

Whitepaper

Electronic Product Information (ePI): Past, Present and Future

Inge Groenewoud



Electronic Product Information (ePI): Past, Present and Future

Introduction

Across Europe, the creation, maintenance, and access to medicinal product information is on the verge of a major transformation. Traditional product information, largely static PDFs approved through regulatory procedures, no longer meets the needs of a digital healthcare ecosystem. Patients, healthcare professionals, regulators, and marketing authorisation holders increasingly require content that is accessible, up to date, interoperable, user-friendly, and reusable.

To address these evolving needs, Electronic Product Information (ePI) has been established as a key initiative of the European Medicines Regulatory Network¹. It is also anticipated to become a core component of the EU Pharmaceutical Package, the most significant reform of EU medicines regulation in over two decades. ePI places structured, digital product information at the center of regulatory modernisation.

This white paper explores the development of ePI in Europe, outlining its evolution, key objectives, and the main milestones that have shaped its current direction. It provides an overview of the benefits associated with ePI and describes the ongoing implementation approach, including recent pilot experiences and the planned roadmap for broader adoption. In addition, it offers insight into what ePI will look like in practice, highlighting key features of the future operating model and what organisations can expect as implementation progresses in the coming years.

According to the key principles² set by EMA/HMA/EC, ePI is defined as authorised, statutory product information for medicines (i.e. SmPC, PL and labelling) presented in a semi-structured format created using the common EU electronic standard (agreed technical features³). This format enables consistent electronic handling supports automated publication across digital platforms and can still be rendered in print when required.

¹ The European Medicines Regulatory Network comprises the closely coordinated regulatory network of national competent authorities in the Member States of the European Economic Area working together with the European Medicines Agency and the European Commission to regulate medicines in Europe.

² Electronic product information for human medicines in the EU: key principles A joint EMA–HMA–EC collaboration, 29 January 2020. https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/electronic-product-information-human-medicines-european-union-key-principles_en.pdf

³ <https://github.com/EuropeanMedicinesAgency/EU-ePI-common-standard>

Recent History

Over the past decade, starting around 2015, electronic Product Information has evolved from a forward-looking concept to a key pillar of Europe's digital health ambitions. Initially, discussions and early initiatives within the European Medicines Agency (EMA), the Heads of Medicines Agencies (HMA), and the European Commission (EC) focused on improving access to medicines information. These efforts gradually evolved into a coordinated, multi-stakeholder program.

Around the same time, the Inter-Association Task Force (IATF) on ePI was established to start a collaboration between the industry associations European Federation of Pharmaceutical Industries and Associations (EFPIA), Association of the European Self-Care Industry (AESGP) and Medicines for Europe. The collaboration provided a common industry forum to contribute to the development and implementation of ePI, taking into account both regulatory objectives and practical considerations for the pharmaceutical industry and other stakeholders. In 2018, several events were held for various stakeholders to (virtually) come together to gather views on ePI, but also to draft a common standard for ePI and develop key principles. Participants included all levels of the pharmaceutical industry, such as the IATF, Coordination Group for Mutual Recognition and Decentralised Procedures - Human (CMDh), National Competent Authorities (NCAs), EMA's Patients' and Consumers' Working Party (PCWP), and Healthcare Professionals' Working Party (HCPWP). A workshop at the end of 2018 brought together patients/consumers, healthcare professionals, the pharmaceutical industry, academia, not-for-profit organisations and regulators to discuss stakeholder needs and concerns, give an overview of the main ePI initiatives ongoing in the EU and decide how to move forward with a common approach. The outcome of the workshop was a draft proposal for 'key principles' for ePI.

This resulted in the publication of the final Key Principles for ePI (2020²), establishing a shared vision for structured, interoperable product information across the EU. The next step involved developing the EU ePI Common Standard, specifying the technical features of ePI as agreed by regulators and stakeholders. The final EU ePI Common Standard was adopted by the EU Network Data Board⁴ in September 2022⁵. This adoption marked an important regulatory milestone, providing a common technical foundation needed for the harmonised creation and implementation across the EU.

The years thereafter were spent on pilot projects and demonstrated that ePI can work in real regulatory procedures. Between July 2023 and August 2024, the use of ePI was tested in a one-year pilot project. Participating authorities included EMA and the national authorities from Denmark (DKMA), the Netherlands (CBG-MEB), Spain (AEMPS) and Sweden (MPA). The overall conclusion of the pilot was to progress towards ePI implementation. Furthermore, a survey⁶ led by the IATF shows that many pilots across Europe have been or will be performed by national competent

⁴ The European Union Network Data Board (EUNDB) was an advisory body co-chaired by the Head of Business Data and Support Department (EMA) and a National Competent Authority (NCA) representative and comprising members representing Member States, the Agency and other key parties (e.g. EDQM, EC and other non-EU regulatory authorities). In 2025, the Network Data Board merged with the Big Data Steering Group to form the Network Data Steering Group (NDSG), a single strategic advisory group responsible for overseeing data strategy and governance within the European medicines regulatory network.

⁵ Report on public consultation on EU ePI Common Standard. *Summary of comments received and next steps*, 2022.

⁶ Overview of the pilots in Europe testing the use of the electronic product information (ePI) for medicines. *A survey conducted by the Inter Associated Task Force on ePI (IATF-ePI: AESGP, Efpi, Medicines for Europe in April & May 2025).*

authorities in collaboration with national stakeholders. These initiatives provided valuable insights into operational workflows, stakeholder expectations, and technical implementation, while also highlighting practical considerations such as schema validation, multilingual handling, and integration with regulatory systems. These insights can inform future implementation efforts.

These key developments marked the transition from concept to reality. Although the early initiatives initially started as an addition to current EU legislation, the new EU Pharma Package indicates a clear direction toward standardized digital product information to improve patient access, update speed, and data interoperability as part of broader regulatory modernisation.

Objectives - Benefits

To gain a proper understanding of the need for ePI, it is essential to outline the core objectives and above all, the benefits it brings to patients, healthcare professionals, regulators, and industry. We live in an increasingly digital world, where access to information is expected to be immediate, accurate, and user-friendly. In this context, conventional paper-based package leaflets and static PDFs can no longer keep pace with the needs of patients and healthcare professionals. As healthcare systems continue to evolve digitally, medicines information must follow the same path and ePI is therefore a necessary step forward.

Looking more closely, the benefits of ePI extend beyond simple digitalisation.

Improved Accessibility

One of the most important advantages is improved accessibility: medicines information becomes easier to locate and consult for both patients and healthcare professionals, anywhere and anytime. Users are no longer dependent on the physical leaflet included in the packaging which may be lost, outdated, or unavailable at the point of need. This is particularly valuable in situations where information needs to be accessed quickly or remotely, supporting more informed decision-making and safer use of medicines. Situations as such could for example occur in emergency care when healthcare professionals must rapidly verify dosing, contraindications or interactions, or during remote consultations where patients and clinicians can review the same information simultaneously. By ensuring rapid access to authorised information, ePI supports safer clinical decision-making and reduces the risk of relying on outdated materials. Even in everyday situations such as when the original packaging is no longer available, access to up-to-date information remains straightforward.

Safer and Timelier Updates

Second, ePI enables more timely updates to product information, especially for safety-critical information. Changes to safety information, dosage instructions, or regulatory requirements can be implemented more rapidly than with paper-based leaflets. Updating printed materials requires lengthy production and distribution cycles, often taking several months to implement safety updates, while existing leaflet editions remain available on the market until they reach the end of shelf-life. ePI reduces the time lag between approval and availability of updated information, helping to ensure that users are not relying on outdated content.

Enhanced Usability and Personalisation

Furthermore, ePI supports improved usability and personalisation. Digital formats allow to present information in ways that better meet the needs of different user groups. For example, the content for patients could be simplified, enlarged or made searchable, with potential future multimedia or interactive elements, all depending on the abilities of the patients. These features support the patients to access information that is most relevant to them and can enhance understanding, support appropriate use, and improve adherence.

Operational Efficiency for Regulators and Industry

In addition, ePI improves operational efficiency by streamlining regulatory and operational processes. Digital management of updates reduces the need for repeated printing, packaging adjustments, and complex distribution activities. This simplifies regulatory and logistic workflows by reducing administrative burden for both regulators and industry, particularly during frequent safety updates or large-scale variations.

Improved Data Interoperability

Another key benefit is enhanced data interoperability. Because the information is structured and machine-readable, it can be more easily exchanged and reused across digital healthcare and regulatory systems. This can facilitate integration with digital tools and services, including electronic health records, e-prescribing tools, national medicines databases and clinical decision support systems, while supporting more consistent and accurate use of medicines information.

Sustainability

Finally, ePI contributes to sustainability and efficiency by reducing the need for paper, printing, and physical distribution, while also lowering environmental impact by the decrease in waste and resource consumption.

In summary, ePI not only aligns medicines information with the digital age, but also enhances accessibility, efficiency, and quality of information across the entire healthcare ecosystem.

Inclusivity and Digital Access Considerations

Even though above listed points all highlight the positive sides of the ePI, a critical side note needs to be emphasized here. Patients with limited digital skills or limited access to internet may face challenges when it comes to the use of ePI. Also, the patients and/or consumers that have a low ability to use digital devices effectively, may be adversely affected.

To address these challenges, a stepwise introduction of ePI has been put forward by the IATF⁷ with the aim of avoiding disruption and allowing time to establish supporting measures. Among these are mechanisms to maintain access to paper leaflets where needed, such as on-demand printing during the transition. At the same time, questions have been raised about the practicality of these arrangements, including their implications for resources, costs and routine operations. These issues continue to be examined in the context of the ongoing reform of the EU pharmaceutical legislation to ensure equitable access for all patient groups.

⁷ Overview of the pilots in Europe testing the use of the electronic product information (ePI) for medicines. A survey conducted by the Inter Associated Task Force on ePI (IATF-ePI: AESGP, Efpia, Medicines for Europe in April & May 2025

Working with ePI in practice

Now that the main benefits have been outlined, let's discuss the practical implications of ePI and what working with ePI will look like for organisations preparing for future adoption.

PLM portal

The ePI pilot that ran from July 2023 to August 2024 used the Product Lifecycle Management Portal (PLM portal) as the central platform to create, edit, submit, approve and publish ePIs. The PLM portal is EMA's web-based platform and is currently already in use for managing electronic applications forms dedicated to variations for human medicines and will be the platform to use for ePI in the near future.

To access the PLM portal, a user will first need to have an active EMA account and their organisation must be registered in EMA's Organisation Management Services (OMS). If these preconditions are met, it will be possible in the future to request the applicable roles in the EMA Account Management System. During the pilot, access was restricted to participating organisations, but broader role assignment will become available closer to the voluntary go-live.

When accessing the PLM portal, the interface for ePI is relatively self-explanatory and intuitive. It helps you navigate through the different steps you need to complete until you reach the structure which should look familiar if you regularly work with product information: the QRD template. In this editor, the content can then be entered and edited within the familiar QRD template structure. The system includes built-in validation checks and uses structured templates and standardised terminology to support consistency and reduce errors.

Implementation Roadmap CAPs

The first procedures that are in scope for a voluntary go-live are vaccines registered via the Centralised Procedure (CAP). According to EMA's roadmap⁸ this will take place in Q4 of 2026, followed by the voluntary implementation of oncology products in the first half of 2027 after which the rest of all CAPs will be allowed to participate in the voluntary go-live of ePIs in the second half of 2027.

The implementation of ePI for CAPs will follow the same approach as was used during the pilot, meaning that applicants will be requested to author/upload ePI at the PLM portal through an extra step in the regulatory process, next to the current Word/PDF submission. This will not affect the assessment of the procedure in any way. It is important to state here that once a product transitions to ePI, it will maintain the electronic format in all subsequent variations to ensure lifecycle continuity.

As the standard format for PI of CAPs needs to be available in multiple languages, this initially does not apply to ePI. The initial implementation of ePI is for English only where all other languages are optional. It will not be fully multilingual once technical and operational frameworks are established. Until then, the standard format of PI in other languages is still available.

⁸ Electronic Product Information (ePI) Roadmap. https://www.ema.europa.eu/en/documents/other/electronic-product-information-epi-roadmap_en.pdf

Future Roadmap for non-CAPs

The roadmap for non-CAPs (Decentralised Procedures, Mutual Recognition Procedures, National Procedures) will follow by the end of 2026, start of 2027.

Publication of ePI

In the future, all ePIs for EU medicines will be displayed on the European Medicines Web Portal (EMWP), once developed. Until the EMWP is launched, the ePIs for CAPs will be published on the EMA website via the EPAR pages. Additionally, NCA's can decide to display ePI on their own national websites as well.

Operational Considerations for Organisations

Transitioning to ePI will require updates to internal processes, including SOP revisions, staff training, and alignment of regulatory operations systems. Organisations should also prepare for structured authoring workflows, schema validation, and integration with existing regulatory information management (RIM) systems.

Conclusion

Electronic Product Information represents a significant step in the evolution of medicines information in Europe, moving from static, paper-based formats towards fully digital, structured and interoperable content. What began as a conceptual initiative has matured through collaboration between regulators, industry and stakeholders into the inclusion into the new EU Pharma Package supported by common standards and successful pilot implementations.

The introduction of ePI brings clear benefits, including improved accessibility, more timely updates, enhanced usability, stronger regulatory efficiency, and better data interoperability across healthcare systems. At the same time, it supports broader goals such as sustainability and the development of a more connected digital health ecosystem. The progress achieved through collaborative efforts between EMA, HMA, the European Commission, national competent authorities, and industry demonstrate that ePI is no longer a conceptual ambition but an operational reality. Pilot outcomes have confirmed the feasibility of structured authoring and digital publication within existing regulatory timelines.

As Europe prepares for phased implementation, beginning with centrally authorised products in 2026, organisations must ensure they are ready for the new workflows, validation steps, and structured authoring practices that ePI requires. This transition will require updates to internal processes, regulatory systems, and staff competencies to ensure smooth adoption

However, the transition also requires careful attention to inclusivity, ensuring continued access for patients who are less digitally enabled or have limited access to digital tools. A phased implementation, supported by transitional solutions such as print-on-demand and parallel availability of paper formats, remains essential.

As implementation progresses from pilots to voluntary rollout and beyond, continued collaboration between stakeholders will be key. ePI is set to become a cornerstone of modern regulatory practice in Europe, enabling a more efficient, transparent, and patient-centered approach to medicines information. As the EU continues to advance towards a more digital regulatory ecosystem, ePI can support more timely information exchange, improved

access to up-to-date medicines information, and future integration with digital health systems and services. This white paper has outlined the history, objectives, benefits, and practical considerations associated with ePI, providing organisations with a clear understanding of what lies ahead. The future of product information is increasingly digital, and ePI marks an important step towards a more connected, responsive and accessible approach to medicines information in Europe.

Contact us today at info@starodub.nl to discuss how we can support you in preparing for the arrival of ePI.



References

- Albertini, Alberto. How Digital Leaflets Meet EU 2026 Compliance Requirements. *A regulatory roadmap for ePI, FMD serialization, and EU digital pharmaceutical compliance*, 23 March 2026. <https://thetraceabilityhub.com/how-digital-leaflets-meet-eu-2026-compliance-requirements/>
- Electronic Product Information (ePI). <https://www.ema.europa.eu/en/human-regulatory-overview/marketing-authorisation/product-information-requirements/electronic-product-information-epi>
- Electronic product information for human medicines in the European Union – draft key principles, 31 January 2019. https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/electronic-product-information-human-medicines-european-union-draft-key-principles_en.pdf
- Electronic product information for human medicines in the EU: key principles A joint EMA–HMA–EC collaboration, 29 January 2020. https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/electronic-product-information-human-medicines-european-union-key-principles_en.pdf
- Electronic Product Information (ePI) Roadmap, 20 March 2026. https://www.ema.europa.eu/en/documents/other/electronic-product-information-epi-roadmap_en.pdf
- ePI pilot report. *Experience gained from creation of ePI during regulatory procedures for EU human medicines*, 2024. https://www.ema.europa.eu/en/documents/report/electronic-product-information-epi-report-experience-gained-creation-epi-during-regulatory-procedures-eu-human-medicines_en.pdf
- ePI Registration Guide. <https://plm-portal.ema.europa.eu/Guidance/article/KA-01023/en-us>
- ePI User Guide for Applicants. <https://plm-portal.ema.europa.eu/Guidance/article/KA-01024/en-us>
- European Medicines Regulatory Network. <https://www.ema.europa.eu/en/glossary-terms/european-medicines-regulatory-network>
- European Union Network Data Board Terms of Reference, 10 January 2018. https://www.ema.europa.eu/en/documents/other/european-union-network-data-board-terms-reference_en.pdf
- Inter-Association Task Force (IATF). Position Papers on Electronic Product Information (ePI), January 2025. <https://www.efpia.eu/media/2sgl2zyh/iatf-position-papers-on-epi.pdf>
- Kaušakienė, Lina. Electronic Product Information (ePI), 4 December 2025. <https://insuvia.com/insights/electronic-product-information/>
- Network Data Steering Group holds inaugural meeting to unlock the value of data, 21 January 2025. <https://ec.europa.eu/newsroom/ema/items/874956/en>
- Overview of the pilots in Europe testing the use of the electronic product information (ePI) for medicines. *A survey conducted by the Inter Associated Task Force on ePI (IATF-ePI: AESGP, Efpia, Medicines for Europe in April & May 2025)*. <https://www.efpia.eu/media/wdak14pb/overview-of-the-pilots-in-europe-testing-the-use-of-the-electronic-product-information-epi-for-medicines.pdf>
- Report on public consultation on EU ePI Common Standard. *Summary of comments received and next steps*, 2022. https://www.ema.europa.eu/en/documents/report/report-public-consultation-eu-common-standard-electronic-product-information-epi-summary-comments-received-and-next-steps_en.pdf
- Spalvieri, S. and Wait, S. Electronic product information (ePI). Securing the future for accessible delivery of medicine information through digitalisation, March 2024.

<https://www.healthpolicypartnership.com/app/uploads/Electronic-product-information-ePI-Securing-the-future-for-accessible-delivery-of-medicine-information-through-digitalisation.pdf>



About Starodub

Reliable, Efficient and Knowledgeable

Starodub BV is a team of expert consultants specialising in Regulatory Affairs, Quality, Operations & Improvement. We help organisations navigate complex EU, FDA and other global regulatory requirements, develop inspection-ready documentation, and implement robust quality systems that support safe and compliant product lifecycle management. We provide regulatory support for a wide variety of products, including Small Molecules, Biotech/Biologics, Vaccines, Medical Devices, in vitro Diagnostic and Combination Products.

Our expertise spans Chemistry, Manufacturing and Controls, regulatory operations including eCTD, and both pre-clinical and clinical regulatory affairs. Support is offered from early development to late-stage commercialization. This end-to-end capability enables consistent regulatory strategy, documentation quality, and lifecycle continuity.

We combine deep pharmaceutical expertise with a structured improvement approach, bringing focus, clarity, and execution discipline to regulatory, quality and production environments. Our methodology is grounded in hands-on GMP experience and supported by proven Lean, Six Sigma, and change-management principles.

We offer support with strategic decision-making process, management of individual and interconnected projects, and leadership of regulatory, quality and production teams. By combining strategic insight with both macro- and micro-level project and people management, we help clients maintain stable product lifecycles while executing changes quickly and efficiently.

Starodub BV is qualified as SME (Small and Medium-sized Enterprises) in the EU, which can provide our clients with administrative, regulatory and financial advantages such as reduced fees and easy access to EMA support.

We operate in full compliance with GxP regulations and ISO 9001/13485 standards. We care deeply about our clients and the patients they serve, and we strive to provide the highest quality, efficiency and reliability in every project.

Let us be your partner, guiding you on the most effective path to regulatory success. Please feel welcome to explore our website and contact us to learn how we can support your organisation.

About the Author

Inge Groenewoud

Inge Groenewoud is a regulatory affairs consultant with extensive experience in working with product information. She has reviewed and updated numerous SmPCs, Package Leaflets and Labelling texts in several languages, also making use of the QRD templates and their relevant appendices. Inge is familiar with the regulatory sources and requirements needed to ensure high-quality Product Information. Her experience with product information has sparked a particular interest in how it will evolve in the future, and in how modern technology can shape its development.



RA Consultant
Starodub BV