DRAFT IMPLEMENTATION PLAN FOR THE ELECTRONIC PATIENT INFORMATION LEAFLET (ePIL)

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List of Abbreviations and Acronyms

Abbreviation / Acronym	Meaning
CP	Centralised Procedure
DCP	Decentralised Procedure
EC	European Commission
EEA	European Economic Area
EHR	Electronic Health Record
EMA	European Medicines Agency
EP	European Parliament
ePIL	Electronic Patient Information Leaflet
EU	European Union
EVC	Electronic Vaccination Card
HCP	Healthcare Professional
MRP	Mutual Recognition Procedure
NUVA	Unified Nomenclature of Vaccines
NCA	National Competent Authority
PLM	Product Lifecycle Management

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The purpose of EUVABECO is to deliver to Member States implementation plans for several tools able to support existing or future vaccination practices.

These implementation plans are practical guides for a Member State to decide upon the launch of an implementation project, assign adequate resources, deploy the given tool and keep it operational after deployment.

They are structured with three main sections:

- Description of the tool is a functional analysis of the tool with an overview, the stakeholders using or contributing to the use of the tool, their respective functional requirements, the non-functional requirements, and a collection of use cases illustrating the desired functions.
- Prerequisites lists the contextual conditions that must be met before the project is launched, and a few workarounds that could be used to anticipate upon their fulfilment.
- Implementation addresses the actual implementation, with the architecture, resources, workflow and planning for the build phase, and the missions to be ensured during the run phase to keep the tool operational.

1 Description of the tool

This section describes functionally the intended tool and its usage. It does not correspond to any specific implementation of the tool.

1.1 Objectives

This section is the overall rationale for the tool.

1.1.1 What is the ePIL?

A patient information leaflet is a technical document provided by the manufacturer that comes with every medicinal product. It gives important details about the prescribed medicinal product and informs the citizen/patient about administration, precautions and potential side effects[1]. The Electronic Patient Information Leaflet (ePIL) refers to an electronic version of the patient information leaflet, rather than the traditional paper leaflet. The content of the ePIL is the same as the paper leaflet and provides detailed information about the medicinal product, including administration, precautions and potential side effects, accessible via digital platforms such as websites and datamatrix codes.

1.1.2 Rationale Behind the ePIL for Vaccines

Vaccines are critical for public health and healthcare systems and need to be supplied efficiently and timely. However, the diverse language requirements for packaging and leaflets across different European Union (EU)/European Economic Area (EEA) countries can hinder supply chain efficiency and limit emergency responses to epidemics, pandemics and vaccine shortages.[2]

Paper leaflet requirements can prevent addressing vaccine shortages swiftly. In emergencies, some countries accept foreign packs, but this is not a general rule and permission is granted by national authorities on a case-by-case basis. Replacing paper leaflets with the ePIL would create more flexibility when it comes to tackling vaccines shortages in Europe.

[1] Herber, O. R., Gies, V., Schwappach, D., Thürmann, P., & Wilm, S. (2014). Patient information leaflets: informing or frightening? A focus group study exploring patients' emotional reactions and subsequent behavior towards package leaflets of commonly prescribed medications in family practices. BMC Family Practice, 15(1). https://doi.org/10.1186/1471-2296-15-163

[2] Vaccines Europe (n.d.). E-leaflet and vaccines common EU packaging. https://www.vaccineseurope.eu/wp-content/uploads/2022/09/VE-CommonPackaging_InfographicSHEET-V10_FINAL_UPDATE_WEB.pdf

As they are administered by healthcare professionals (HCPs), rather than being self-administered, vaccines could be the first type of medicinal product to be transitioned to the ePIL. Replacing paper leaflets with ePILs for vaccines can significantly improve vaccine distribution and access. The use of ePILs can address shortages in the EU, expedite production, streamline distribution, and enhance the efficiency of vaccination campaigns. They also facilitate the transfer of vaccines between EU Member States during public health emergencies, such as epidemics, pandemics, wars, or natural disasters.

The ePIL addresses the following challenges:

- Timeliness and Accuracy: ePILs enable real-time updates, ensuring the most current and accurate health authority approved information is always available, unlike paper leaflets that can be outdated.
- Flexibility: ePILs facilitate compliance with regulatory requirements and exemptions during emergencies, expediting vaccine distribution by reducing the need for extensive paper documentation.
- Logistical Efficiency: ePILs simplify vaccine packaging and distribution by providing a single digital source for information, reducing production time and logistical complexities.
- Environmental and Energy Savings: ePILs reduce the reliance on paper, contributing to environmental sustainability by minimising paper use and the associated energy.
- Refrigeration and Storage Optimisation: ePILs minimise the need for bulky packaging, which could maximise storage capacity for vaccines that require refrigeration.

The ePIL addresses the following political imperatives:

- Protection of People: Ensuring the security of supply of vaccines in a timely manner is critical for overall public health security. Ensuring a secure supply of medical information in a timely manner is critical for maintaining vaccine confidence.
- Urgent Need for Digital Tools: In the face of current global challenges, including geopolitical tensions, wars, border issues, displaced populations, and climate change, there is an urgent need to act now. The digitalisation provided by ePIL offers a timely solution to these pressing issues.
- Geopolitical Context: The current geopolitical climate, marked by ongoing crises, underscores the necessity of robust, adaptable healthcare tools. The ePIL system must be designed to function effectively amidst such challenges, providing reliable and accessible patient information.

In conclusion, the ePIL represents a significant advancement in how patient information is disseminated, offering a more flexible, efficient, and environmentally friendly solution that is particularly valuable during public health emergencies.

1.2 Involved stakeholders and their expectations

These are all the actors within the implementing Member State using or contributing to the use of the tool once it has been implemented. Their expectations are requirements for any implementation of the tool.

For the successful implementation of the ePIL, various stakeholders play crucial roles, each with specific expectations and responsibilities. The key stakeholders are:

- Citizens/Patients
- Healthcare Professionals (HCPs)
- National Competent Authority (NCA)

- European Medicines Agency (EMA)
- European Commission (EC)
- Vaccine Manufacturers
- Electronic Health Record (EHR) Suppliers
- e-Health Infrastructure Operators

1.2.1 Citizens/Patients

Individuals who receive, access, and use the ePIL expect easy access to accurate and timely information about their medicinal products, user-friendly interfaces and multilingual information.

1.2.2 Healthcare Professionals (HCPs)

HCPs include hospital practitioners, general practitioners, pharmacists, and nurses, who administer vaccines and provide trustworthy information to the public. They expect efficient systems to access and deliver ePILs, potentially integrated with existing electronic health records (EHRs) and prescribing systems, and the assurance that the ePILs are up-to-date and accurate. HCPs that administer vaccines can vary among EU Member States.

1.2.3 National Competent Authority (NCA)

NCAs, primarily responsible for the authorisation of medicinal products available in the EU that do not pass through the centralised procedure, expect ePIL systems to facilitate efficient regulatory processes and ensure the authenticity and accuracy of information. The list of NCAs in the EU/EEA can be found here.

1.2.4 European Medicines Agency (EMA)

The EMA, overseeing the centralised marketing authorisation procedure, expects ePILs to meet EU standards for quality, safety, and efficacy. The EMA oversees regulatory standards and manages its database for centrally approved medicinal products. It is also responsible for the Product Lifecycle Management (PLM) Portal, the pilot project that includes hosting and accessing ePILs.

1.2.5 European Commission (EC)

The EC expects compliance with EU legislation and alignment of ePIL initiatives with broader European objectives.

1.2.6 Vaccine Manufacturers

Vaccine manufacturers seek streamlined regulatory processes for incorporating ePILs, with flexibility to update content in real-time and reduce logistical burdens by replacing paper leaflets with digital versions. They also advocate for globally aligned industry standards to avoid the complexity of differing requirements across regions and request flexibility in how ePIL content is disseminated, enabling companies to implement patient-focused mechanisms for delivery.

1.2.7 Electronic Health Record (EHR) Suppliers

EHR suppliers, providing digital systems for storing and managing patient health records, expect solutions for seamless ePIL integration.

1.2.8 e-Health Infrastructure Operators

Operators maintaining the technical infrastructure required for managing and sharing ePIL data securely and efficiently expect consistency with national or European regulations and integration with citizen portals and healthcare systems.

1.3 Constraints

Constraints are the non-functional requirements on the tool. They do not correspond to a function to be performed by the tool, but not respecting them would impair the viability of the tool.

For the successful implementation of ePIL, various constraints must be addressed. These constraints involve legal requirements, marketing authorisation procedures and printing requirements.

1.3.1 Legal Framework

For medicinal products, EU legislation mandates that information appears on all packaging components in the official national language(s) of the country of distribution. With 24 official languages in the EU/EEA and some countries having up to three official languages, this creates logistical challenges. The small market size of many EU countries means vaccines often need to be delivered in small volumes with country-specific packs, further complicating the supply chain. Additionally, vaccines require refrigerated storage, limiting space and necessitating minimal packaging content. This constraint limits multilingual packs to a maximum of three languages, adding complexity.[3]

The implementation of the ePIL is grounded in the existing legal provisions of the EU, particularly Directive 2001/83/EC, which governs the labelling and packaging of medicinal products. The Directive allows for certain flexibilities, especially under exceptional circumstances such as public health emergencies.

During emergencies like the COVID-19 pandemic, the EC and the NCAs exercised these flexibilities to streamline the approval and distribution process of COVID-19 vaccines. For instance, Member States have allowed the use of QR codes to provide access to translated package leaflets, and in some cases, have permitted the distribution of vaccines with minimal on-pack information, relying instead on digital resources for detailed patient information.

In the proposed revisions to the General Pharmaceutical Legislation, the EC and the European Parliament (EP) have suggested that Member States may eventually provide package leaflets electronically only. This change, anticipated to be possible from 2028, would allow for a fully digital provision of medicinal product information, potentially eliminating the need for paper leaflets inside packaging. The legislation also emphasises patients' rights to request a printed copy of the package leaflet free of charge, ensuring that no patient is left behind. If implemented, these revisions could allow the use of ePILs instead of paper leaflets without the current requirement of an exemption.

1.3.2 EU Regulatory Procedures for a Marketing Authorisation

Marketing authorisation is the official approval granted by a regulatory authority to market a medicinal product within a certain jurisdiction. It ensures that the product meets necessary standards of quality, safety, and efficacy before being made available to the public.

For the implementation of the ePIL, the different regulatory procedures to marketing authorisation must be considered. The procedure through which a medicinal product receives its marketing authorisation dictates whether the exemption to use an ePIL instead of a traditional paper leaflet should be sought from the EMA or an NCA.

[3] Vaccines Europe (n.d.). E-leaflet and vaccines common EU packaging. https://www.vaccineseurope.eu/wp-content/uploads/2022/09/VE-CommonPackaging_InfographicSHEET-V10_FINAL_UPDATE_WEB.pdf

The two main procedures for obtaining marketing authorisation in the EU are the centralised procedure and the national marketing authorisation procedures, which include the decentralised and mutual recognition procedures[4].

The **centralised procedure (CP)** involves a single application that leads to one evaluation and one marketing authorisation valid across all EU Member States, as well as Iceland, Norway, and Liechtenstein. This results in a unified set of product information for HCPs and citizens/patients in all official EU languages.

The national marketing authorisation procedures consist of the decentralised procedure, mutual recognition procedure and national procedure.

- **Decentralised Procedure (DCP)**: For products not yet authorised in any EU Member State, the decentralised procedure allows simultaneous applications in multiple countries, resulting in coordinated national approvals.
- **Mutual Recognition Procedure (MRP)**: For products already authorised in one EU Member State, the mutual recognition procedure allows other Member States to recognise this authorisation, facilitating broader market access.
- **National Procedure:** Independent national procedures are limited to medicines which are to be authorised and marketed in only one Member State. This procedure is nowadays rarely followed for new products.

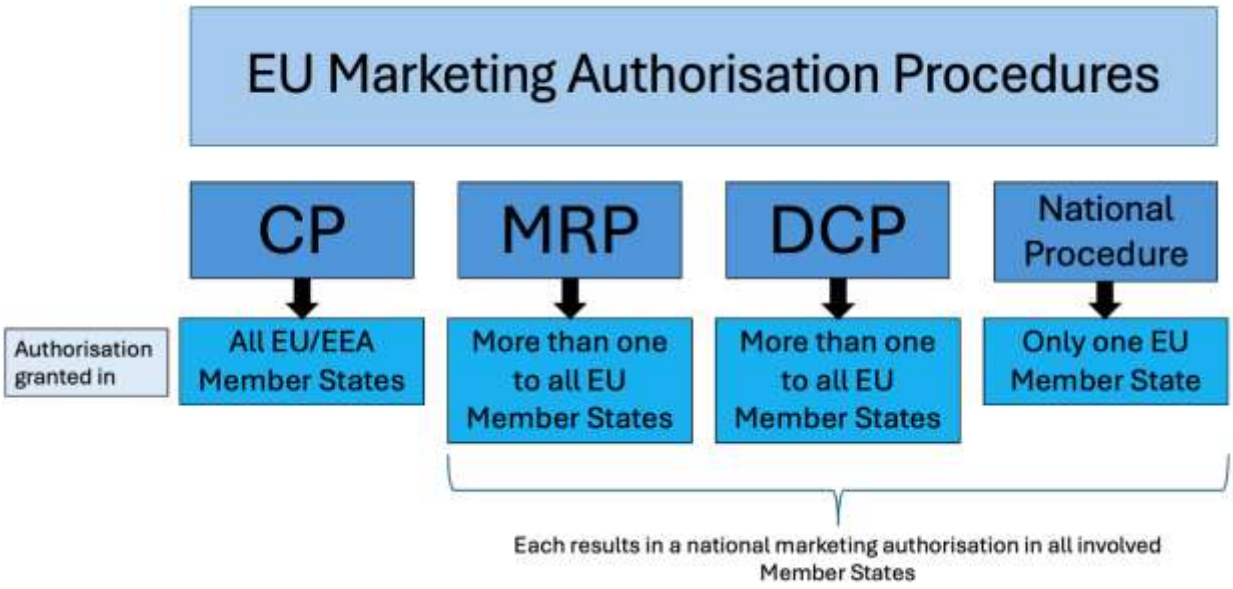

Fig1: EU Marketing Authorisation Procedures[5]

1.3.3 Implications for the ePIL Implementation

According to EU legislation, namely Regulation (EEC) No 2309/93 and Regulation (EC) 726/2004, new vaccines must go through the centralised procedure to obtain marketing authorisation in EU.

[4] EMA (n.d.). Authorisation of medicines. https://www.ema.europa.eu/en/about-us/what-we-do/authorisation-medicines#national-authorisation-procedures-10946

[5] EUPATI. (n.d.). 5. EU Regulatory Procedures for a marketing authorisation (MA). https://learning.eupati.eu/mod/book/tool/print/index.php?id=893

However, some existing vaccines that obtained marketing authorisation before this legislation was in place were approved via national marketing authorisation procedures (including DCP and MRP) and continue this pathway for marketing authorisation maintenance. Therefore, when looking for trustful source of the patient information leaflet content, both the EMA and the NCAs websites need to be consulted.

The implementation of the ePIL involves several key considerations regarding regulatory compliance and the permissions required from both the EMA and NCAs. The process for obtaining a waiver from the legal obligation to include paper leaflets will vary depending on the marketing authorisation pathway of the medicinal product.

Centralised Procedure (CP): For medicinal products authorised through the CP, the EMA is the primary authority. As seen during the COVID-19 crisis, for CP products, a general exemption was granted where the EMA led the process but consulted with NCAs across the EU. This collaboration allowed for national recommendations to be made, and some Member States required the paper leaflet to be provided separately from the packaging. Therefore, for the exclusive use of the ePIL for products authorised through the CP, both the EMA and NCAs would need to be consulted to ensure compliance across all relevant jurisdictions.

National Authorisation Procedures (DCP and MRP): For medicinal products authorised through the DCP or the MRP, the relevant NCAs of the Member States are responsible. The NCA of each Member State involved in the authorisation process would need to grant permission to waive the legal obligation of paper leaflets. This means that for these products, manufacturers must navigate the regulatory requirements of each individual country where the product is marketed. The list of NCAs in the EU/EEA can be found here.

1.3.4 Printing Logistics and Financial Responsibilities

For medicinal products, including vaccines, a significant constraint of the implementation of the ePIL is the debate over the logistics and financial responsibility for printing ePILs in pharmacies for those citizens/patients who require or prefer a paper version of the leaflet. Determining who will bear the costs of printing—whether it will be the responsibility of manufacturers, pharmacies, or another entity—remains unresolved. However, as vaccines are administered by healthcare professionals, this constraint should not be an issue for the implementation of the ePIL for vaccines. It is acknowledged that patients have the right to obtain a paper leaflet, with possible solutions including printing by a professional, such as the dispenser or care provider, or self-service printing options available at kiosks in pharmacies, retail outlets, healthcare centres, or community printing hubs.

In conclusion, while the implementation of ePILs offers significant benefits in terms of flexibility, efficiency, and environmental sustainability, addressing these constraints is crucial. Obtaining regulatory exemptions and resolving printing logistics are critical to the successful adoption of ePILs within the EU healthcare system.

1.4 Use cases

The use cases are illustrative scenarios representing how the actors identified above could use the tool to meet their expectations. They are as many use cases as needed to describe every desired function of the tool.

1.4.1 Use Case for a Centrally Approved Vaccine

Lisa and Daniel are a young couple living in EU-country B, though they are originally from EU-country A. With a young child due for vaccinations, they want to ensure they have accurate information about the vaccines their child will receive, in their native language. Lisa and Daniel use the search function on the EMA's database for centrally approved medicinal products to find the meningococcal group B vaccine "XYZ". The patient information leaflet is available in the Product Information section and can be accessed in all EU languages, including Lisa and Daniel's native language from country A. This allows them to access and understand the most up-to-date and accurate information about the vaccine their child will receive.

Fig2: Search EMA database for vaccine "XYZ"

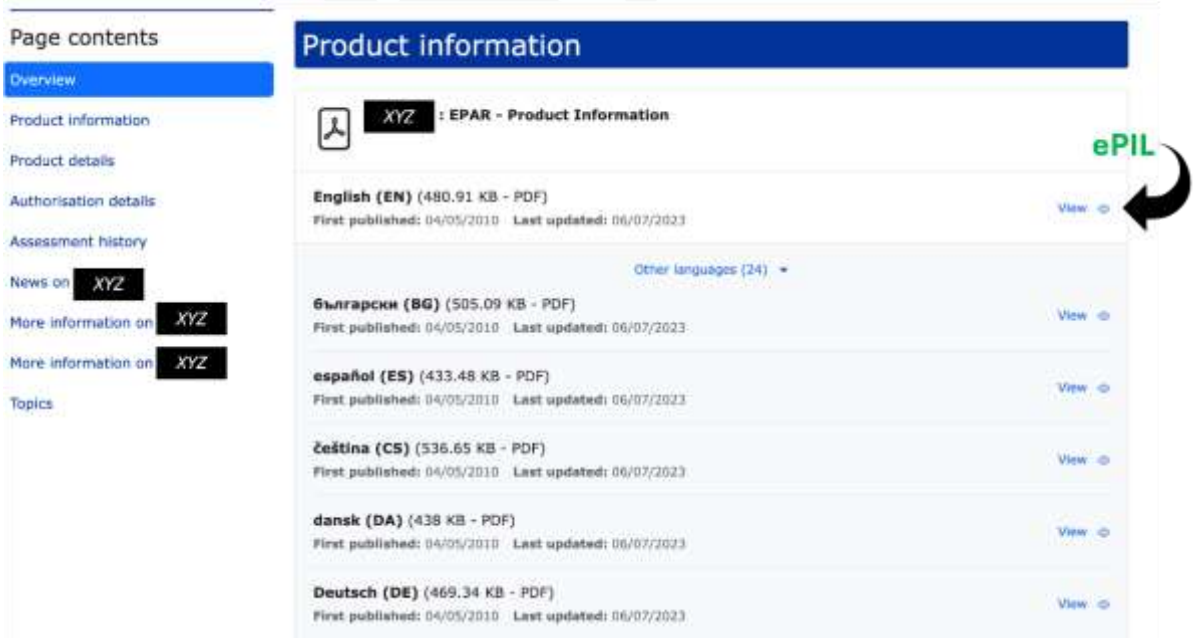

Fig3: ePILs available in all EU languages on EMA database

1.4.2 Use Case for a Nationally Approved Vaccine

Maria, a resident of EU-country A, is on holiday in EU-country B when she is bitten by an animal. She is promptly administered a rabies vaccine "XYZ" by a local doctor. However, the paper leaflet accompanying the vaccine is in the local language of country B, which Maria does not understand. To find reliable information, Maria visits the EMA's website and navigates to the list of National Registers of Authorised Medicines. She selects the link for her home country, which takes her to her national health authority's website. There, she uses the search function to find the rabies vaccine "XYZ" and accesses the patient information leaflet in her native language, allowing her to review the latest information on the vaccine's precautions and potential side effects with confidence.

Fig4: EMA's list of national registers of authorised medicines

1.4.3 Use Case – Change of Leaflet Content

Vaccine manufacturer ABC produces the COVID-19 vaccine "XYZ," which has been centrally approved by the EMA. Due to the ongoing COVID-19 pandemic, ABC has received an exemption allowing the patient information leaflet to be accessed by scanning a datamatrix code on the vaccine's outer packaging, instead of providing a paper leaflet. ABC gathers more data on the vaccine and needs to amend the information on the vaccine's potential side effects in the patient information leaflet. Rather than reprinting paper leaflets—a process that could delay distribution and cause vaccine shortages—ABC submits a request via Variation administrative procedure to the EMA to update the content of the digitally available patient information leaflet for vaccine "XYZ" across all EU languages. The EMA processes this request, ensuring that citizens/patients and healthcare professionals have immediate access to the most current and accurate vaccine information, simply by scanning the datamatrix code on the packaging.

1.4.4 Integration with Electronic Vaccination Cards (EVCs) and Other Channels

The ePIL could be integrated with the Electronic Vaccination Card (EVC). The EVC could serve as an entry point for accessing ePILs. By linking vaccination records with ePILs, patients/citizens and HCPs

could easily obtain the most up-to-date information on vaccines, including usage instructions, safety information, and potential side effects. With EVCs and other channels being linked to the ePILs, individuals like Lisa and Daniel (Use Case 1.4.1) and Maria (Use Case 1.4.2) would no longer need to manually search websites for vaccine information. Instead, they could simply use the EVC or scan a datamatrix code to instantly access the most up-to-date information about their vaccines in their native language.

To ensure broad accessibility, ePILs could be made available through various channels:

- EVC: A portable, self-contained, dual format document provided to citizens to carry their vaccination history without loss of information across different health jurisdiction. The EVC could link to the EMA's platform hosting the ePILs.
- NCAs' Websites: The websites of the NCAs could link to the EMA's platform hosting ePILs.
- Datamatrix Code Scanning: An application to scan the datamatrix codes on medicinal product packaging could lead to the ePIL. Using datamatrix codes (which are already present on the outer packaging) instead of QR codes would avoid having to add additional information on the outer packaging of the medicinal product.

1.4.5 Accessing ePILs for Centrally and Nationally Approved Vaccines

You want to access the electronic Patient Information Leaflet (ePIL) of a specific vaccine, in the case of no URL or datamatrix code linking to the vaccine's ePIL.

Determine Approval Type:

- Search for your vaccine in the **EMA Database**.
    - If the vaccine **appears in the EMA database**, it means the vaccine was **centrally approved**.
    - If the vaccine **does not appear in the EMA database**, it was **not centrally approved**, and you will need to search the **national database** of the country where the vaccine was administered.

Was the vaccine centrally approved by the EMA?

- **Yes** → Proceed to the EMA's **Centrally Approved Medicinal Products Database**.
    - Search for the vaccine.
    - The ePIL will be available in all EU languages.
    - You can download the leaflet in your native language.
- **No** → Proceed to the EMA's list of **National Registers of Authorised Medicines** and select the website for the country where the vaccine was approved.

2 Prerequisites

2.1 Assessment of prerequisites

Prerequisites represent a context or resources that are not specific to the tool but needed for its implementation or operation. They form a general background that should exist to guarantee the correct operation of the tool, once deployed.

2.1.1 Operational

For the ePIL platform to be effective, it must be hosted by a trusted authority that ensures the reliability and credibility of the information provided. The EMA, which hosts its database for centrally approved medicinal products and the PLM Portal, plays a crucial role in this regard. Trust in the EMA

by both healthcare professionals and citizens/patients is essential for the successful adoption and utilisation of ePILs. This trust is built through transparent operations, regular updates based on the latest scientific evidence, and clear communication regarding the safety and efficacy of medicinal products. Additionally, the EMA's established relationships with NCAs and other stakeholders reinforce its authority and credibility.

It is important to note that the EMA's PLM Portal is currently a pilot project and does not yet provide electronic product information for all authorised medicinal products in the EU, but only a selection. While we would ideally rely on the PLM Portal, it is not yet complete. Therefore, in the interim, the EMA's database for centrally approved medicinal products will be utilised, as it provides product information, including the patient information leaflet, in all EU languages for centrally approved medicinal products. For medicinal products that were not centrally, but nationally approved, national registers will need to be accessed. A list of the national registers, which host the patient information leaflets in national languages, can be found on the EMA's website here.

2.1.2 Legal and ethical

Currently, EU legislation mandates that patient information leaflets must be provided in paper form. To implement ePILs exclusively, exemptions will be required. Depending on the marketing authorisation of the medicinal product, these exemptions would need to be obtained from the EMA (in consultation with the NCAs) for centrally authorised products or from NCAs for products authorised through decentralised or mutual recognition procedures. Navigating these regulatory requirements adds complexity to the implementation process. Countries implementing ePILs need clear guidance on how to contact the appropriate NCA to seek authorisation for exemptions. This includes obtaining contact details and procedural information to streamline the approval process.

Proposed revisions to the General Pharmaceutical Legislation suggest that, starting possibly from 2028, Member States may be allowed to provide package leaflets electronically only, with the stipulation that patients can request a printed copy free of charge. This legislative change could potentially eliminate the need for current exemptions by allowing for fully digital medicinal product information, as already demonstrated during emergencies like the COVID-19 pandemic.

2.1.3 Policy

Stakeholder Engagement: Engage with policy stakeholders (on national and regional level) to build support for the ePIL, emphasising the benefits of improved patient information and environmental impacts.

2.1.4 Technical

The successful deployment of ePILs requires robust technological infrastructure. This includes the development and maintenance of secure digital platforms where ePILs can be accessed, ensuring these platforms are user-friendly and accessible to individuals with varying levels of digital literacy. The platform to host the ePILs has already been established by the EMA and a group of NCAs as part of their one-year pilot to test the use of electronic product information. The pilot project started in July 2023 and the platform with the ePI authoring tool can be accessed on the EMA's Product Lifecycle Management Portal. As the PLM Portal is not complete yet and currently only provides a small amount of ePILs, the EMA's database for centrally approved medicinal products will be utilised in the interim. This database provides product information, including the patient information leaflet, in all EU languages for centrally approved medicinal products. For medicinal products that were not centrally, but nationally approved, national registers will need to be accessed. A list of the national registers, which host the patient information leaflets in national languages, can be found on the EMA's website. An example for an existing platform on national level that hosts ePILs is Infomed, Portugal's national

database for medicinal products for human use. In Belgium, the Federal Agency for Medicines and Health Products Database provides ePILs in French, Dutch and English.

2.2 Filling the gaps

Meeting the prerequisites is generally a long-term action that goes far beyond the scope of the implementation plans. This section presents workarounds that could help to initiate the implementation despite the lack of some prerequisites, although background effort will be required to catch up.

2.2.1 Legal and ethical

In cases where full authorisation is not immediately achievable, ePILs can be introduced as an additional resource alongside traditional paper leaflets. This dual approach allows stakeholders to gradually adapt to digital formats while maintaining compliance with existing regulations. In case of this "Plan B", real world evidence could be collected to support the removal of the paper leaflet in the future.

2.2.2 Policy

Proposed revisions to the General Pharmaceutical Legislation suggest that, starting possibly from 2028, Member States may be allowed to provide package leaflets electronically only. This shift would eliminate the need for exemptions currently required to use ePILs instead of paper leaflets.

3 Implementing

The implementation of ePILs leverages the existing infrastructure provided by the NCAs and the EMA's database for centrally approved medicinal products, which will be utilised as the PLM Portal is not yet complete. The implementation of the ePIL focuses on ensuring broad accessibility through various channels. These channels could include the use of NCAs' websites and datamatrix code applications and the integration of the ePIL in the EVCs, as described in chapter 1.4.4. This section outlines the necessary steps for the successful deployment and integration of ePILs into the existing system, focusing on the phases of building, running, and validating the implementation.

3.1 Build

This section is the core of the implementation plan. It details how the tool is constituted, which roles should be present in the project team, the tasks they will have to perform, and a typical planning for implementation. It can be complemented with further supporting resources elaborated during the EUVABECO project.

3.1.1 Architecture

The goal is to provide a link to the ePIL for each vaccine. The ePILs itself are hosted on existing platforms (EMA or NCA databases), and the key task is to ensure citizens/patients and HCPs are directed to the correct ePIL through the Unified Nomenclature of Vaccines (NUVA) system or other mechanisms.

Steps:

1. Integration of ePIL links into NUVA:
    - The NUVA (Unified Nomenclature of Vaccines) system will store a reference to the ePIL.
    - For each vaccine, the NUVA code will be linked to the correct ePIL (hosted on existing platforms, the EMA and NCA databases)

- The ePIL may be available in multiple languages, and links for each language and country will need to be specified.

2. Provide a Portal for Manufacturers:
   - Vaccine manufacturers will be responsible for maintaining their ePIL links.
   - A portal could be provided for manufacturers to upload, update, and manage ePILs, associating them with the appropriate NUVA code and language code.
   - The links should be regularly reviewed and updated to ensure accuracy.

3.1.2 Project team

The project team will consist of:

- Technical Team: Responsible for developing and maintaining integration with various access channels. Implements the technical aspects of linking vaccines to the ePIL, such as configuring the NUVA system.
- Legal Team: Ensures compliance with regulatory and legal requirements.
- Manufacturers: Ensure that the correct ePIL is provided for each vaccine and is continuously updated.
- Health Authority Team: Provides oversight and ensures alignment with regulatory standards.

3.1.3 Workflow

The implementation workflow involves the following key stages:

Framing the Structure:

- Define which systems (e.g., NUVA) will be used to link vaccines to their ePIL.
- Identify how to retrieve the links from the host websites (EMA and NCAs).

Identifying Participating Systems:

- Identify the systems (e.g., EVC reader, clinic website, national immunisation registries) that will include the ePIL links.

Defining the Lookup Mechanism:

- Establish the mechanism through which the NUVA system or similar platforms will link the vaccine codes to the correct ePIL URLs.

Providing Manufacturer Access:

- Develop the portal for manufacturers to upload and maintain ePIL links, ensuring they align with the correct vaccine codes and languages.

Deploying Access Systems:

- Ensure that healthcare providers and patients can easily access the ePIL through existing systems, such as patient portals, health apps, or printed QR codes on vaccination records.

3.1.4 Typical planning

Activity	M1	M2	M3	M4	M5	M6
1 Framing the Structure						
2 Identifying Participating Systems						
3 Defining the Lookup Mechanism						
4 Providing Manufacturer Access						

5 Deploying Access Systems						

3.1.5 Build resources

This implementation plan is not intended for any particular tool. Rather, it is up to the implementer to choose the tools to implement the plan based on their resources and preferences. Resources regarding NUVA can be found in Implementation Plan 5.1/5 (Implementation Plan for the European Vaccination Card), Section 3.1.5 (Build Resources).

3.1.6 Verification

Channel Testing**:** Ensure that the integration with digital channels is seamless and ePILs are easily accessible.

3.2 Run

Once the tool has been deployed, there is still a need for lasting resources to support its adoption and ensure its maintenance. This section details these further actions.

3.2.1 Governance

- Updating ePIL Links: Ensure that manufacturers update their ePILs as new vaccines or new versions are approved.
- Monitoring Access: Monitor the effectiveness of the system to ensure citizens/patients and HCPs have uninterrupted access to ePILs.

3.2.2 Monitoring

- Monitoring of the number of ePIL accesses by citizens/patients and HCPs.

3.2.3 Communication

- Educational Campaigns: Organise campaigns to educate healthcare professionals and citizens/patients about ePILs and how to access them. For example, this could be communicated on the physical packaging of the medicinal product.
- Stakeholder Meetings: Regularly meet with stakeholders to provide updates and gather feedback.
- User Support: Establish support channels to assist users with any issues related to ePIL access and usage.

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