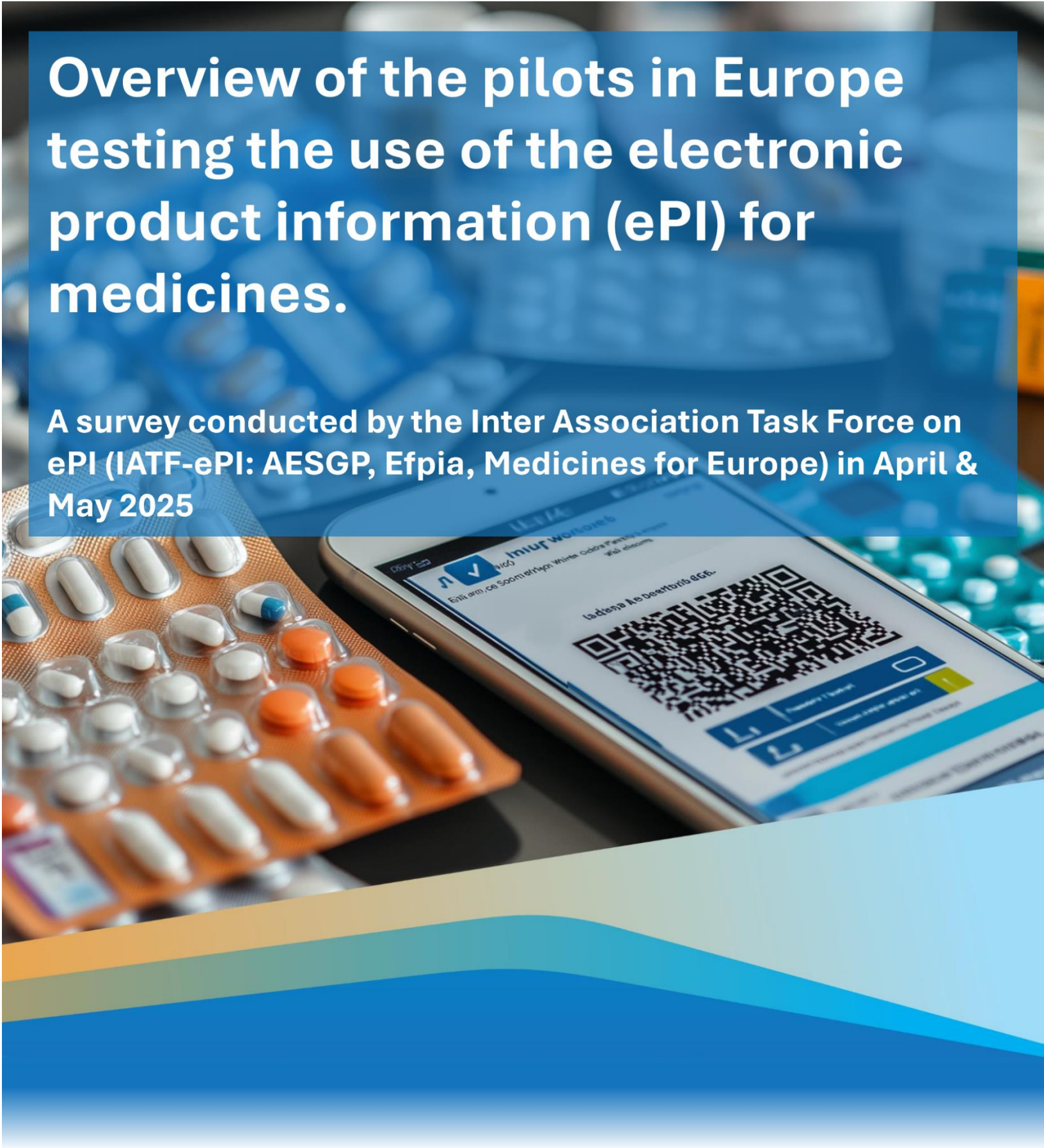
Overview of the pilots in Europe testing the use of the electronic product information (ePI) for medicines.

A survey conducted by the Inter Association Task Force on ePI (IATF-ePI: AESGP, Efpia, Medicines for Europe) in April & May 2025



AESGP
VOICE OF EUROPEAN SELF-CARE INDUSTRY

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European Federation of Pharmaceutical Industries and Associations

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Inter-Association Task Force (IATF)

Pilots in Europe testing the use of the electronic product information (ePI) for medicines.

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***Caveat:**. The cut-off date for the results of the survey presented in this document is the end of Q2 2025. Since that date, there have been some development and evolution about the ePI pilots in Ireland, in Germany, … However, these have not been taken into account in the presented results in order to have one single cut-off date for the statistical analysis of the results and a comprehensive interpretation of these results. This illustrates how fast the situation about ePI is evolving across Europe.*

Executive summary

In accordance with the current European legislation, a paper leaflet must be included in each pack of a medicinal product. This leaflet contains important information and guidance on the proper use of the respective medicinal product, approved by the competent regulatory authorities.

The European pharmaceutical legislation is currently under review. The proposed revision includes the introduction of electronic patient information (ePI) and creates the possibility for the future transition from paper leaflets to electronic product information , driven by Member States' readiness.

The Inter Association Task Force on ePI (IATF-ePI: AESGP, Efpia, Medicines for Europe) conducted a survey on the status of ePI pilot projects across Europe. These pilots are run by the national competent authorities, approved by the European Commission where necessary, and are conducted in collaboration with national stakeholders. They aim to prepare Member States, pharmaceutical industry, healthcare professionals (HCPs), and patients for the transition from traditional paper-based patient information leaflets (PILs) to digital formats. This transition aligns with the ongoing revision of European pharmaceutical legislation and represents a significant step forward in modernizing medicinal product information.

The report provides an in-depth overview of ePI pilots in 31 European countries, highlighting the progress made, challenges faced, and key insights gained from these initiatives. The findings underscore the potential of ePI to improve accessibility, ensure up-to-date information, and support environmental sustainability.

The report emphasizes the importance of sharing knowledge and best practices from successful pilots to support countries that have yet to launch ePI initiatives. Insights from ongoing pilots demonstrate that ePI can be successfully integrated into healthcare systems, ensuring patient safety while addressing environmental and logistical challenges.

This report showcases the progress made in implementing ePI across Europe and highlights the critical need for continued collaboration among stakeholders.

KEY FINDINGS FROM THE REPORT:

- **ePI Pilots in Action**:
  - Fourteen countries, including Belgium, France, Portugal, and the Nordic region, are actively running ePI pilot projects.
  - Seven additional countries, such as Austria, Germany, and Cyprus, are in the planning stages of launching pilots.
  - The running pilots focus on hospital-only and healthcare professional-administered products, while some planned pilots (e.g., France and UK) will explore broader applications for prescription and) non-prescription medicines.

- **Nordic Collaboration**:
  - The Nordic pilot (Finland, Denmark, Norway, Sweden, and Iceland) adopts a unique approach by allowing English-only outer packaging and labelling, while providing ePI in local languages. This initiative aims to reduce packaging complexity and improve medicine availability across the region.

- **Positive Outcomes**:
  - Belgium/Luxembourg: After a seven-year pilot, 97% of hospital pharmacists confirmed that the absence of paper PILs caused no inconvenience in their daily practice, and 100% reported no issues for physicians.
  - Portugal: A survey of healthcare professionals after one year of piloting revealed strong support for ePI, with hospital pharmacists and nurses reporting easy access to ePI and minimal need for paper copies.

- **Countries Without Pilots**:
  - Ten countries, including Bulgaria, Hungary, and Italy, have not yet initiated ePI pilots, citing legal, technical, or resource constraints.

Introduction

Each pack of a medicinal product contains a paper leaflet. This leaflet contains important information and guidance on the proper use of the respective medicinal product, approved by the competent regulatory authorities. This is in accordance with the current European legislation, which states that a paper leaflet must be included in each pack of a medicinal product. An electronic version of the leaflet is in most European countries also available online from various trusted sources (e.g. national compendia or website of (national) medicines agencies).

The European pharmaceutical legislation is currently under review. The proposed revision includes the introduction of electronic product information (ePI) and creates the possibility for the future transition from paper leaflets to ePI. A gradual transition to the ePI, driven by Member States' readiness, is proposed. Moreover, an Implementing Act will be foreseen to establish the common standards for ePI, to ensure a harmonized structure throughout all Member States. This would allow for the information to be retrieved across different e-health platforms for citizens throughout the EU.

EMA has conducted a pilot exploring the system for creation and testing of ePIs (standardized electronic product information) in real regulatory procedures. The report for this pilot is currently available.[i]

Moreover pilot projects (ePI pilots) have been set-up by the national competent authorities in several countries (and even including European approval where necessary), or are being planned in the near future. This is to ensure the readiness of Member States, the general population and the healthcare professionals, to phasing in ePI, as well as to ensure a future smooth and inclusive transition from paper to ePI (phasing out of paper at one point of time).

This report aims to provide an overview of whether, when, and under which conditions ePI pilots are conducted in 31 European countries. It should be noted that the pilot conducted in the Nordics (Finland, Denmark, Norway, Sweden, Iceland) is slightly different in its objective from the other planned or ongoing pilots in Europe. In the Nordics the objective is to increase the availability of medicines by reducing packaging complexity and it has a different methodology, since in the pilot, English-only outer packaging and labelling is allowed while the ePI is provided in the respective Nordic languages.

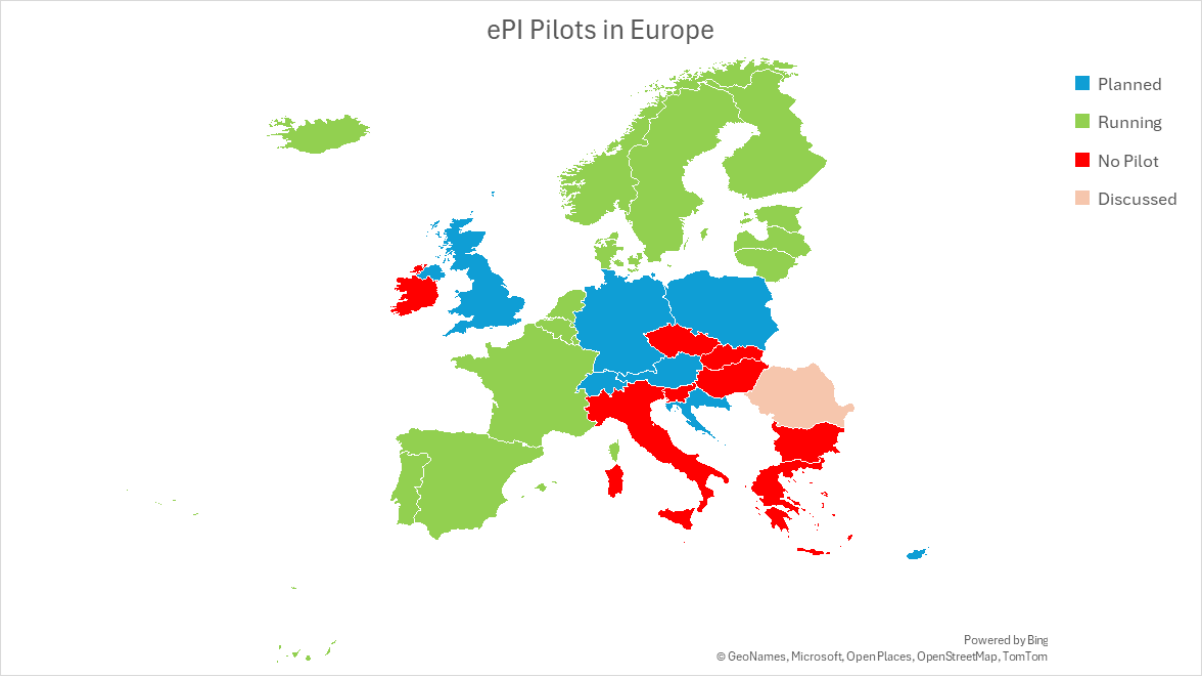
Methodology of the Survey

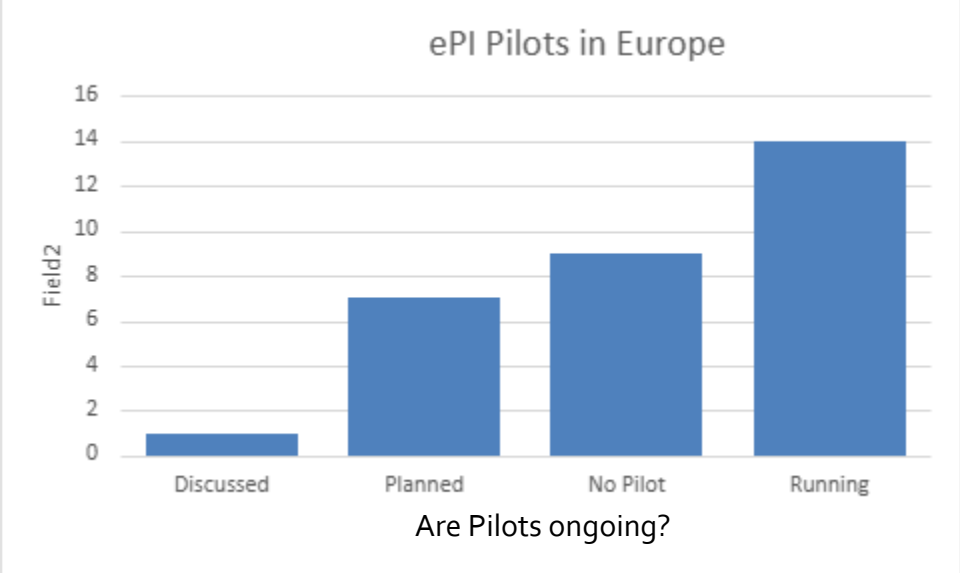
For this report, a Monkey survey (see annex 1Annex 1: list of questions in the survey) has been conducted in Q2 2025 among regulatory experts of local affiliates of several pharmaceutical companies, as well as of national trade associations in the following 31 European countries: Austria, Estonia, Latvia, Lithuania, Belgium, Luxembourg, Bulgaria, Croatia, Cyprus, Czech Republic, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, The Netherlands, Finland, Denmark, Norway, Sweden, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Switzerland, Malta and the United Kingdom. The responses received from several contact persons for the same country have been combined to obtain one consolidated representative response per country. Based on these consolidated responses, a summary of the gathered information has been prepared for each country, and graphics have been extracted to illustrate the results.

Pilots in Europe testing the use of the electronic product information (ePI) for medicines.

Results

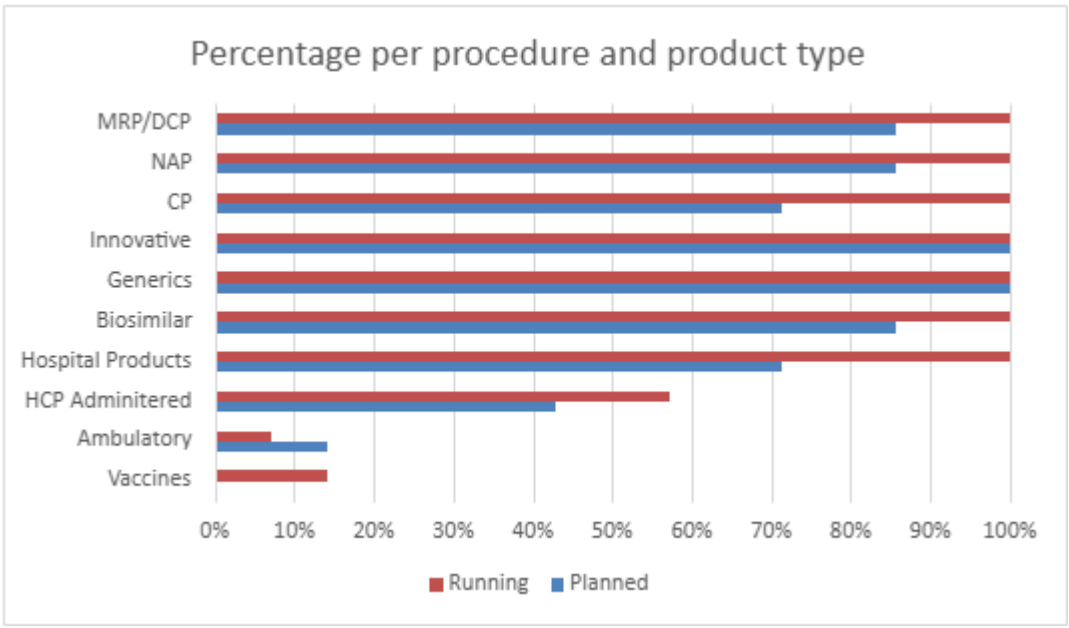
Some graphics about the main results of the survey

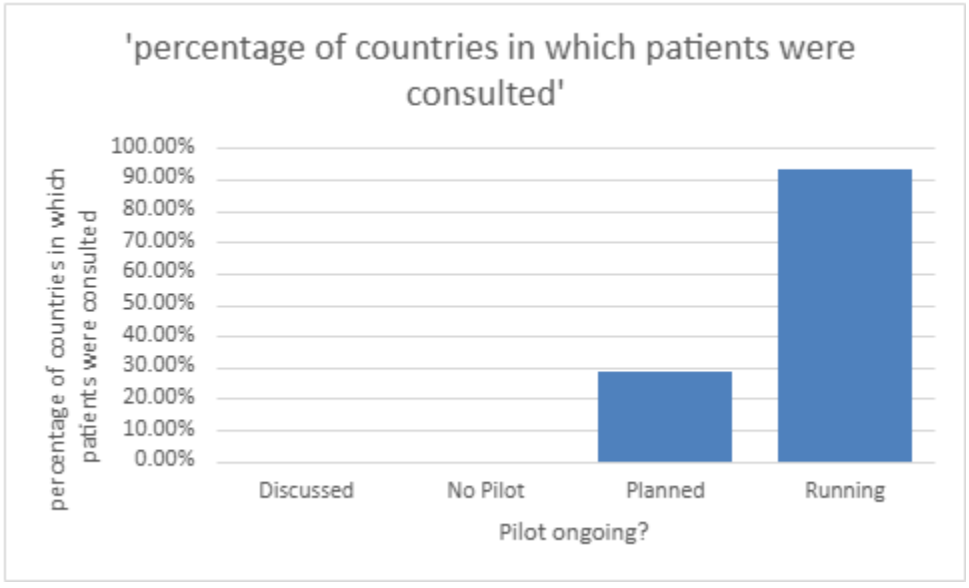


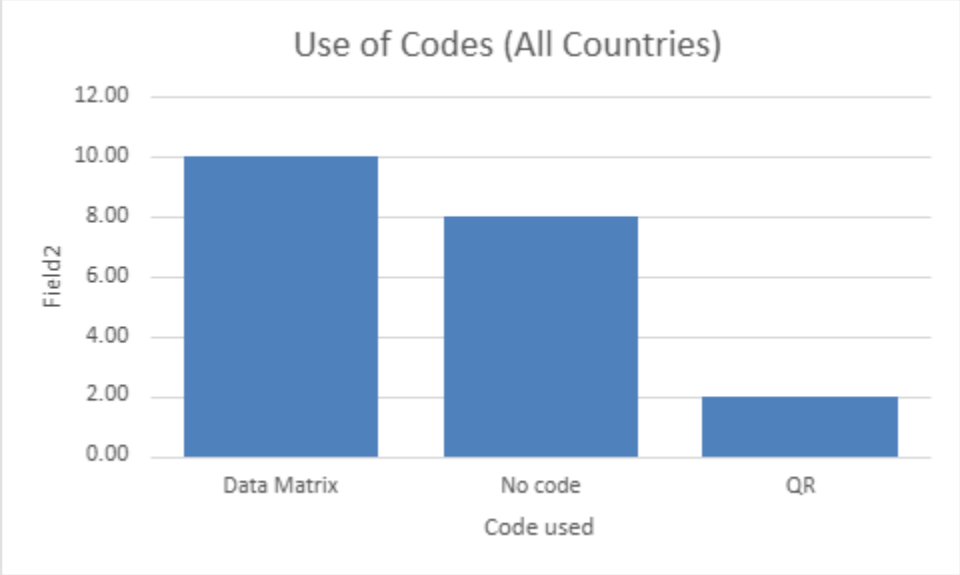


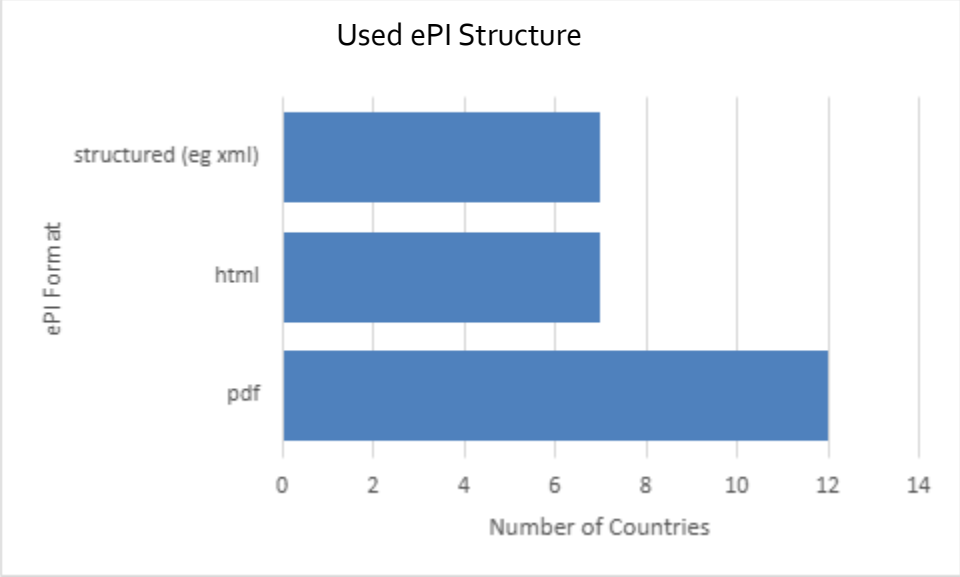
Are Pilots ongoing?

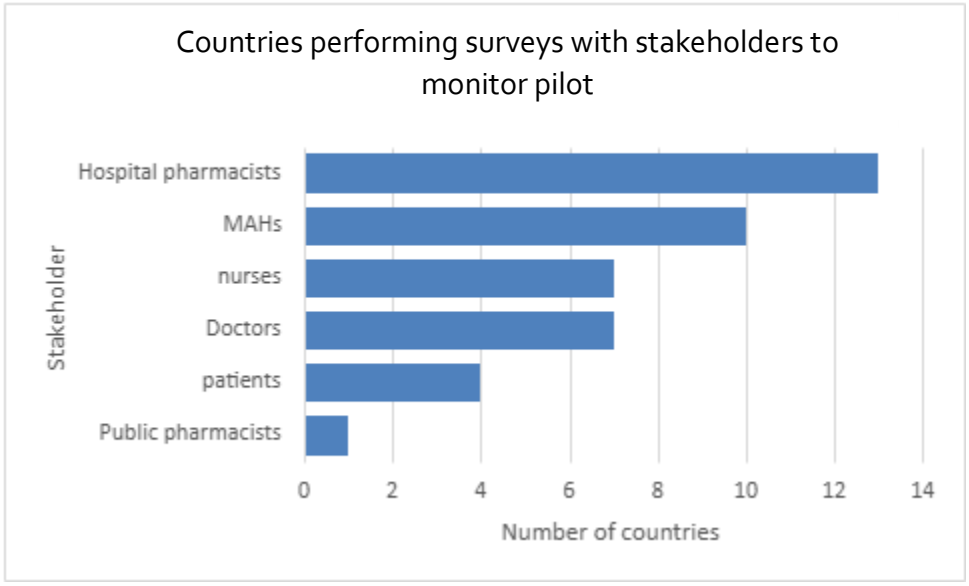
Pilots in Europe testing the use of the electronic product information (ePI) for medicines.










Countries performing surveys with stakeholders to monitor pilot
Hospital pharmacists
MAHs
nurses
Doctors
patients
Public pharmacists
Stakeholder
0
2
4
6
8
10
12
14
Number of countries

Summary of the ePI pilot status in each responding country

Austria

Any pilot planned or running?

Austria is currently in the phase of planning an ePI pilot, with discussions ongoing among stakeholders. As of now, no pilot has been implemented, and details remain under evaluation. No concrete timeline has been set for the start of the pilot, and key technical, financial, and organizational issues remain: securing funding, addressing technical challenges, such as linking the scanned pack to the correct batch-specific ePI. Austrian regulators emphasize that batch-level linking of ePI is essential to ensure reliability and traceability, especially in hospital and clinical settings.

Stakeholders consultation and involvement

There has been no general public or patient consultation on the topic. Stakeholder engagement is still developing, with limited active support from the national competent authority (AGES-MEA), which is observing rather than driving the initiative. Stakeholders involved in planning discussions include: MAHs, National Competent Authority (AGES-MEA), Trade Associations, Austrian Medicines Verification System, Ministry of Health. One key challenge is opposition from the Pharmacy Chamber, which strongly advocates for retaining the paper version of the patient information leaflet (PIL).

Medicinal products included in the Pilot

The planned pilot is expected to include all products carrying a 2D Data Matrix Code (as per EU Directive 2011/62), across CP, NAP, and MRP/DCP, including generics, biosimilars, and innovative medicines. The number of products will depend on company interest and participation.

Format of ePI and access to ePI in the pilot

The initial distribution format for ePI will be PDF, with plans to move toward structured formats (XML/HTML) in the future. A dedicated app solution is preferable, and the possibility of linking ePIs to packaging via the existing 2D Data Matrix code is being explored.

Baltics (Estonia, Latvia, Lithuania)

Estonia:

Any pilot planned or running?

A pilot is running in Estonia from 16 June 2021 and will run until 31 December 2026.

Stakeholders consultation and involvement

Involved stakeholders are the Health Authorities, the pharmaceutical industry (MAHs) and hospital pharmacists.

Medicinal products included in the pilot

The pilot concerns hospital products, healthcare administered products and vaccines. Products from all types of procedure and all legal basis are included. There are 77 products included; not all are released to market.

First experience/lessons learned and results

Feedback from hospital pharmacists is positive, endorsing the implementation of paperless-PIL hospital packs.

Latvia:

Any pilot planned or running?

A pilot is running in Latvia from 1st of January 2022 and will run until the 31st of December 2026.

Stakeholder's consultation and involvement

Stakeholders involved are the State Agency of Medicines, Health Ministry of the Republic of Latvia, the pharmaceutical industry (MAHs), and hospital pharmacists.

Medicinal products included in the pilot

The pilot concerns only hospital products, but vaccines are under discussion now. Products from all types of procedure and all legal basis, are included. There are 42 products included; not all are released to market.

Access to ePI in the pilot

QR code is not mandated on the packs. One technical solution for EU wide platform would be very beneficial. In parallel, an option to print paper PIL at pharmacy shall be implemented in case the pilot would include prescription medicines dispensed at retail pharmacy

First experience/lessons learned and results

Most hospital pharmacists use ePI in daily practice. Specialists consider ePI to be easily accessible. The experience of the ePI project is evaluated positively. Hospital pharmacists would also support the inclusion of vaccines in the project. Only a small proportion would be against ePI for all drugs used in the hospital.

Some experts from the health authorities see a risk for patients not receiving paper PIL for medicines outside hospitals.

Lithuania:

Any pilot planned or running?

A pilot is running in Lithuania from 1st of January 2022, and will run until the 31st of December 2026.

Stakeholders consultation and involvement

Stakeholders involved are the Health Authorities, the pharmaceutical industry (MAHs) and hospital pharmacists.

Medicinal products included in the pilot

The pilot concerns only hospital products. Products for all types of procedure and all legal basis are included. There are 54 products included; not all are released to market.

First experience/lessons learned and results

The most challenging task was obtaining internal approval within pharmaceutical companies, followed by the time required to change the local Health Authorities VVKT opinion.

Conclusion about the pilot in the Baltics

In the Baltics, the most challenging situation for the pilots is when there are multilingual packs (EE/LV/LT or LT/LV or EE/LT). All Health Authorities then have to accept the inclusion of the pack to the pilot. There are different inclusion criteria in Baltic countries, but closer cooperation between Baltic Health Authorities is expected.

What would strengthen the pilots is leveraging experience from other countries, particularly regarding technical solutions, and increasing public awareness through more articles about the benefits of ePI.

Belgium/Luxembourg

Any pilot planned or running?

A pilot is currently running in hospitals in Belgium and Luxembourg. The pilot started in August 2018 based on a derogation given by the European Commission and ends in August 2025 (7-year pilot project). The Belgium/Luxembourg authorities have asked the European Commission whether a transition period could be considered between the end of the pilot and the implementation of the revised European pharma legislation, during which participating medicines in the pilot would be allowed to remain without inserted paper leaflet, and have received a positive response from the European Commission.

Stakeholders consultation and involvement

The Belgian consumers association has conducted a survey on consumers' perceptions of ePI.

Different stakeholders in both Belgium and Luxembourg have been involved in the set-up of the monitoring of the pilot: European and national competent authorities, hospital pharmacist associations, national pharma trade associations.

Medicinal products included in the pilot

Hospital-only products could be included in the pilot independent of the authorization procedure (central, national, MRP/DCP). There was no principle of restriction for biosimilar, innovative medicines, but all candidates had to be validated by the Belgian and Luxembourg authorities before entering the pilot. Up to 129 products have been included in the pilot.

Format of ePI and access to ePI in the pilot

The electronic leaflet is made available via a trusted online source (no code is placed on the pack of the products in the pilot), under pdf of semi-structured format depending on the source.

First experience/lessons learned and results

The results of the pilot have been monitored through surveys among hospital pharmacists and MAHs of participating products. The most important findings are[ii]:

- When responding hospital pharmacists have had to consult the PIL of participating medicines:
    - 97% consulted the e-PIL version and 3 % printed the leaflet from an online source.
    - 97% would agree that the PIL is removed from the packaging of the medicines restricted to hospital use.
- Confirmation that patients solicit very rarely the hospital pharmacists to receive the PIL.
- 100% declare that the absence of the paper PIL in the packaging has not caused any inconvenience in their daily practice.
- Moreover, according to 100% of the hospital pharmacists, the absence did not cause any inconvenience to physicians and for 97% of the hospital pharmacists, the absence did not cause any inconvenience to nurses.
- Aggregated total of 4 290 712 sold packs, throughout the pilot project.
- Only 12 questions related to the absence of the paper PIL were submitted by the healthcare professionals to the participating pharma companies.

The main encountered challenges for the set-up and the conduct of the pilot have been:

- Uncertainty related to the attribution of the derogation by the European Commission.
- Implementation of the validated candidates in a timely manner, and the communication about the batch release without paper leaflet to the authorities (incl. alignment of the different production units)
- Shared packs with the Netherlands

The Belgian and Luxembourg Authorities have received from the European Commission the approval to keep products already included in the pilot without any paper leaflet inserted until the future European legislation on ePI comes into force.

Bulgaria

Any pilot planned or running?

In Bulgaria, the implementation of an ePI pilot has not yet been initiated, and there is currently no awareness of any general consultations with patients regarding the ePI concept. Key stakeholders have not been identified or mobilized, and discussions about setting up a pilot have not yet taken place.

Reason(s) for not considering a pilot?

Several factors contribute to the lack of progress in establishing an ePI pilot in the country. There is a significant lack of information and awareness among key stakeholders about the benefits and pathways for implementing ePI. Moreover, the Bulgarian Health Authorities (BG HA) and local trade associations do not prioritize ePI, likely due to competing regulatory and healthcare initiatives.

The absence of structured dialogue and collaboration between the Bulgarian Generic and Innovative pharmaceutical associations has resulted in fragmented advocacy and strategy development. Additionally, there are concerns about the limited technical infrastructure and digital readiness within regulatory bodies and the healthcare system, which hinder the deployment of ePI.

Regulatory uncertainty and a lack of clear guidance on ePI implementation, governance, and alignment with EU frameworks further complicate the situation. There are also concerns regarding resource allocation and costs associated with establishing and maintaining an ePI system, especially in the absence of clear incentives. Lastly, low public and healthcare professional demand may deprioritize ePI within national digital health strategies.

Overall, the combination of these factors has led to a lack of movement towards the implementation of an ePI pilot in Bulgaria.

Croatia

Any pilot planned or running?

In Croatia, the implementation of an ePI pilot is still in its planning phase.

Stakeholders consultation and involvement

As of now, there has been no general consultation with patients regarding the e-PIL, and authorities are still determining how to approach the subject.

The Croatian Chamber of Pharmacists, the Ministry of Health, the Croatian Agency for Medicinal Products and Medical Devices (HALMED), and various pharmaceutical associations are involved in discussions about the pilot's setup. The project is expected to be led by the Chamber of Pharmacists, while HALMED and other stakeholders will monitor the pilot's progress .

Medicinal products included in the pilot

An exemption from the European Commission is required for the pilot, and only hospital-use products are included, specifically intravenous (IV) products, with a test period of 24 months planned to assess the results before evaluating the potential for including prescription (Rx) and over-the-counter (OTC) medicines. The authorization types for the pilot will include Centralized Procedure (CP), National Authorization Procedure (NAP), and Mutual Recognition Procedure/Decentralized Procedure (MRP/DCP). Both generic and innovative products are expected to be part of the pilot, with around 20 products proposed thus far.

Format of ePI and access to ePI in the pilot

The ePI will be published on HALMED's website, where all related documents will be available in PDF format.

First experience/lessons learned and results

Stakeholders have been informed about the pilot's start and scope through meetings, emails, and publications on the agency's website. However, the project faces challenges, including technical issues related to making the information easily accessible and linking it to the e-PIL on packaging. Additionally, the older population in Croatia and their low level of electronic literacy pose hurdles for implementation.

While the Agency supports the pilot, it prefers not to lead it, and there has been slow negotiation among the various stakeholders involved. Some companies that already use 2D codes are not interested in participating, although all stakeholders involved in the project are in favor of the pilot. The overall pace of the project is hindered by the involvement of many stakeholders and the need for coordinated action.

Cyprus

Any pilot planned or running?

On the 19th of March 2025, Cyprus Health Authorities met with representatives of SFEK (Trade Association) and subsequently distributed slides about a pilot project with a deadline for declaring interest (=15/4/2025). Project is titled “Pilot project for pharmaceutical products without PIL in the hospital setting”. According to the presentation shared with attendees, the aim of the pilot project is to “To assess the impact of allowing pharmaceutical products used in the hospital setting without PIL in the package; Avoid shortages of pharmaceutical products. Replacing the paper leaflet by the electronic leaflet will allow for faster manufacturing and import among EU member states; will enable access to the most updated version of product information; will prepare for the new pharma legislation which aims to allow the use of electronic versions of the PIL for providing drug information; will allow to demonstrate equivalent access to the current approved information; will reduce the environmental impact”.

The Cyprus authorities pilot program was just a preliminary market assessment to evaluate MAH interest. It is not known how many companies responded, MAHs were supposed to declare interest till 15.04.2025 and this info is not shared.

Until now, the project is discussed, but it does not run yet.

Stakeholders consultation and involvement

It would involve the pharmaceutical industry, the Hospital pharmacies, the Nurses, the Doctors.

Medicinal products included in the pilot

Products in scope are only hospital products, could be from any type of procedure and from any legal basis.

Although "Multi-country packs allowed if the other member state does not object to the no PIL product", the multi-country pack seems to be the biggest hurdle. Cypriot Finished Products are often identical with those in Greece (i.e. there are limited stand-alone, Cyprus-only hospital products). Whereas Greek Heath Authorities do not allow paperless products. So, the above combined limits the selection of eligible products.

Access to ePI in the pilot

The link of the PIL for the QR code can be obtained via PhS e-services (product search), however more clarifications may be given in the future.

Czech Republic

Any pilot planned or running?

There has been no general consultation about the ePI in Czech Republic. No pilot to test ePI is running or planned.

Reasons for not considering a pilot

The local health authorities are first waiting for the outcome of the pilots running in the other European member states and for the revision of the European legislation. The current valid legislation in place in the country does not support ePI.

France

Any pilot planned or running

An ePI pilot is currently running in France. The set-up of the pilot has necessitated a derogation from the European Commission. The pilot started in January 2025 (call for candidates has been launched in October 2024) and will end in October 2027.

Stakeholders consultation and involvement

This pilot has been organized by the ANSM in concertation with the national trade associations of the pharma industry. The stakeholders have been informed via meetings, e-mails and communications of the competent authorities.

A patient consultation on ePI was also organized by the French competent authorities (ANSM), but the results have not been communicated.

Medicinal products included in the pilot

Hospital-only products (including biosimilars) could be included as well as retail pharmacy products (RX, OTC, vaccines, HCP-administered products), all marketing authorization procedures being considered. In fact, any product belonging to the ATC classes identified to be in the pilot is involved. A total of around 420 hospital products and 170 retail pharmacy products are included.

Format of ePI and access to ePI in the pilot

The paper leaflet is taken out of the packaging in hospital-only products and remains in the packaging of the retail pharmacy products. The ePI is published on the ANSM website (html format for MRP-DCP products, pdf for CP products). A QR code will be added on the retail pharmacy product packaging, linked to the ANSM website.

First experience/lessons learned and results

The monitoring of the pilot will be done by the ANSM and includes surveys in MAHs, doctors, hospital and public pharmacists, patients, nurses (including hospital nurses). There will be satisfactory questionnaires, monitoring of the QR code use, number of clics on the database,...

The expected main challenges are:

- from an industry point of view:
    - technical feasibility: adaptation of the packaging lines at the manufacturing sites
    - complaints and question management
- from an authority point of view:
    - communication plan to patients and HCPs
    - inclusion of new compagnies
- from a retail pharmacist point of view:
    - how to manage people who don't have a smart phone to flash the QR code
- from a hospital HCP and nurse point of view
    - change of habits

Germany

Any pilot planned or running?

One ePI pilot project in hospitals is planned but there is no starting date foreseen yet. The main discussion point that prevent this pilot to start is related to legal constraints for the conduct of such pilot, which need first to be solved.

Stakeholders consultation and involvement

The pilot is still under discussion/negotiation between the different stakeholders around the table, which are the German Trade Associations, the Health Authorities, the hospital pharmacists.

Medicinal products included in the pilot

Hospital-only products will be included with no restriction for biosimilars, generics, innovative medicines; however, each one will need to receive an exemption permit.

Format of ePI and access to ePI in the pilot

The ePI will be published on a new platform provided by the DiGItal-Projekt, and will be available via project app, health insurance apps, hospital software. The existing 2D barcode will be used. The format of the ePI will be a pdf at the initial transition phase and thereafter a xml and app-based format. The conversion of the word file will be done with an automated converter by Rote Liste Service GmbH. There will be also a manual review and approval process to ensure full compliance.

First experience/lessons learned and results

To evaluate the results of this pilot, surveys will be conducted in MAHs, doctors and hospital pharmacists, as well as nurses.

The main challenges for the set-up and the execution of the pilot are related to the fact that the national legislation doesn't allow such a pilot. Hence, discussions are ongoing to find the best solution. This legal uncertainty is to be considered together with the time needed to organize the supply of the medicines.

Note: Another pilot is running in Germany, aiming at testing the integration of ePI in apps of social health Insurance (SHI). It has started in August 2024 and will end in December 2026.

For this project, all German trade associations, health authorities, hospital pharmacists, SHI organisations and IT providers have been involved. all type of products (hospital, ambulatory, Rx, OTC, vaccines, HCP administered) could be included.

Greece

Any pilot planned or running?

In 2024 the trade association discussed with the Greek Health Agency (EOF) a proposal to start a pilot. EOF was reluctant to assign any resources. The trade association is currently starting the discussion directly at the level of Ministry of Health, and were expecting a more positive reaction.

Reasons for reluctance/hesitancy to consider a pilot

EOF's hesitation was due to uncertainty about the resulting workload. Industry offered the scenario of running a pilot without removing the paper PIs from candidate products, claiming that in this manner the workload would be minimal, but EOF remained hesitant.

The Hospital Pharmacists were interested and viewed the proposal positively.

What could be supportive is the current status of ongoing or completed pilots in other EU countries, including evidence of the positive experience gained from these pilots. Greece may also be influenced by the recent interest from the Cypriot HA to run their own pilot because there are common packs with Cyprus to a significant degree.

Timing did not help in the process. The Ministry of Health was considering a reorganization of EOF. At the same time, a reduction of EOF resources and their concern that the project would entail a workload that could be unmanageable was the main reason for the negative reaction. The trade association is currently resetting and starting to discuss directly with the Ministry of Health, expecting a positive reaction.

Hungary

Any pilot planned or running?

There is no pilot running in Hungary, but discussions have been taken place. HU HA had capacity problems and could not support this project. The trade association has re-opened the topic with the agency in Q1 2025. This time, the agency seems to be open to the pilot.

Reasons for reluctance/hesitancy to consider a pilot

First, the National association of Hungarian Manufacturers wanted to run a pilot, especially with Hospital Products. As a first step, a few (5) products should have been selected for derogation and defined for this project. It was not finalized by HU HA, the products were not selected and finally the Pilot was not running.

Currently the industry is working on the preparation of a pilot on the trade association level.

The HU HA is waiting for the amendment of the current legislation. There are no guidelines to which a harmonized ePI pilot can be conducted.

What can probably help is the positive experiences in other countries, although the health culture is very different, and Hungarian Health Authority is committed to the patient safety, so they still support the printed PIL especially for elderly patients who has limited knowledge for the use of technical devices.

Past objections from the agency has included capacity issues, leadership approach, pending EU legislation changes, local legislation obstacles. It seems now that these obstacles can be overcome. However, new regulation should be effective first, which clearly regulates ePI use.

Iceland

Any pilot planned or running?

Iceland participates in the Nordic pilot, but before the Nordic pilot, Iceland ran its own national pilot, initiated by the Ministry of Health and inspired by the Belgium–Luxembourg pilot. It ran from 2021 to 2024. Its main objectives were to evaluate whether the use of electronic patient information leaflets (ePILs) ensured safe medicinal treatment and to assess whether the initiative could increase the availability of hospital products on the Icelandic market.

Stakeholders consultation and involvement

The pilot was supported by the Icelandic Medicines Agency (IMA) and Icelandic hospitals. Contact persons at hospitals, identified by the Ministry of Health, promoted the project locally and ensured access to the ePILs (via internet, tablets, or computers. A dedicated Icelandic and English webpage on the IMA website provided project information, and participation requests were submitted to IMA by email.

Medicinal products included in the pilot

The project focused exclusively on hospital products and, in total, 46 medicinal products have participated.

Format of ePI and access to ePI in the pilot

No QR codes were used; patient information was made available as PDF files in the well-established online Medicinal Products Information Catalogue hosted by the IMA. Participating products were identified in this catalogue, and IMA published an updated list on its website. Paper PILs in Icelandic were not required if available in another language. Labelling changes were not included in the scope.

First experience/lessons learned and results

Three surveys among healthcare professionals (HCPs) and two among marketing authorization holders (MAHs) were conducted during the project period to assess access, use, and reading of ePILs.

Ireland

There is currently no pilot running in Ireland. There have been some discussions and there is some consideration of a local pilot in 2026.

Italy

Any pilot planned or running?

There is no foreseen ePI pilot in Italy at the moment. It appears that the Italian Competent Authorities (AIFA) have denied the possibility to start a pilot.

Stakeholders consultation and involvement

Some concertation has taken place between the pharma industry trade associations, the competent authorities and the patient associations, but no positive conclusion to set-up a pilot came out of the discussion.

Reasons for not considering a pilot

AIFA rejected the project primarily due to the absence of a database capable of keeping the PI up to date. At that time, no reports had been published on pilot projects in other countries, and the overall experience was still limited. As a result, AIFA was not confident that removing the paper version would have no impact on patients safety.

In early June 2025, during a Pharmaceutical symposium the EMA ePI project was discussed and presented. On that occasion, AIFA appeared open to restarting the discussion on the pilot.

Currently, pharma companies are collaborating to prepare surveys for patients and HCPs to support the initiative.

Malta

There is no pilot to test ePI running or planned in Malta.

Netherlands

Any pilot planned or running?

A pilot is running in the Netherlands from September/October 2024 and will run until 31 December 2026. It would be preferred for the pilot to be continued after December 2026, however, no official announcements for an extension have been made.

Stakeholders consultation and involvement

Stakeholders involved are the MEB; IGJ (Inspectorate); Ministry of Health, Welvare and Sport; patient organizations; association of hospital pharmacists; hospitals; VIG (Association for Innovative Medicines) and member companies.

In preparation for the ePIL pilot, amongst others HCP and patient organizations have been asked about their opinion on leaving out the paper leaflet for hospital products. A similar consultation will be conducted at the end of 2025.

Medicinal products included in the pilot

It concerns hospital-only products and healthcare professional administered products. Products for all types of procedures and all legal basis, are included. In the first round, 65 products are included. Every 3 months, new products can be proposed

Format of ePI and access to ePI in the pilot

In the pilot, the ePI can be accessed through the existing MEB website. Maybe at a later stage, a structured format will be applied.

First experience/lessons learned and results

The most difficult in setting up the pilot was to align all stakeholders, and to get the approval by Headquarters of participating companies.

What is the most challenging in the pilot is feasibility of packaging without paper leaflet on production lines, and looking for alternatives, if necessary (inserting blank paper or limiting size of carton), as well as the need for submitting variations to change packages (sizes).

Nordics (Finland, Denmark, Norway, Sweden and Iceland)

Any pilot planned or running?

As of January 1st, 2025, the Nordic countries have launched a joint ePI pilot coordinated by their national competent authorities and supported by relevant trade associations.

The pilot is scheduled to run for five years, until January 1st, 2030.The main objective of the pilot is to increase the availability of medicines in the Nordic region by reducing packaging complexity and facilitating easier market access.

This is achieved by allowing English-only outer packaging and labelling, while providing the ePI in the respective Nordic languages. The approach is intended to ease regulatory and logistical burdens on manufacturers, while ensuring patients and healthcare professionals still have access to national-language product information.

Medicinal products included in the pilot

The pilot currently focuses on hospital-only and healthcare professional-administered products.

Format of ePI and access to ePI in the pilot

ePI is made accessible through various national platforms. In Norway, ePIs are available on www.felleskatalogen.no, a platform maintained by the national trade association, which also handles

automatic conversion of approved Word documents to structured formats like XHTML. In Denmark, ePIs are published via www.indlaegsseddel.dk, Sweden through www.lakemedelsverket.se and Iceland through www.ima.is/electronic-patient-information/. While these platforms hosted by the agencies provides PDFs, XHTML formats are available on external platforms such as medicin.dk (Denmark) and fass.se (Sweden), but these are not referred to in the pilot.

First experience/lessons learned and results

In Denmark, a survey showed generally positive public attitudes toward ePILs, with minor concerns raised about elderly users. In Norway a survey conducted in 2023 found that over 60% of patients already make use of ePI. Felleskatalogen will monitor usage of ePI in Norway during the pilot, while no formal surveys have yet been announced in the other countries.

Among the challenges encountered are the harmonization of texts across the Nordic region, especially MRP/DCP and NP-approved products, and the relatively low number of products currently eligible under the pilot. Stakeholders have noted the need to broaden the scope to better demonstrate the benefits of digital information and cross-country packaging solutions.

Poland

Any pilot planned or running?

An ePI pilot is planned, but there is no start date yet due to legal constraints that first need to be clarified/solved.

Stakeholders consultation and involvement

Pharma industry trade associations, ministry of health and competent authorities have been involved in the set-up of this pilot,

Medicinal products included in the pilot

The pilot will include hospital-only medicinal products and HCP-administered medicinal products (all registration procedures considered). At this stage, there is no information about restriction for generics, biosimilars or innovative medicines.

Format of ePI and access to ePI in the pilot

It is still to be confirmed where the ePI will be published, but it is foreseen to make it available via a code (2D barcode or QR code) on the packaging. The ePI will be displayed in pdf format.

First experience/lessons learned and results

Surveys will be conducted in MAHs, doctors, hospital pharmacists, patients, nurses, to understand how often the paper leaflet has been requested by patients and if the use of the electronic leaflet is successful.

Currently, the main challenges for the set-up and the conduct of the pilot are related to:

- the local legal ground for the execution of the pilot
- the lack of communication from the authorities about the process and the technical aspects of the pilot
- the adaptation of the production line, the internal processes and systems at the industry level
- the management of the website and disclaimer needed to achieve telematics data

Portugal

Any pilot planned or running?

Portugal launched a national ePI pilot for hospital-only medicines on 15 September 2023. The pilot is expected to run until 15 September 2025, with a possible extension depending on progress and outcomes. The goal of the pilot is mainly to evaluate if HCPs are able to access product information even if it is only available in electronic format.

Stakeholder consultation and involvement

The pilot is led by INFARMED, I.P. (National Authority of Medicines and Health Products), in collaboration with APFH (Portuguese Hospital Pharmacists Association), APIFARMA (Portuguese Association of the Pharmaceutical Industry), and EQUALMED (The Portuguese Association of Medicines for Health Equity).

Medicinal products included in the pilot

62 products were included as of April 2025, including generics, biosimilars, and innovative products authorized under CP, NAP, and MRP/DCP. 31% of the products were generic products and 34,5% of the products were oncology products.

Format of ePI and access to ePI in the pilot

The pilot did not require modification of packaging, and no 2D codes were used. Instead, hospital stakeholders accessed electronic package leaflets (ePILs) in PDF format via INFARMED's Infomed database and a dedicated project website[iii]:

First experience/lessons learned and results

A survey conducted after one year into the pilot showed the following:

- The majority of the HCPs considered this initiative to be positive.
- Hospital pharmacists reported easy access to ePILs and limited need for paper copies.
- Nurses were the main users of PILs and they reported easy access to ePILs. 30% received patient requests for access, and in 50% of those cases, a paper copy was provided.
- The lack of a paper leaflet had no negative impact on clinical practice or access to information by healthcare professionals (HCPs).
- 80% of HCPs supported eliminating paper leaflets for hospital medicines, even when patients occasionally requested them.
- MAHs were positive about the pilot, and no batch release issues were reported.

The main challenges involved defining relevant KPIs for pilot evaluation, encouraging greater MAH participation to ensure scalable impact, addressing operational constraints (e.g., packaging/leaflet requirements at manufacturing sites), and alignment across countries, as different criteria may deter global companies from participating.

Romania

Any pilot planned or running?

There is currently no pilot in Romania but a potential pilot with nationally approved hospital-only medicinal products is under discussion. However, due to the lack of resources at the national competent authorities level, there is no concrete implementation yet.

Stakeholders consultation and involvement

There has been no general consultation of the patients in the country about ePI.

Slovakia

There is no pilot ongoing in Slovakia. Industry is in favor of a pilot and there have been discussions. However currently there is no legal framework available to run a pilot.

Slovenia

Any pilot planned or running?

There is no ePI pilot in Slovenia.

Reasons for not considering a pilot

The option of a pilot has been discussed with the local competent authorities. However, while they were interested (and supportive) in ePI, they did not see the added value of having a pilot in Slovenia, given the good evidence and the insight about ePI already gathered in other member states. Such a project was not in line with their capacity, their financial plan, and their focus plan.

Spain

Any pilot planned or running?

Spain has implemented a national pilot on ePI for hospital-only medicines, launched in January 2022 and officially concluded in June 2024. Although the pilot has ended, its results have not yet been formally published. No further extension is planned, but future broader implementation is under consideration by AEMPS (Spanish Agency of Medicines and Medical Devices), depending on the pilot outcomes.

Stakeholder consultation and involvement

Stakeholders involved included AEMPS, SEFH (The Spanish Society of Hospital Pharmacists), Farmaindustria (The National Trade Association of the Spanish based pharmaceutical industry), AESEG (Spanish Generic Medicines Association), and hospital pharmacy representatives (e.g., Vocalía de Hospitales - National Hospital Pharmacy Committee).

Medicinal products included in the pilot

The pilot included 141 (42 + 99) products across two phases, focusing on hospital generics with parenteral administration. It covered CP, NAP, and MRP/DCP authorization types and included generics, biosimilars, and innovative medicines meeting specific eligibility criteria.

Format of ePI and access to ePI in the pilot

The ePIs were published on the AEMPS CIMA platform https://cima.aemps.es/cima/publico/home.html Conversion from Word to HTML was performed automatically.

First experience/lessons learned and results

Surveys were conducted among doctors, hospital pharmacists, and nurses. The overall satisfaction rating was 4.05 out of 5. Key suggestions for improvement included:

- Adding batch numbers and expiry dates in a standardized and accessible format.
- Expanding the scope of the project to cover a wider range of medicines.
- Updating equipment to ensure compatibility with various barcode formats.
- Improving hospital IT systems to enable end-to-end reading and integration of barcodes across clinical workflows.

While the hospital pilot was considered successful, strong opposition remains against removing paper leaflets for retail medicines. A 2022 study by the consumer association OCU showed that 78% of patients preferred the paper leaflet. This has contributed to resistance from several stakeholders against expanding ePI to retail medicines. Spanish Medical Association (OMC), General Council of Pharmacists (CGCOF), Consumers' and Users' Organization (OCU), and patient and elderly advocacy groups have warned that digital-only information could widen health inequalities and risk patient safety. These groups advocate for ePI as a complement, not a replacement for printed package leaflets.

The Spanish Authorities have received from the European Commission the approval to keep the pilot open until the future European legislation on ePI comes into force, and the authorization of the expansion of the number of medicines to further collect data and evidence.

Switzerland

Any pilot planned or running?

There is a new law under review in Switzerland that would allow to have an ePI for products that are exclusively used in hospital or administered by HCPs. The timing of this law is not known yet, but it allows to foresee a ePI pilot.

Stakeholders consultation and involvement

The set-up of this pilot will be discussed likely between Swissmedic, pharma trade association and HCP organisations.

Medicinal products included in the pilot

Hospital-only medicinal products and HCP-administered medicinal products will be included with no restriction for generics, biosimilars, innovative medicines.

Format of ePI and access to ePI in the pilot

The ePI will be published on Swissmedic website. the other details of the setting of this future pilot are not defined yet.

United Kingdom

Any pilot planned or running?

There is no pilot running yet in the UK, but there is a pilot planned in future. The timelines of the pilot nor the details are available. Originally, there was lack of MHRA engagement, but now MHRA and government have publicly acknowledged the case for ePI, so probably more momentum will be built soon.

Stakeholders consultation and involvement

Industry wide UK Electronic Patient Information Task Force, MHRA, DHSC and patient organizations are involved in the discussions

Medicinal products included in the pilot

. The scope has still to be defined but will likely not include hospital products and will focus on prescription and OTC medicines.

General conclusion

This overview of the pilots in Europe testing the use of ePI shows that several pilot projects have been set up by the national competent authorities in various European countries to ensure the readiness of member states, the general population, and healthcare professionals for the transition to ePI. These pilots aim to ensure a smooth and inclusive transition from paper to ePI.

Currently in Europe there are pilots running in fourteen countries (Belgium, Luxembourg, Estonia, Latvia, Lithuania, France, The Netherlands, Norway, Portugal, Spain, Sweden, Denmark, Finland, Iceland), and planned pilots in seven countries (Austria, Croatia, Cyprus, Germany, Poland, Switzerland, United Kingdom) to test ePI. Ten countries do not foresee to run a pilot (Bulgaria, Czech Republic, Greece, Hungary, Ireland, Italy, Romania, Slovakia, Slovenia, Malta).

It is interesting to point out that in the majority of the European countries where a pilot is running or planned, the stakeholders – marketing authorization holders, patients, hospital pharmacists, nurses – have been consulted about ePI. In France, public pharmacists have additionally been involved because in this country the running pilot is considering medicinal products in ambulatory setting next to the hospital setting.

The scope of the running or planned pilots focuses primarily on hospital and healthcare professionals administered medicinal products. France and United Kingdom are two exceptions with local authorities considering the inclusion of ambulatory medicinal products (on prescription products as well as self-administered products) in the pilot. For all pilots, there is a general acceptance of all types of approval procedures (central, national) for inclusion and all types of products (innovative products, ATMPs, generics, biosimilars[iv]).

It should be noted that the pilot conducted in the Nordics (Finland, Denmark, Norway, Sweden, Iceland) is slightly different from the other planned or ongoing pilots in Europe since it aims specifically at increasing the availability of medicines by reducing packaging complexity, and it foresees that English-only outer packaging and labelling is allowed while the ePI is provided in the respective Nordic languages.

On one hand, it has not always been an easy journey and various challenges have been or are faced by the different countries when implementing ePI pilots, and have to be overcome, such as

- technical and logistical issues encountered by the marketing authorization holders to adapt the production lines and the supply chains,
- stakeholders engagement issues, and
- regulatory constraints.

The main reasons for countries not to conduct a pilot are related to legal obstacles/constraints, lack of capacity or resources at the level of the local authorities or the absence of a database capable of keeping up to date ePI.

On the other hand, positive outcomes and promising results have already been demonstrated by some of the pilots. In Belgium/Luxembourg, the final results after seven years show that 100% of the hospital pharmacists having participated in the pilot and responded to a survey declare that the absence of the paper patient information leaflet in the packaging has not cause any inconvenience in their daily practice, or the daily practice of the physicians in an hospital setting. It comes to 97% when talking about the daily practice of the nurses in hospital settings. In Portugal, a survey conducted after one year of piloting emphasizes that the majority of hospital healthcare professionals consider this experience to be positive. The hospital pharmacists report an easy access to the ePI and limited need for paper copies in their practice. The nurses also report an easy access to the ePI. In general, the absence of paper patient information leaflet has no negative impact on clinical practice or access information by healthcare professionals in hospital;

These encouraging results show the key insights the pilots can bring in the ePI implementation process, and this overview emphasizes the need for continued collaboration and communication among stakeholders to address the challenges and ensure the successful implementation of ePI across Europe. Ten countries have reported that sharing an overview of the currently running pilots, their scope, their outcome, the local challenges that have had to be overcome, the found solutions could help to (re-)engage the discussion on pilot in their country. This report supports such a request.

[i] electronic product information (ePI) pilot report
[ii] Het pilootproject e-PIL | pharma.be & download
[iii] https://extranet.infarmed.pt/INFOMED-fo/
https://www.infarmed.pt/web/infarmed/ef
[iv] except in the Netherlands

Annex 1: list of questions in the survey

Name, company/association, email address	
Name of your country	define countries, dropdown
has there been already any general consultation of the patients about the ePI in your country?	yes/no, explain
Is an ePI pilot currently running, planned, or has one already been completed in your country?	(Please select one: Running / Planned / Completed / No pilot
If running, planned or completed go to Y1	Direct
If no pilot go to N1	
What was or is the start date of the pilot? (If planned, please indicate the expected date)	
What was or is the end date of the pilot? (If running or planned, please indicate the expected end date. If completed, indicate the actual end date)	
If running, will extension beyond the end date be possible?	
Which stakeholders and authorities were/are involved in the discussions on the setup of the pilot?	
Which stakeholders and authorities are/will be involved in the monitoring on the pilot?	
Was or will an exemption from the European Commission be required or obtained for the pilot?	
Which products were, are, or will be included in the pilot? (Describe criteria eg Hospital, ambulatory, vaccin, healthcare professional administered, RX, OTC, additional information)	
Which authorisation type were, are, or will be included	CP, NAP, MRP/DCP
Were, are, or will generic products be included?	yes/no, explain
Were, are, or will biosimilar medicines be included?	yes/no, explain
Were, are, or will innovative products be included?	yes/no, explain
How many products were, are, or will be involved?	
Where has the ePI been published, or where will it be published? (Please state websites/apps and affiliation)	
How were stakeholders informed (or how will they be informed) about the start, scope, and modalities of the pilot? (E.g. via meetings, emails, newsletters, public announcements, etc.)	
Was, is, or will any code related to the packaging be used to link to the online ePI?	yes/no, explain
If yes, which code(s) were, are, or will be used? (E.g. 2D Data Matrix, QR code, barcode, etc. Please explain.)	
In which format was, is, or will the ePI be displayed? (E.g. PDF, HTML, XML, app-based format, etc.)	
How were, are, or will the original PI Word files be converted to a structured format such as XML or HTML?	
Was, is, or will the conversion from Word to a structured format be manual, automatic, or a combination of both? (Please specify if possible)	
How much time did, does, or will it take to convert one PI document to a structured format (e.g. XML/HTML)? (Please provide an average or range, and mention factors that affect the time if relevant.)	
Have surveys been conducted, are they ongoing, or are any planned to monitor the pilot?	
Which stakeholders were, are, or will be involved in these surveys? MAHs, (Doctors, Hospital pharmacists, patients, etc….)	
Please describe the most important results of these surveys?	
If available, please provide link(s) to publicly available information on the pilot and any related survey results. If not publicly available, please send the material by email to…	
What were, are, or are expected to be the main challenges encountered during the setup or implementation of the pilot?	
What were, are, or are expected to be the main hurdles encountered during the implementation or execution of the pilot?	
Has the running/completed pilot demonstrated an impact on the (existing) shortage of some medicines by using ePI?	Yes/no/not evaluated, explain
Has the running/completed pilot demonstrated an impact on the availability (additional products on the market) of medicines by using ePI?	Yes/no/not evaluated, explain

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