AESGP
VOICE OF EUROPEAN SELF-CARE INDUSTRY



AESGP Position Paper

Electronic Product Information for Non-Prescription Medicines: Key principles for implementation and user access

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Executive Summary

AESGP supports the transition to electronic Product Information (ePI) as an important opportunity to improve access to trusted, up-to-date and accessible information for non-prescription medicines.

For the self-care sector, implementation should focus on enabling intended users to access the electronic Patient Information Leaflet (ePIL) in a simple, reliable and user-friendly manner, without unnecessary complexity or delay.

AESGP considers QR codes to be the most practical and proportionate user-facing solution for the initial implementation of ePIL for non-prescription medicines.

QR codes can be accessed through standard smartphone cameras, are already widely used, and can provide a simple and flexible link from the medicine pack to the relevant ePIL without requiring dedicated applications or significant new infrastructure.

Introduction

The proposed Directive of the European Parliament and of the Council on the Union code relating to medicinal products for human use[1] (repealing Directive 2001/83/EC and Directive 2009/35/EC) introduces the mandatory requirement to implement electronic Product Information (ePI). This change in how medicinal product information is shared represents an important step towards modernising and improving access to clear, up-to-date and reliable product information. For non-prescription medicines (NPMs) in particular, ePI has the potential to enhance accessibility and safer self-selection by intended users while supporting innovation and digitalisation in the sector.

ePI encompasses the electronic provision of the complete authorised product information, which includes the summary of product characteristics (SmPC), package leaflet and labelling. As the package leaflet is the element directly intended to provide users with the relevant information to use the medicine safely and appropriately, **the transition to the electronic Patient Information Leaflet (ePIL) should be a main priority in the initial implementation of ePI**. This is particularly important for NPMs, where users may select and use a medicine without direct involvement of a healthcare professional.

The value of providing the package leaflet in electronic formats has been widely recognised. The joint key principles on ePI for human medicines in the EU[2] published by the European Medicines Agency (EMA), Heads of Medicines Agencies (HMA) of EU Member States and the European Commission (EC) highlight several key benefits of ePI for public health. Among those, expanding access to information on medicines is especially relevant to users of NPMs as it can contribute to more informed decisions and safer self-selection. Additionally, accessibility for users with physical impairment or learning difficulties will also be enhanced through visual adaptability options suitable to different needs, which will greatly support users with low health literacy.

To allow these benefits to materialise for intended users, the initial implementation

[1] Proposal for a Directive of the European Parliament and of the Council on the Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC.

[2] Electronic product information for human medicines in the EU: key principles. A joint EMA-HMA-EC collaboration

should focus on delivering a simple, effective and workable solution, without making the realisation of these benefits dependent on the development of more advanced functionalities or infrastructure. The core functionality should be made available to users without unnecessary delay, while allowing scope for further functionalities and improvements to be introduced as the system evolves. In this context, users should be able to access the relevant ePIL through a consistent, intuitive and reliable pathway.

This paper outlines the areas where AESGP members have identified common guiding principles for ePI implementation, particularly with regard to user access to the ePIL, reflects the emerging alignment on user-friendly technical solutions, and highlights considerations for the role of EU-level infrastructure in supporting consistency and predictability in implementation.

A note on the terminology used

- In the context of this paper, **package leaflet (PL)** and **patient information leaflet (PIL)** are considered equivalent terms and refer to the leaflet included in a medicinal product pack that provides information for end users, such as patients and caregivers.
- The term **electronic Product Information (ePI)** refers to the product information framework as a whole, encompassing the SmPC, labelling, and package leaflet. Throughout this paper, ePI is referenced when discussing the broader ecosystem, implementation considerations, interoperability, and data exchange mechanisms.
- The term **electronic Patient Information Leaflet (ePIL)** refers specifically to the patient-facing package leaflet made available through digital means. Throughout this paper, ePIL is referenced when discussing user access, user interface considerations, accessibility, and overall user experience.

Key guiding principles for accessibility and implementation of ePI

Through dedicated expert discussions, AESGP members have identified a set of core principles that should underpin the future implementation of ePI, including the development of solutions for accessing the ePIL from non-prescription medicine packs. These principles reflect a shared commitment to feasibility, usability, accessibility and user-centric design, while taking into account the practical considerations associated with implementation across the NPM sector.

Accessibility-focused principles

Ease of access for users

Users should be able to access the ePIL through a simple scan using a standard smartphone camera, without requiring a dedicated application. The access pathway should be intuitive and require minimal steps, recognising that NPMs are often selected and used by individuals without the direct involvement of a healthcare professional.

Trustworthy information

Users should be able to access the ePIL from relevant and authorised sources, ensuring confidence in its accuracy, completeness and authenticity. Successful implementation will require robust mechanisms for version management, localisation and publication to ensure that users are consistently directed to the correct and most up-to-date information. The governance and operational arrangements supporting these processes require further clarification and should be developed collaboratively between regulators and industry stakeholders.

Consideration should also be given to situations where the information contained in paper leaflets already present in the supply chain differ from a more recently approved digital version. In this context, a potential solution could be including a clear reference in the paper leaflet directing users to the ePIL for the most up-to-date approved information. This would provide a practical means of ensuring that users can access the latest information even where older paper leaflets remain in the supply chain.

Simplicity and consistency of user experience

Where possible, the solution for the ePIL should avoid the unnecessary addition of codes on the pack, while recognising that, in the short term, this might not always be an option for NPMs. Ensuring that users can easily identify and recognise the code intended for accessing the ePIL is fundamental for supporting a simple and consistent user experience. In the longer term, convergence towards a single code should be pursued where feasible, while maintaining flexibility to meet diverse national regulatory requirements.

Implementation-focused principles

Use of existing standard data & infrastructure

Implementation should make use of existing standards, data elements and infrastructure wherever possible. Codes and access mechanisms should build on information and processes already used by manufacturers within established regulatory, packaging and supply-chain systems, avoiding unnecessary new data requirements or technical processes solely for the purpose of ePI. This would facilitate implementation across the NPM sector and support interoperability with existing systems.

Proportionate implementation

Implementation of ePI should be proportionate to the benefits delivered to users and should make use of existing technologies and established processes wherever possible. The initial implementation should avoid significant new infrastructure, governance structures or bespoke data systems where these are not necessary to provide a clear user benefit. More advanced functionalities can be introduced progressively as the system and supporting infrastructure evolve.

Minimal operational impact

The implementation of ePI should minimise unnecessary impacts on packaging, manufacturing, supply chain operations and product availability. The digitalisation of the package leaflet content should be achievable through simple, scalable and readily deployable measures, without creating unnecessary complexity or cost for manufacturers, regulators or intended users.

A user-friendly solution for non-prescription medicines

The EMA draft reflection paper on linking to ePI from EU medicine packages[3] invites manufacturers of NPMs to investigate potential pathways for linking ePI to the medicine package. Based on the principles and implementation considerations described above, and in particular the need to enable simple access to the ePIL through direct scanning by mobile phones, **quick response (QR) codes represent the most practical and proportionate user-facing solution currently available to deliver access to the ePIL for NPMs**. While future technological developments and access models should remain open for consideration, the immediate priority should be to enable intended users to access the approved package leaflet in a simple and reliable manner, providing a practical foundation for further evolution of the ePI system.

In considering the most appropriate user-facing solution for NPMs, QR codes offer a number of advantages in terms of accessibility and implementation when compared to 2D Data Matrix codes.

- **For end-users**, QR codes are widely recognised as a means of accessing online information using a smartphone and can generally be scanned directly using the native camera functionality, without requiring a dedicated application. They therefore provide a simple and familiar entry point to the relevant ePIL, while allowing the underlying technical infrastructure and access pathways to evolve over time.
- **For industry**, building ePI access for NPMs around infrastructure associated with prescription-medicine serialisation could introduce additional costs and operational requirements for manufacturers, including potential changes to packaging lines, artwork management and data management processes. Such requirements should be considered against the specific characteristics and needs of NPMs and the objective of providing users with simple access to the ePIL. QR codes can provide a user-facing access point without requiring NPMs to reproduce the full infrastructure associated with prescription-medicine serialisation.

Given the current implementation timelines, solutions should prioritise rapid deployment using existing technologies that can be readily implemented across the NPM sector. QR codes are already widely used as a means of providing access to digital information and can therefore provide a readily recognisable entry point for users.

Taken together, these considerations support the use of QR codes as the preferred user-facing access point for the implementation of ePIL for NPMs. This approach would provide users with a simple and familiar means of accessing the ePIL, while allowing the underlying technical infrastructure and access pathways to evolve over time.

[3] EMA Draft Reflection paper on linking to electronic product information (ePI) from EU medicine packages

Ensuring consistency and predictability in implementation

Implementation of ePI across the EU should be harmonised, with all Member States using the same standard and a common central repository. A consistent approach to the technical standards and infrastructure will be essential to ensure a seamless and predictable implementation across Member States.

For this reason, AESGP strongly supports the establishment of an **EMA-HMA central ePI repository as the single authoritative source of approved ePI, including the package leaflet, for all medicinal products**. A central repository would provide a consistent basis for the management of approved product information across the EU, supporting data integrity, consistency and regulatory oversight.

Close collaboration between the EMA, national competent authorities (NCAs) and industry will be essential to ensure that the central repository remains aligned with the latest approved information and that intended users are consistently directed to the most current authoritative version of the ePI. This will also help build user confidence and trust in the system.

The underlying technical architecture should be interoperable and aligned with the EU ePI Common Standard and relevant HL7 FHIR-based approaches. In particular, the availability of appropriate technical infrastructure to access and reuse the information held in the central repository will be important to support the development of consistent and user-friendly access pathways.

AESGP therefore welcomes the EMA's ongoing development of the ePI application programming interface (API) as an important component of this infrastructure. The API can facilitate the reusability and interoperability of ePI content by consuming systems, providing the basis for user-facing solutions to access the underlying approved information.

For end users, however, the availability of ePI data in a central repository and through an API should **translate into a simple, recognisable and consistent pathway to the relevant ePIL**. AESGP therefore supports exploring, together with the EMA, NCAs and other industry stakeholders, how such a common user-facing access pathway could be established across the EU. In particular, the solution should:

- **Reinforce trust** through a recognisable regulatory environment
- **Support a consistent use experience** across Member States
- **Reduce implementation complexity** for industry while maintaining a high level of regulatory confidence
- **Minimise fragmentation** of presentation formats and user experiences
- **Facilitate future interoperability** with broader EU digital health initiatives, including the potential reuse of data from PMS.

To support such an approach, clear governance arrangements will be essential. In particular, responsibilities should be clearly defined for ensuring that the ePIL displayed to users reflects the latest approved version, synchronising updates between the EMA, NCAs and marketing authorisation holders and ensuring appropriate quality control and regulatory oversight.

In summary, a central EU repository and common standard should form the basis for a consistent and predictable implementation of ePI across Member States. The ePI API can provide an important technical layer to support interoperability and reuse of ePI content, while a consistent user-facing access pathway can translate this infrastructure into a predictable, trusted and user-friendly experience for intended users.

Conclusion and **Recommendations**

AESGP supports the transition to ePI as an important opportunity to improve access to trusted, up-to-date information for non-prescription medicines. For NPMs, the main priority should be to enable intended users to access the approved ePIL in a reliable, trusted and consistent manner.

- To realise its full value, **ePIL for NPMs must be accessible from the medicine pack in a way that is simple, trusted and intuitive for users,** while remaining feasible for industry and aligned with regulatory expectations.
    - For these reasons, **AESGP considers QR codes to be the most appropriate and balanced option for NPMs, as they offer a widely accepted and flexible access point and are the preferred user-facing solution.**
    - By contrast, **2D Data Matrix codes are not considered a proportionate user-facing solution for NPMs**, given the additional complexity they could create on users and the disproportionate implementation burden on industry.
- To support a consistent EU-wide approach, **AESGP strongly supports the establishment of an EMA-HMA central ePI repository as the single authoritative source of approved ePI for all medicinal products**, underpinned by common standards and interoperable technical infrastructure.
    - The ePI API can provide an important technical layer to support **interoperability and reuse of ePI content**, while a common and user-friendly access pathway should enable users to move from the code on the medicine pack to the relevant ePIL in a simple and recognisable manner.

Important implementation questions, including version management, localisation and governance arrangements, will require further discussion and clarification among the EMA, NCAs and industry stakeholders to ensure that users are consistently directed to the latest approved information applicable to the relevant market and language.

AESGP looks forward to continued collaboration with the EMA, NCAs and other industry stakeholders to establish a proportionate, reliable and sustainable approach to ePI implementation that delivers its benefits to users without unnecessary complexity.

About

The Association of the European Self-Care Industry (AESGP) is a non-profit organisation which represents the manufacturers of non-prescription medicines, self-care medical devices and food supplements in Europe, an area also referred to as consumer healthcare.

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