td>
<td>Jun 30, 2023</td>
<td>Major approval</td>
<td>Sarah Approver</td>
<td>-</td>
<td>-</td>
<td>Initial change orders addressed, available for the...</td>
</tr>
<tr>
<td>1+</td>
<td>SPMC-Ao12-4433</td>
<td>Jun 25, 2023</td>
<td>New branch</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>Adjusting the dosage and administration informati</td>
</tr>
<tr>
<td>1</td>
<td>SPMC-TM88-HY93</td>
<td>Jun 24, 2021</td>
<td>Major approval</td>
<td>Alan Approver</td>
<td>-</td>
<td>-</td>
<td>First Basis point</td>
</tr>
</tbody>
</table>
Looking ahead - Synergies with AI

**Content Design**
- Search/Suggest
- Auto-propagation
- Auto-completion
- Paraphrasing

**Content Integrity**
- Content Accuracy
- Glossary/Style
- HA Knowledge Base
- Workflow Integrity

**Content Transformation**
- Language Translation
- Lay Summaries
- Document Summaries
- Verb Tense

**Content Enrichment**
- Topic Classification
- Information Extraction
- Redaction
- Reporting Changes

**Content Distribution**
- Chatbots
- Digital Submissions
- Export Transformations
- Enhanced Findability

**Enabling Technologies**
- Migrate Structured and Unstructured Data
- RAG with target clustering, hybrid search and prompt engineering
- GenAI with configuration layer
- NLP/Text Extraction
- Ongoing ESB/API Development

Auto-propagating correct content into correct documents
Auto-completing with prompts
Auto-translation of content
Auto-summaries of content
Auto-classification of content
Auto-redaction of content
Auto-delivery of content via new channels

Auto-tagging content with metadata
Extracting content to enhance semantic meaning
Enhanced findability of content
Digital submissions and chatbot enhancements

Automatically transform content based on project characteristics
Machine-aided checks of content completeness and accuracy
Leverage AI to deliver content via new channels and in new forms.

Docuvera
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

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

BPI Bundesverband der Pharmazeutischen Industrie e.V.

Rote Liste Service GmbH

vfa. Die forschenden Pharma-Unternehmen

Carbon Footprint of Package Leaflets – Summary of a Study // Rote Liste ePIL Summit 2024

05 March 2024
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

Carbon footprint as one means for sound decisions and improvements
Life cycle of package leaflets (paper-based)

Key:
- Transport / data transfer
- End-of-life management

1. Approved PL (file)
2. Printing
3. Assembly & Storage
4. Retail
5. Rework
6. Medical practice
7. Public pharmacy
8. Hospital
9. Mail order pharmacy
10. Patient

End-of-life management
Life cycle of package leaflets (paper-based)

Detailed view: File to confirmed printed PL

1. Transmitting file to printing company
2. Print at producer’s site
3. Goods dispatch
4. Transport printing company - producer
5. Goods receipt
6. Quality check
7. Inhouse transport
8. Printing
9. Assembly & Storage
10. Retail
11. Medical practice
12. Public pharmacy
13. Hospital
14. Mail order pharmacy
15. Patient
16. Discharge of outdated PL

Resources: energy consumption, paper, printing ink etc.
Upstream resource use e.g. of paper production: water, cellulose, energy

Estimated values for frequency of revision

Print at producer’s site

Rejected PL

Print

Goods dispatch

Transport printing company - producer

Goods receipt

Quality check

Inhouse transport

Rejected PL

Process - Steps, 49 relevant for the study

Approved PL (idea)

Rework

Rejected PL

Discharge of outdated PL

62 Process-Steps, 49 relevant for the study
Overview of Data collection: Reality

Data collection
- by data catalogues & interviews with companies
- Research in general & German drug market

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

Survey (DE & EN)

08.11.2022
22.12.'22 → 27.01.2023 → 21.02.'23

Weeks from start

Answered surveys

Input data for CF model

Last survey received
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
Data input bases on survey & general assumptions, if data not available.

Sensitivity analyses
1. Inbound distance of printed PL
2. Repositioning of PL between producers’ sites
3. Distribution distances
4. Shares of distribution paths

Input data for CF model

IFA database

Germany scenario

Scenario ...
Basic scenario:
Printing and supply of printed leaflets

**Electricity**
- 0.034 kWh/m²
- 2.76 nWh

**Approved PL (53 kB file)**
- 653 km
- 272 km
- 653 km

**Paper**
- 272 km
- 0.33 g/m²
- 12%

**Printing ink**
- 653 km
- 0.0815 m²/PL
- 3%

**Printing companies**

**Producers of pharmaceuticals**
- 230 km
- 40%
- 30 km transport between own site
- 10% of printing process
- Rework covered by surcharge approach; estimated by 4% of upstream emissions
- 5 kg transport box
- 50 packages
- 8 g PP strap band
- multiple use box

**no glue etc.**

**Package leaflet:**
- 4.0856 g/PL
- 0.0815 m²/PL
- 56 g

**418 kg pallet**
- ~ 94,000 leaflets
- 13.4 kg cardboard
- 0.4 kg LDPE foil
- single use Euro pallet

**204 kg pallet**
- 2.767 packages
- 29 kg cardboard
- 0.3 kg LDPE foil
- single use Euro pallet

Key:
- Transport with:
  - solo truck/truck-trailer
  - light duty vehicle / CEP
  - car/pedestrian
- no transport

Parameter based on survey
Parameter assumed
**Basic scenario:**

**Distribution distances of pharmaceuticals**

- **Producers of pharmaceuticals**
  - **indirect**
    - 362 km
    - 50% solo / 50% TT
    - load factor: 58% / 28% palletised
  - **direct**
    - 316 km
    - 50% solo / 50% TT
    - load factor: 58% / 28% palletised
    - 207 km
    - 50% solo / 50% TT
    - load factor: 58% / 28% palletised
    - 310 km
    - 50% solo / 50% TT
    - load factor: 58% / 28% palletised

- **Retail**
  - 175 km
  - 100% LDV boxes

- **Medical practice**
  - 175 km
  - 100% LDV boxes

- **Public pharmacy**
  - 5.5 km
  - 100% car boxes

- **Hospital**
  - 175 km
  - 100% LDV boxes

- **Mail order pharmacy**
  - 175 km
  - 100% LDV boxes
  - 100 km
  - 100% LDV boxes

**Patient**

**Key:**
- Transport with
  - solo truck/truck-trailer
  - light duty vehicle / CEP
  - car/pedestrian
  - no transport

Parameter based on survey
Parameter assumed
### Basic scenario: Share of distribution paths

<table>
<thead>
<tr>
<th>Distribution Path</th>
<th>Share of Distribution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Producer</td>
<td>60%</td>
</tr>
<tr>
<td>Retail</td>
<td>56%</td>
</tr>
<tr>
<td>Public pharmacy</td>
<td>71%</td>
</tr>
<tr>
<td>Medical practice</td>
<td>1%</td>
</tr>
<tr>
<td>Hospital</td>
<td>3%</td>
</tr>
<tr>
<td>Mail order pharmacy</td>
<td>15%</td>
</tr>
</tbody>
</table>

- **Producers:** 100%
- **Retail:** 100%
- **Public pharmacy:** 100%
- **Medical practice:** 100%
- **Hospital:** 100%

*due to non-matching shares, manual correction by 1%
### Grouping of results for the carbon footprint

<table>
<thead>
<tr>
<th>Cluster</th>
<th>Processes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Upstream PL</td>
<td>File transfer, paper for PL: production, inbound transport</td>
</tr>
<tr>
<td>Printing of PL</td>
<td>Production, inbound transport of ink, electricity use, waste paper</td>
</tr>
<tr>
<td>Transport to producer*</td>
<td>Transport from printing company to producer, *production and end-of-life (eoL) of transport packaging</td>
</tr>
<tr>
<td>Producer processes</td>
<td>Repositioning between sites, surcharge for wasted PL</td>
</tr>
<tr>
<td>Distribution</td>
<td>Transport direct or indirect from producer to patient</td>
</tr>
<tr>
<td>Disposal of PL in market</td>
<td>End-of-life (eoL) of PL</td>
</tr>
<tr>
<td>Rework surcharge</td>
<td>Share of reworked PL</td>
</tr>
</tbody>
</table>
Basic scenario: Results for the carbon footprint

- **7.3 g CO₂e / PL**
- ca. ± 3.7% estimated in sensitivity analyses
  - + 3.8% // -3.6%

Diagram showing the percentage contributions to the carbon footprint:
- Upstream PL
- Printing of PL
- Transport to producer*
- Producer processes
- Distribution
- Disposal of PL in market
- Rework surcharge

* incl. transport packaging

Slide 14
Scenarios for paper-based leaflet

<table>
<thead>
<tr>
<th>Scenario</th>
<th>CO₂e/package leaflet</th>
</tr>
</thead>
<tbody>
<tr>
<td>Germany</td>
<td>7.0 g</td>
</tr>
<tr>
<td>General retail</td>
<td>3.2 g</td>
</tr>
<tr>
<td>OTC</td>
<td>4.5 g</td>
</tr>
<tr>
<td>Prescription only</td>
<td>8.8 g</td>
</tr>
</tbody>
</table>

- **Rework surcharge**
- **Disposal of PL in market**
- **Distribution**
- **Producer processes**
- **Transport to producer**
- **Printing of PL**
- **Upstream PL**

* incl. transport packaging

+25% for Germany (7.0 g to 8.8 g) and -54% for General retail (3.2 g to 4.5 g).
Life cycle of package leaflets (digital)

1. Approved PL (file)
2. Integration eLeaflet in database
3. Provision of eLeaflet for download
4. Scan of PZN on pharmaceutical package
5. Search of PZN in online database
6. Available APPs
7. Medical practice
8. Public pharmacy
9. Hospital
10. Mail order pharmacy
11. Patient

Key:
Transport / data transfer
Underlying data for calculating GHG emissions

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

• 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**

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

Even under unrealistic use assumptions greenhouse gas reduction in digital scenario by two thirds.

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
# Estimation of Total PL Size and Weight, Germany 2022

<table>
<thead>
<tr>
<th></th>
<th>Total Printing Size [km²]</th>
<th>Total Paper Size [km²]</th>
<th>Total Weight [t]</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Prescription only</strong></td>
<td>195 km² (95% CI: 186 – 204 km²)</td>
<td>98 km² (95% CI: 93 – 102 km²)</td>
<td>4,639 t (4,407 – 4,872 t)</td>
</tr>
<tr>
<td><strong>OTC</strong></td>
<td>78 km² (95% CI: 74 – 82 km²)</td>
<td>39 km² (95% CI: 37 – 41 km²)</td>
<td>1,867 t (1,769 – 1,965 t)</td>
</tr>
<tr>
<td><strong>IQViA</strong></td>
<td>126 km² (95% CI: 119 – 133 km²)</td>
<td>63 km² (95% CI: 60 – 66 km²)</td>
<td>3,011 t (2,854 – 3,169 t)</td>
</tr>
</tbody>
</table>

Margin of error as 95% CI derived from unit sizes a as main error source
# Estimation of Total PL Size and Weight, Germany 2022: Extrapolation Production Waste

<table>
<thead>
<tr>
<th></th>
<th>Total Printing Size [km²] (double sided)</th>
<th>Total Paper Size [km²] (single sided)</th>
<th>Total Weight [t]</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Dispensed/Sold</strong></td>
<td>▪ Total</td>
<td>273 km² (95% CI: 260 – 286 km²)</td>
<td>137 km² (95% CI: 130 – 143 km²)</td>
</tr>
<tr>
<td></td>
<td>▪ IQViA</td>
<td>321 km² (95% CI: 305 – 337 km²)</td>
<td>161 km² (95% CI: 153 – 168 km²)</td>
</tr>
</tbody>
</table>

|                | 273 km² (95% CI: 260 – 286 km²) | 137 km² (95% CI: 130 – 143 km²) | 6,507 t (95% CI: 6,176 – 6,837 t) |
| **Dispensed/Sold and Production Waste** | ▪ Total | 320 km² (95% CI: 305 – 336 km²) | 160 km² (95% CI: 152 – 168 km²) | 7,622 t (95% CI: 7,235 – 8,010 t) |
|                | ▪ IQViA | 376 km² (95% CI: 358 – 395 km²) | 188 km² (95% CI: 179 – 197 km²) | 8,963 t (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 a 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$_2$e  10.8 t CO$_2$e = average annual GHG emissions of German inhabitant$^{(1)}$
3,100 (3,663) Circumnavigations by Mid-Range Car

Potential Reduction by using ePL (only) > 90%

(1) BMUV: https://www.bmuv.de/media/kohlenstofdfussdruck-pro-kopf-in-Deutschland, status 2/2022
The results are published in pharmind
(e)PIL Carbon Calculator der Roten Liste

https://www.epilcarboncalculator.com
ePIL Pilot Germany: State of Preparations

Berlin, 5th March 2024 – DRAFT
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

**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 "digital" and the project is planned with a focus on Germany, it was decided to call it:

**diGItal pilot project**
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
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

Carbon footprint

1. g CO₂ per package
2. g CO₂ per use case

VERTRÄULICH / CONFIDENTIAL

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**diGItal pilot project**

**Legal discussions**

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**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.

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**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 date, 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® 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.
diGiital pilot project – main pillars
The diGiital pilot project addresses acute and long-term challenges

Overcoming supply shortages - diGItale 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 - diGiital 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.
This presentation includes forward looking statements which are subject to future decisions. The contents are therefore - if needed - subject to future change.

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**

1. Identification of supply shortage & information towards diGital team
2. Request by MAH & approval from the authorities for the affected product
3. Upload the digital package leaflet to the platform and assign the relevant NTIN
4. Distribution of authorised products and publication of the appropriate ePIL
5. Scan of pack in other language by patient / HCP with app and display of digital package leaflet in national language

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

VERTRÄULICH / CONFIDENTIAL

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**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 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

The pilot project uses existing technologies, databases, apps and user channels to maximise speed and results.
This presentation includes forward looking statements which are subject to future decisions. The contents are therefore, if needed, subject to future change.

1 Based on existing and proved GI4.0 technology
2 Additional features not yet implemented

Statutory Health Insurance
## Involved stakeholders

### A large number of stakeholders are necessary for successful implementation

<table>
<thead>
<tr>
<th>Involved Stakeholders</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Associations (BAH, BPI, ProGenerika &amp; vfa)</strong></td>
<td>Act as initiators and representatives for the interests of pharmaceutical companies.</td>
</tr>
<tr>
<td><strong>Pharmaceutical companies</strong></td>
<td>Participate in the pilot, receive regular updates and can provide feedback for optimization.</td>
</tr>
<tr>
<td><strong>Authorities</strong></td>
<td>Responsible for the exemption authorization as well as permits for delivery shortage products.</td>
</tr>
<tr>
<td><strong>Technology partner</strong></td>
<td>Possible partners for the integration of ePILs in other applications in order to reach as many users as possible.</td>
</tr>
<tr>
<td><strong>digItal Pilot PMO</strong></td>
<td>Responsible for the conceptualisation, coordination and implementation of the project.</td>
</tr>
<tr>
<td><strong>Patients</strong></td>
<td>Users of the ePILs, which can provide valuable feedback.</td>
</tr>
<tr>
<td><strong>Hospitals</strong></td>
<td>For hospital pilot, support of hospitals especially a sample for questionnaires is necessary to collect data.</td>
</tr>
<tr>
<td><strong>Further stakeholders</strong></td>
<td>Other associations and interest groups are important multipliers (e.g. ADKA, ABDA, payors, etc.)</td>
</tr>
</tbody>
</table>
### diGital pilot project – Differentiation factors (1/2)

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

<table>
<thead>
<tr>
<th>Pilot projects in other European countries</th>
<th>diGital pilot project</th>
<th>Extended data collection Involvement of other stakeholders</th>
</tr>
</thead>
<tbody>
<tr>
<td>Supply shortages Better provision of information</td>
<td>- Addressing supply shortages is not part of the existing pilots.</td>
<td>- There is no batch reference to ePILs today.</td>
</tr>
<tr>
<td>- Batch Actuality of ePIL</td>
<td>- Rudimentary data collection focusing on hospital pharmacists.</td>
<td></td>
</tr>
<tr>
<td>- Extended data collection</td>
<td>- Expanded data collection from various stakeholders to gather evidence for legislation.</td>
<td></td>
</tr>
<tr>
<td>- Involvement of other stakeholders</td>
<td>- When using the GI4.0 app and website, access figures can be recorded anonymously in accordance with data protection laws (DSGVO).</td>
<td></td>
</tr>
</tbody>
</table>

#### 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.

This presentation includes forward looking statements which are subject to future decisions. The contents are therefore - if needed - subject to future change.
### diGital pilot project – differentiation factors (2/2)

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

<table>
<thead>
<tr>
<th>4</th>
<th>5</th>
<th>6</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>App usage</strong></td>
<td><strong>Extended user group</strong></td>
<td><strong>International cooperation</strong></td>
</tr>
<tr>
<td><strong>Pilot projects in other European countries</strong></td>
<td><strong>Germany &amp; other pilot countries</strong></td>
<td><strong>Optional</strong></td>
</tr>
<tr>
<td>▪ Previous pilots only use websites to display the ePIL and usually refer to static PDFs.</td>
<td>▪ Addition of a further large market to existing and planned pilots in other European countries (Belgium, Luxemburg, Baltic states, Portugal, Spain, France, etc.).</td>
<td>▪ Pilot projects have so far been primarily national in scope and multi-market packs are not taken into account.</td>
</tr>
</tbody>
</table>

| **diGital pilot project** | **Use of an app to improve the availability of information and thus improve handling in everyday clinical practice.** | **In addition: More efficient use of packaging lines may increase efficiency and availability of products participating in pilot projects** |
| ☐ | ▪ Integration of ePILs in other applications, e.g. ePA, is conceivable. | ☐ |

<table>
<thead>
<tr>
<th><strong>Pilot projects in other European countries</strong></th>
<th><strong>Germany &amp; other pilot countries</strong></th>
<th><strong>International cooperation</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>▪ Possible cross-border cooperation offers a new, relevant approach for pilot projects.</td>
<td>▪ The use of multi-market packs without package inserts can be tested.</td>
<td>☐</td>
</tr>
</tbody>
</table>
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
- 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

Chair and Vice-Chair
- 3 Strategy / regulatory policy representatives per association
- 3 Coordinators (1 per association)

Steering committee

Leadership team for Coordination and collaborative management of actives and tasks of the WGs
- 1 lead and two co-leads

WG on Contents

WG Implementation and technical aspects
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
Making ePI accessible to everyone
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Date: 05/March/2024

ROTE Liste Summit, Berlin 2024
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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.
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?
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.
“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-lingual 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 CO2 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 CO2 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.