IATF position paper on phasing in of electronic product information and phasing out of the paper package leaflet

Executive Summary

The implementation of electronic Product Information (ePI) and the removal of the paper package leaflet provides significant advantages for patients, healthcare professionals, industry, regulators and the environment by offering accessible and up-to-date information on medicines in an accessible digital format. ePI also strengthens supply chain agility and is a unique opportunity to mitigate and prevent shortages while significantly contributing to environmental sustainability.

The legislative revision proposed by the European Commission [Dir Article 63] acknowledges the importance of ePI, makes the future transition from paper product information to ePI possible and increases the flexibility to make patient information more impactful. However, the proposed gradual implementation of ePI, driven by Member States' readiness, could be challenging to operationalize, particularly if it is not implemented in a harmonized way and the Member State by Member State implementation period extends over a lengthy period. As such, IATF proposes the following implementation:

1. IATF underscores that the phasing in of ePI (which is currently already taking place) should precede the phasing out of paper package leaflets. Existing ePI platforms such as National Competent Authority and Industry websites and compendia could be used as solutions to initiate the transition before ePI becomes fully available on the EMA/HMA portal. This phasing in of ePI should be supported by an EU-wide education and awareness campaign. ePI should be implemented across the EU in a harmonized way, with all Member States adopting the same standard and utilizing the same EMA/HMA portal as a repository for ePI. The portal should be available 1 year after entry into force of the new directive, fully operational with all key requirements implemented by 2 years after entry into force and fully populated with all ePI 4 years after entry into force.

2. The phasing out of the paper package leaflet should start with products not intended for self-administration (Healthcare Professional (HCP)-administered products) first in all Member States and immediately after entry into force of the new legislation. For all other products the “Member State by Member State” implementation phase should be kept as short as possible and should be followed by a pan-EU implementation through a delegated act of the European commission. Any implementation strategy, whether initiated by individual Member States or through a European Commission delegated act, should strive for simplicity and be prepared in alignment with Industry stakeholders.

3. While the landscape of internet access among EU citizens strengthens the case for the widespread adoption of ePI, it is crucial to continue providing accessible medicinal information to the small minority without regular internet access or with limited digital skills. Therefore, a solution that strikes a balance between completely removing paper and fully retaining paper, such as printing at the point of

dispensation, seems to be one of the best solutions at the moment. Industry has assessed potential alternatives and will discuss them further with stakeholders."

Advantages of introducing electronic Product Information

The introduction of electronic Product Information (ePI) offers several distinct advantages that directly impact patient care as well as the regulatory processes related to product information. Firstly ePI ensures that the information provided is **always up to date**, reflecting the most recent Health Authority-approved product information. It enables the **use of different media formats**, such as videos and interactive elements, allows search functionality and introduces the ability to adjust font sizes, to **enhance the understanding and accessibility of product information according to patient needs and to improve health literacy.** Additionally, ePI allows for a **more impactful delivery of content and opens the possibility of personalized content** to both patients and healthcare professionals (HCPs). From a regulatory perspective, the adoption of ePI could streamline processes for both the pharmaceutical industry and the competent health authorities, and will lead to **greater efficiencies in the end-to-end review, approval and dissemination** of product information.

Advantages of removing the paper package leaflet

The removal of paper package leaflets presents several advantages that directly contribute to the efficiency and sustainability of pharmaceutical distribution and usage.

Shifting from paper leaflets to ePI reduces **the risk of patients and healthcare providers relying on outdated versions of medicinal information**, especially in the case of safety updates**,** ensuring that the most current guidance is always followed. Additionally, **the availability of medicines may be increased,** particularly through the facilitation of multi-country/multi-language packs and easier reallocation of packs across Member States. This approach allows for **more streamlined packaging processes and reduces the logistical burden** associated with producing and distributing different leaflets for various markets, as well as ensuring patients can access the product information even if the pack is written in a language they are not fluent in. **Environmental benefits** are another key advantage, as the reduction in paper and ink use directly contributes to decreased waste and resource consumption, aligning with broader sustainability goals.

Are EU citizens ready for the use of electronic Product Information, and is the paper package leaflet still required?

The readiness of EU citizens for the adoption of electronic Product Information (ePI) is supported by **encouraging Eurostat statistics, which reveal that internet access among EU citizens (at least once a week) stands at 90% in 2023 (72% in 2014) and continues to rise[1].** This trend is expected to significantly increase in the coming years, with projections indicating that by 2034, the percentage of EU citizens regularly accessing the internet will increase to 97% overall, and to 87% among those aged 65-74 Alongside internet access, Eurostat statistics also show that in 2023 almost 90% of EU citizens had basic digital skills in at least 2 areas and that all Member States that did have low internet access rates in 2014 are quickly catching up (e.g. Romania evolved from 48% (2014) to 88% (2023) with regards to the percentage of citizens accessing the internet at least every week). Such projections underscore a rapidly diminishing digital divide, highlighting the growing feasibility of ePI as a primary source of medicinal

[1] Eurostat datasets : Statistics | Eurostat (europa.eu)

information for nearly all EU citizens. Figures 1 and 2 show the described trends with regards to internet access and basic digital skills.

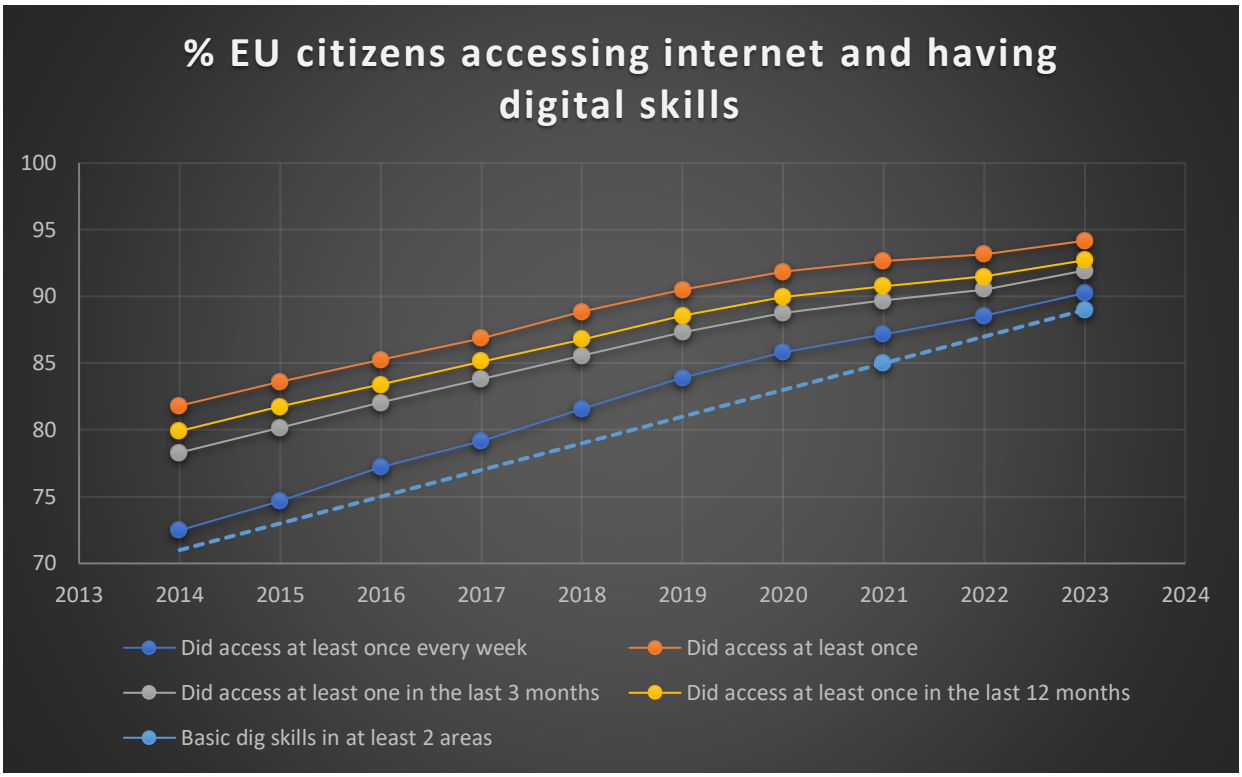

Figure 1. Internet Access (at least once a week) is at 90% and is rapidly increasing

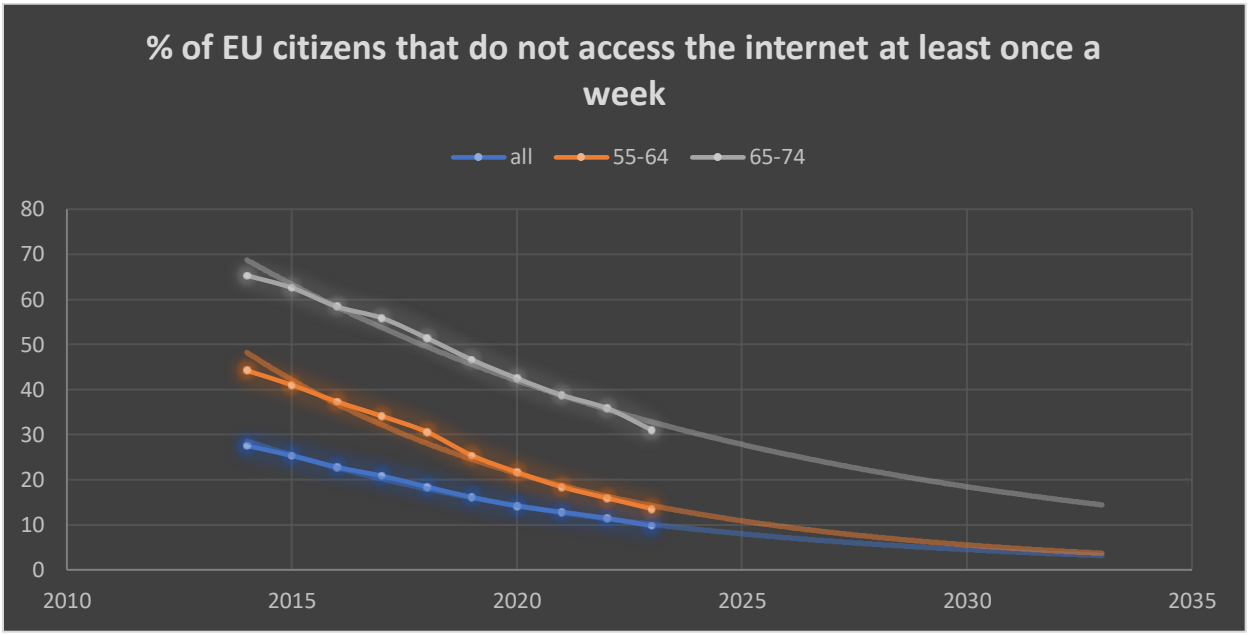

Figure 2. In 10 years from now (2034) the % of EU citizens that do not regularly access the internet will have dropped to 3% (all), 3% (55-64) and 13% (65-74).

Despite the positive trajectory towards universal internet access and increased digital skills, **the pharmaceutical industry remains committed to ensuring that no patient is left behind** in the transition from paper to electronic product information. Recognizing the importance of inclusivity, the industry is open to engaging in constructive discussions with stakeholders regarding the provision of printed information for those who may still require this or alternative ways of providing the information, thereby balancing the push for digital innovation with the practical needs of individuals dependent on traditional formats. In this regard, IATF has also developed a paper on the alternatives to the paper leaflet.

In conclusion, while **the landscape of internet access among EU citizens strengthens the case for the widespread adoption of ePI**, it is crucial to continue providing accessible medicinal information to the small minority without regular internet access. **However, maintaining the paper leaflet entirely for this ever-decreasing minority is disproportionate. Therefore, a solution that strikes a balance between completely removing paper and fully retaining paper, such as printing at the point of dispense seems to be one of the best solution at the moment. Industry has assessed potential alternatives and will discuss them further with stakeholders."**

IATF proposal for the introduction of electronic Product Information

Below, the IATF puts forward a considered proposal regarding the introduction of electronic Product Information (ePI) within the European Union (EU), emphasizing a strategic and phased approach to ensure a seamless transition from traditional paper package leaflets to digital formats.

Strategic phasing in of ePI before phasing out of paper package leaflets

IATF underscores that the phasing in of ePI (which is currently already taking place) should precede the phasing out of paper package leaflets. Several existing ePI platforms such as National Competent Authority and industry websites and compendia could be used as solutions to initiate the transition before ePI becomes fully available on the EMA/HMA portal designed as the ePI repository.

Educational and awareness campaign

A crucial component of the proposal is the execution of an educational and awareness campaign at the EU level. This campaign would aim to inform EU citizens, patients and HCPs about the introduction of ePI and its advantages, ensuring a smooth transition for all stakeholders. National specifics and preferences could be incorporated into this campaign to address the unique needs of each Member State and its citizens. In this way we aim to enhance digital health literacy through the introduction of ePI in the most optimal way.

Harmonization and implementation across the EU

The IATF proposes that implementation of ePI across the EU should be harmonized, with all member states adopting the same standard and utilizing the same portal as a repository for ePI. This will be crucial for increased efficiency, a more seamless implementation and shared learnings across the Member States.

While the standard and portal would be consistent, dissemination methods, such as apps and websites, may vary at the national level to accommodate local preferences.

This proposal aligns with the position of the EU Parliament, which supports the general introduction of ePI, the creation of a harmonized standard for ePI within one year of the revised pharmaceutical legislation coming into force, and the implementation by the EMA of a platform to host all EU ePI within two years of the legislation coming into force.

Inclusion of all medicinal products

It's important that the EMA portal should cater to both medicinal products approved by the EMA (centrally approved products, CAP) and medicinal products approved by Member States (nationally approved products, NAP, MRP, DCP). This inclusive approach ensures that all medicinal products within the EU benefit from the transition to ePI and makes the transition operationally manageable.

Proposed timelines

- Implementation of the EMA/HMA Portal: the portal is proposed to be available one year after the revised pharmaceutical legislation takes effect. From this point onwards ePI can be introduced on a voluntary basis.
- Operational Status: the portal should become fully operational at the EU level and in all Member States two years after the legislation comes into force. At this time, all system requirements should be fully implemented.
- Mandatory Inclusion of ePI: all ePI for medicines should be included on a mandatory basis four years after the legislation comes into force.

System requirements of the EMA Portal

The proposal highlights several requirements for the EMA system that should be completely implemented at the start of the operational phase, including but not limited to the avoidance of duplicative work related to submissions and maintenance of product information, interoperability with other systems, the use of structured formats and the availability of easy to use solutions for uploading ePI to the platform. The complete elimination of PDF or Word documents for submissions is also emphasized to streamline the process and enhance efficiency.

IATF proposal for the removal of the paper package leaflets

The IATF calls for a transition towards the removal of paper package leaflets into distinct phases and considerations for products administered by healthcare professionals (HCPs) and self-administered products, alongside a vision for a unified EU-wide implementation.

This proposal is designed to navigate the transition with sensitivity to the diverse needs and capabilities across the EU, while also addressing the specific requirements of different types of medicinal products.

Transition for HCP-Administered Products (products not intended for self-administration)

For medicinal products administered by HCPs, we propose to allow for **an expedited removal of paper package leaflets**. This process could commence **in all Member States immediately after the revised EU General Pharmaceutical Legislation takes effect** (using existing ePI platforms), reflecting the controlled environment in which these products are used, with direct oversight by healthcare professionals. This is as well supported by several successful pilot projects in EU Member States such as for example in

Belgium, Luxemburg, Spain and the Baltics. The decision to remove the paper leaflet remains with the Marketing Authorization Holder (MAH). This proposal has received support from the European Parliament, highlighting an agreement on the practicality and safety of accelerating the transition for these products.

Transition for Self-Administered Products

In contrast, the transition for self-administered products is more gradual. The decision to remove paper leaflets for these medicinal products could initially be taken on a Member State by Member State basis (as per the Parliament's proposal). This approach takes into account the varying levels of digital readiness and accessibility across the EU, ensuring that the transition does not disadvantage any Member State or patient group. However, this tailored approach introduces several challenges such as risk of patient confusion, increased complexity in packaging, supply chain and artwork management, implications for packaging line and technical functionality and availability concerns. As such, a pan-EU implementation through a delegated act of the European Commission the strongly preferred option after a short period of Member State by Member state implementation.

Vision for a unified EU-wide implementation

Recognizing the complexities and inefficiencies that could arise from a fragmented approach, the IATF underscores the importance of transitioning to a pan-EU implementation of ePI. This could be facilitated through a delegated act as proposed by the European Commission, which envisages a possible unified implementation 18 months after five years (6,5 years) from the legislation's entry into force. The IATF, however, advocates a more accelerated timeline, accelerated timeline for a pan-EU approach – 18 months after one year (2,5 years total) from entry into force.

IATF also emphasizes that any implementation strategy, whether initiated by individual member states or through a European Commission delegated act, should strive for simplicity and be prepared in alignment with Industry. For example, implementation timelines could be based on patient access route but should avoid overly complex criteria that could hinder the transition's effectiveness and its ultimate goals.

AESGP

The Association of the European Self-Care Industry (AESGP) is the official representation of manufacturers of non-prescription medicines, food supplements, and self-care medical devices in Europe.

efpia

The European Federation of Pharmaceutical Industries and Associations (EFPIA) represents the research-based pharmaceutical industry operating in Europe.

medicines for europe
better access. better health.

The Medicines for Europe is the official representative body of the European generic biosimilar and value-added pharmaceutical industry.

Annex

European Commission proposal	European Parliament Position	IATF proposed changes to the European Commission proposal
Article 63 of the Directive - General principles on package leaflet 1. A package leaflet shall be mandatory for medicinal products. 2. The package leaflet shall be written and designed in a clear and understandable way, enabling users to act appropriately, when necessary with the help of healthcare professionals. 3. Member States may decide that the package leaflet shall be made available in paper format or electronically, or both. In the absence of such specific rules in a Member State, a package leaflet in paper format shall be included in the packaging of a medicinal product. If the package leaflet is only made available electronically, the patient's right to a printed copy of the package leaflet should be guaranteed upon request and free of charge and it should be ensured that the information in digital format is easily accessible to all patients.	Article 63 of the Directive - General principles on package leaflet 1. package leaflet shall be mandatory for medicinal products. 2. The package leaflet shall be written and designed in a clear and understandable way, enabling users to act appropriately, when necessary with the help of healthcare professionals. 3. Member States may decide that **for individual medicinal products, categories of medicinal products or for all medicinal products,** the package leaflet shall be made available **both** in paper format **and electronically** or electronically **only. In the latter case, the decision shall be made only following a consultation of patients, carers and other relevant stakeholders**. In the absence of such specific rules in a Member State, a package leaflet **shall be made available electronically and be included** in paper format in the packaging of a medicinal product. If the package leaflet is only made available electronically, the patient's right to a printed copy of the package leaflet should be guaranteed upon request and free of charge and it should be ensured that the information in digital format is easily accessible to all patients **as well as written and designed in a clear and understandable way**.	Article 63 of the Directive - General principles on package leaflet 1. package leaflet shall be mandatory for medicinal products. 2. The package leaflet shall be written and designed in a clear and understandable way, enabling users to act appropriately, when necessary with the help of healthcare professionals. 3. Member States may decide that the package leaflet shall be made available in paper format or electronically, or both. In the absence of such specific rules in a Member State, a package leaflet in paper format shall be included in the packaging of a medicinal product**. If a Member State decides that the package leaflet shall be only made available electronically, it shall not preclude the marketing authorisation holder from providing the package leaflet in paper format in addition to the electronic format on a voluntary basis.** If the package leaflet is only made available electronically, the patient's right to a printed copy of the package leaflet should be guaranteed upon request and free of charge and it should be ensured that the information in digital format is easily accessible to all patients.

		3a (New) By derogation from paragraph 3, where the medicinal product is not intended to be delivered directly to the patient, the package leaflet may be made available electronically only.
	3a (New) If a Member State has decided that the package leaflet is only to be made available electronically, patients shall be made aware of their right to a printed copy of the package leaflet. **3b (New) If a Member State decides that the package leaflet shall be made available ectronically, a paper package leaflet in addition to the electronic format may be made available on a voluntary basis by the marketing authorisation holder in addition to the electronic package leaflet.**	
4. By derogation from paragraphs 1 and 2, where the information required under Articles 64 and 73 is directly conveyed on the outer packaging or on the immediate packaging, a package leaflet shall not be required.	4. By derogation from paragraphs 1 and 2, where the information required under Articles 64 and 73 is directly conveyed on the outer packaging or on the immediate packaging, a package leaflet shall not be required **4a (New) By way of derogation from paragraph 3, where the medicinal product is intended for dispensation and administration by a qualified healthcare professionals rather than for self administration by the patient, the package leaflet may be made available only electronically.**	4. By derogation from paragraphs 1 and 2, where the information required under Articles 64 and 73 is directly conveyed on the outer packaging or on the immediate packaging, a package leaflet shall not be required.
5. The Commission is empowered to adopt delegated acts in accordance with Article 215 to amend paragraph 3 by making mandatory the electronic version of the package leaflet. That delegated act shall also establish the patient's right to a printed copy of the package leaflet upon request and free of charge. The delegation of powers shall apply as of [OP please insert the date = five years following 18 months after the date of entering into force of this Directive].	**5. Deleted**	5. The Commission is empowered to adopt delegated acts in accordance with Article 215 to amend paragraph 3 by making mandatory the electronic version of the package leaflet **and removing the obligation to include a package leaflet in paper format in the package.** That delegated act shall also establish the patient's right to a printed copy of the package leaflet upon request and free of charge. The delegation of powers shall apply as of [OP please insert the date = ***one*** year~~s~~ following 18 months after the date of entering into force of this Directive].
6. The Commission shall adopt implementing acts in accordance with the examination procedure referred to in Article 214(2) to establish common standards for the electronic version of the package		

leaflet, the summary of product characteristics and the labelling, taking into account available technologies.	6. By ... [12 months from the date of entry into force of this Directive], the Commission shall adopt implementing acts in accordance with the examination procedure referred to in Article 214(2) to establish common standards for the electronic version of the package leaflet, the summary of product characteristics and the labelling, taking into account available technologies.	6. The Commission shall adopt implementing acts in accordance with the examination procedure referred to in Article 214(2) to establish common standards for the electronic version of the package leaflet, the summary of product characteristics and the labelling, taking into account available technologies **at the latest by [1 year after publication of the text].**
	6a (New) The Agency shall make available a system to accommodate the electronic product information after consultation with Member States and the relevant stakeholders. The system shall be available at the latest by [24 months from the date of entry into force of this Directive].	**6a (New) After consultation with Member States and relevant stakeholders, the Agency shall implement a system providing public access to the electronic version of the package leaflet, the summary of product characteristics and the labelling on the database provided in Article 138 of [revised Regulation (EC) No 726/2004] The system shall be implemented by the Agency and used by all Member States at the latest by [30 months after publication].**
7. Where the package leaflet is made available electronically, the individual right to privacy shall be ensured. Any technology giving access to the information shall not allow the identification or tracking of individuals, nor shall it be used for commercial purposes.	7. ***When accessing*** the package leaflet electronically, the individual right to privacy shall be ensured. Any technology giving access to the information shall **en*sure the protection of personal data in accordance with Regulation (EU) 2016/679 and Directive 2002/58/EC and shall*** not allow the identification***, profiling*** or tracking of individuals, nor shall it be used for commercial purposes ***including***	7. Where the package leaflet is made available electronically, the individual right to privacy shall be ensured. Any technology giving access to the information shall not allow the identification or tracking of individuals, nor shall it be used for commercial purposes.