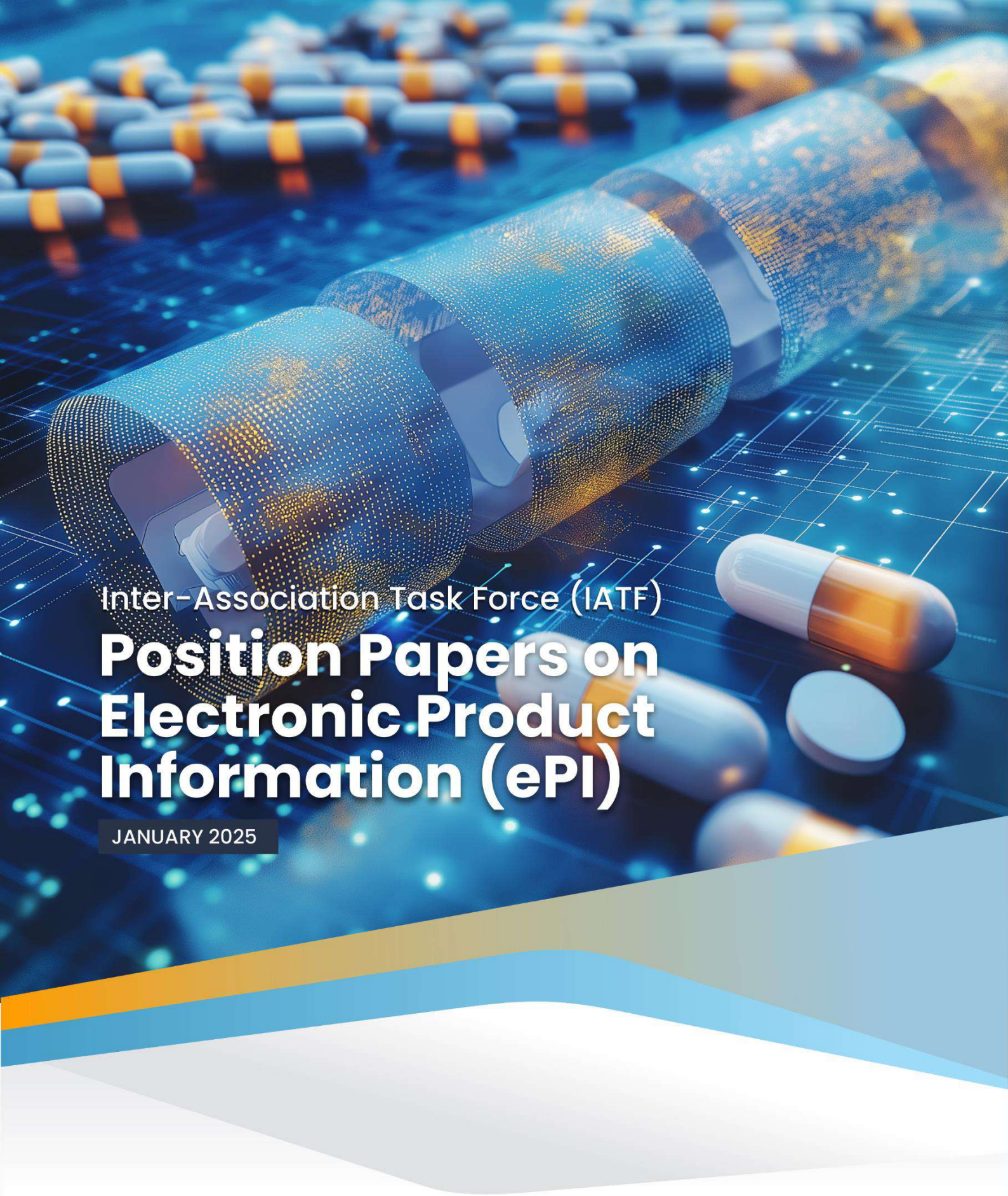

Inter-Association Task Force (IATF)

Position Papers on Electronic Product Information (ePI)

JANUARY 2025

AESGP
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Introduction

The Inter-Association Taskforce (IATF) on electronic Product Information (ePI) is a collaboration between the industry associations AESGP, EFPIA and Medicines for Europe. The collaboration started in 2016, to come up with a combined response to the Nivel Report [1]which was published in 2015.

The IATF aims to provide a representative cross-EU industry forum, which can partner with stakeholders to identify solutions, focussing on:

- Developing improved product information content, layout and readability within current and future legislation and guidance.
- Supporting the development of a standardized ePI structure and common portal as a single source of truth to facilitate data upload and dissemination of electronic product information, as well as to create regulatory efficiency.
- Stimulating the transition from paper to electronic product information to unlock value for Patients, HCPs, Consumers, Health Authorities, Industry and the Environment.
- Leveraging ePI to increase the impact and the use of the information available in the PI to drive better health literacy.

In line with these goals and in the framework of the currently ongoing revision of the general pharma legislation, the IATF has developed several papers expressing their position on (1) how to move towards ePI and the progressive removal of paper package leaflets, (2) how to practically implement ePI from a technological point of view, (3) how the content of product information can be improved and (4) how the use of multi country packs can be stimulated.

In this document we have bundled all these papers together and you can find an overview of the different papers per category below, new papers might be added to this list:

- **Moving towards ePI**
  - Phasing in of electronic product information and phasing out of the paper package leaflet
  - Alternative ways of providing the printed package leaflet of medicinal products

[1] Study on the package leaflets and the summaries of product characteristics of medicinal products for human use

- **Technological** implementation ePI:
  These papers are under discussion with EU Regulators and will be included later
  - ID Paper
  - ePI Vision

- **Content of product information**
  - Key Information Section
  - Removal of the name and address of the manufacturer in the PL
  - Position to add disposal information on the labelling of medicinal products
  - Facilitating Medicines Availability and Environmental Benefits through Language Exemptions and Electronic Product Information (ePI)

- **Support of multi-country packs**
  - Support multi country packs and simplify supply chain
  - Overview of potential obstacles for using multi-country packs caused by the proposals for the revised Pharmaceutical legislation

- **Other topics related to the Pharmaceutical Reform**
  - Awareness Cards for Antimicrobials in the EU Pharmaceutical Reform

Phasing in of electronic product information and phasing out of the paper package leaflet

Position Paper

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

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

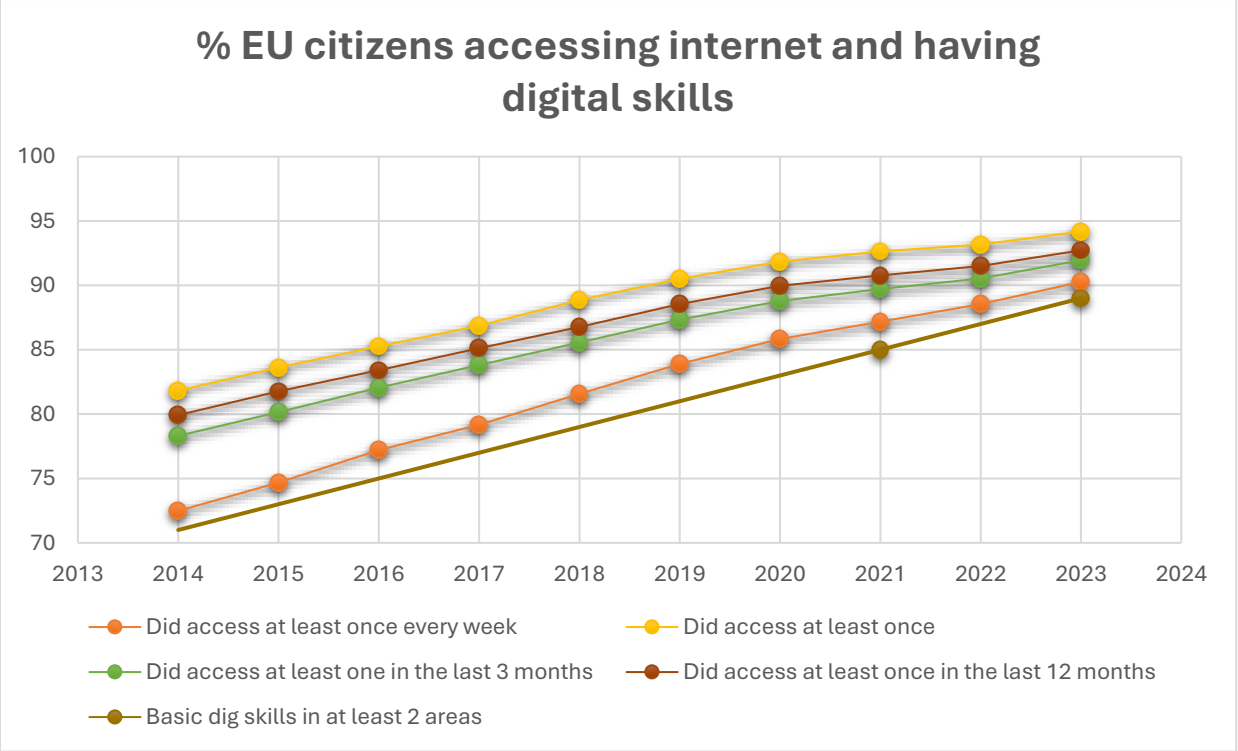

Figure 1. *Internet Access (at least once a week) is at 90% and is rapidly increasing*

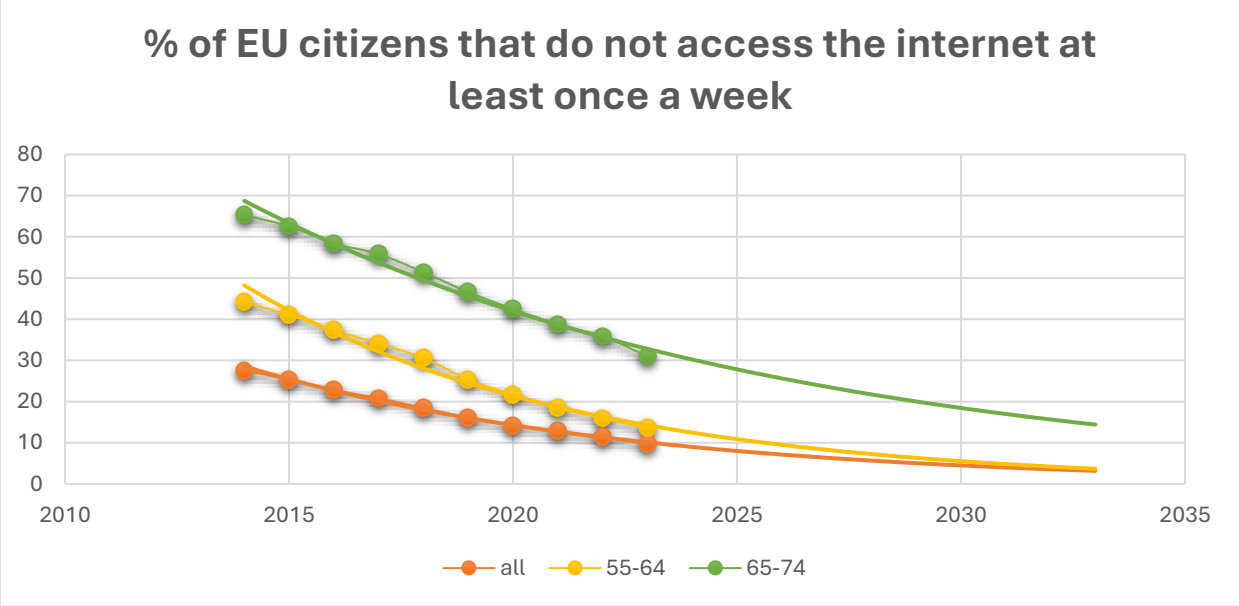

Figure 2*. In 10 years from now (2034) the % of EU citizens that do not regularly access the internet will have dropped to 3% (all), 3% (55-64) and 13% (65-74).*

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 solutions at the moment. Industry has assessed potential alternatives and will discuss them further with stakeholders."**

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.

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 underlines 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.

Alternative ways of providing the printed package leaflet of medicinal products

Position Paper

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Alternative ways of providing the printed package leaflet of medicinal products

Background

The European Commission´s (EC) draft proposal for a new pharmaceutical directive[3] introduces a new requirement for providing package leaflets electronically. Further it opens up the possibility for package leaflets to be provided electronically only in future[4], thereby facilitating the future removal of paper package leaflets which are currently provided inside the packaging of all medicinal products.

In such a transition to electronic package leaflets, it will be important to consider the needs of patients/consumers with low digital literacy, low ability to use digital devices effectively, and/or limited internet access. To this end, the EC´s draft proposal includes a clear provision guaranteeing the patient's right to a printed copy of a package leaflet upon request, at no cost to the patient, if a package leaflet is only made available electronically. This guarantee upon request was taken forward by the European Parliament (EP) in their proposed amendments to the Commission's draft proposal[5]. The EP went one step further by including an additional provision to ensure that patients are made aware of their right to a printed copy.[6]

[3] 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 (COM/2023/192)

[4] Article 63 paragraph 3 as proposed by the EC: 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.

[5] European Parliament legislative resolution of 10 April 2024 on the 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 (COM(2023)0192 – C9-0143/2023 – 2023/0132(COD)) (P9_TA(2024)0220)

[6] Article 63 paragraph 3a (new) as amended by the EP: 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.

Considering these legislative developments, this paper aims to explore and evaluate possible practical ways to fulfil the requirement of the provision of printed copies of package leaflets upon patient/consumer request. While the options discussed in this document are not exhaustive, they are intended as a starting base for discussions with relevant stakeholders, and to encourage further testing of their feasibility in pilots. The IATF duly acknowledges that the transition to electronic package leaflets will only be successful if all stakeholders work together to address the need of some patients/consumers for printed copies of package leaflets, and that they participate in a step-by-step roll-out and implementation of solutions that safeguard these patients'/consumers' needs and preferences.

Benefits of electronic package leaflets

When compared to a package leaflet provided in the medicinal product's packaging, electronic package leaflets can bring many benefits for patients/consumers, namely the:

- Provision of the most up-to-date information on a medicinal product's safety, benefits and condition of use;
- Opportunity for patients to choose out of the available authorised language versions of the package leaflet;
- Opportunity for patients to access information in large print;
- Improved access for patients to certain medicinal product that could be out of stock in a given country. Electronic product information available in several EU languages will enable manufacturers to move medicinal products easily from countries with excess supply to those where there are peaks in demand.

By having the digital version as the main source of information, and as the source of printing when requested, patients will be able to receive the most up-to-date information and, where available, in the language of their choice.

Removing the paper leaflet from the medicinal product's packaging will also bring benefits to the environment and a potential increase in the availability of medicinal products as electronic product information can support alleviation of shortages.

As technologies develop, patients/consumers will also be able to benefit from additional features of electronic package leaflets such as:

- User-friendly interfaces that support and motivate patients to read and understand package leaflet information;
- Search functionalities for quick access to specific content;

- Further accessibility functions for users with diverse abilities (e.g. text to speech, adaptable font size/zoom);
- Additional regulator-approved information material (e.g. instructions for use in video format);
- Incorporated electronic notifications of safety alerts (e.g. new information on side effects);
- Customization of the information relevant for a specific patient.

Therefore, it is important that stakeholders at the same time as addressing ways of providing printed copies of the package leaflet, also continue working together to tackle digital literacy and access issues so that patients/consumers can reap the full benefits of electronic package leaflets over time.

Exploring alternative ways of providing the paper version

AESGP, EFPIA and Medicines for Europe have come together under the IATF umbrella to discuss various ways of providing a printed copy of the electronic leaflet to patients.

This document does not contain a complete list of all the ideas that were discussed in the IATF´s meetings. It does, however, present three promising options which warrant further exploration.

These are:

1. Printing by a professional such as the medicinal product dispenser/seller or care provider, (e.g. at a pharmacy, health care centre, patient or elderly care facility)

… and two self-service solutions:

2. Printing by the patient at a self-service printing kiosk located within a pharmacy, retail outlet, health centre or hospital, and
3. Printing by the patient at a self-service kiosk at a community printing hub in a suitable public location

All three options anticipate using scanning technologies with existing 2D data matrix codes or linear barcodes on the medicinal product packaging. This will safeguard that the correct leaflet for the dispensed or sold medicinal product is always printed, avoiding potential errors from manually searching for a specific leaflet.

The positive and negative aspects of these three options are compared in more detail in Appendix I together with additional reflections and considerations for implementation.

Printing by a medicinal product dispenser/seller or care provider requires interaction with a third-party at the point of sale/care and will add additional workload to dispenser/seller or care provider. From the patient's point of view though, this may be the most convenient solution, and the interaction between

the patient and the dispenser/seller or caregiver could have added benefits, such as providing opportunity to read or discuss parts of the package leaflet together with a qualified professional.

The two self-service solutions for printing don't require interaction with a third-party, but some patients may need help to handle them. They are probably more suitable for digitally educated individuals and urban areas with accessible public premises for placing the necessary technical equipment.

Each of the three solutions differ in terms of their implementation, accessibility, and suitability for different patient demographics and locations.

In addition, each option has practical and financial implications, which need to be analysed further. The recommended solutions need to be tested by real-life pilots to see if the practice matches the vision, to familiarize patients, and to foster dialogue and collaboration amongst stakeholders.

Other possible solutions were considered but not discussed in detail in this paper. These included courier delivery of package leaflets upon prescribing, and the delivery of printed resources by the manufacturer. However, these options had a higher number of negative aspects, such as reduced timeliness of information, and difficulty keeping the information up-to-date.

Besides the three options discussed for providing printed copies of electronic package leaflets, in the transition to electronic package leaflets, it is also important that varying ways of accessing the electronic package leaflet digitally are developed which accommodate varying digital literacy levels. Options such as secure email to patients which could utilise existing dispensing software, and the use of patient portals could be explored. This could reduce on the number of requests for printed copies of the electronic package leaflet.

Finally, it is anticipated that a combination of approaches for providing package leaflet information will be needed to best serve diverse patient/consumer needs and preferences. Additional support services such as toll-free information numbers and helplines already established in some regions could also be considered to further support patients/consumers with questions about the package leaflet.

Conclusion

After analysing alternative ways of providing paper package leaflets to patients, the IATF recommends that several solutions should be considered and sometimes having a combination of multiple solutions might be the best for patients/consumers.

There will be no "one-size-fits-all" solution in Europe, so we need to define the best possible approach in a particular country/region while making use of already existing processes, services and infrastructure of each country/region. We also need to take into consideration the variety of types of products, patients, consumers and ways of supplying and dispensing medicinal products in a specific country.

The IATF recommends that these proposals are discussed and analysed further with stakeholders and are tested by real-life pilots to confirm if they are viable in terms of implementation, acceptance, and to familiarize patients/consumer with the concept of electronic package leaflets.

The IATF believes that electronic package leaflets will offer additional value compared to paper package leaflets and calls for an open dialogue between all stakeholders on recognition of electronic package leaflet as the main source of information to patients.

The IATF´s ultimate aim is to ensure that no patient is left behind in the transition from paper leaflets to electronic leaflets. We are open to engaging in constructive discussions with stakeholders on the provision of package leaflets, recognizing the importance of balancing digital innovation with the needs of those requiring traditional formats.

Appendix I – Comparison of ways of providing the printed copy of a package leaflet of a medical product

The tables below compare three possible ways to provide a printed copy of package leaflets to patients and consumers of medicinal products upon request. The three options listed are not exhaustive. This considers a future scenario where package leaflets are provided *electronically only* and are no longer required inside the packaging of each medicinal product.

The tables below aim to describe the potential positive and negative aspects of each method and offer some additional reflections and considerations for implementation.

Method 1	PRINTING BY MEDICINAL PRODUCT DISPENSER, SELLER OR CARE PROVIDER
Description	Printing by a professional such as the medicinal product dispenser/seller, or other care provider including health centres, patient or elderly care facilities.
Positive aspects	▪ Patient gets immediate access to the printed package leaflet together with the medicinal product at the point of dispensing or sale. ▪ Patients are served directly by the dispenser/seller/care provider, offering an opportunity for a verbal explanation of the leaflet and answering of queries from a qualified professional. ▪ Expected to be the most supportive option for people with a disability, those socially disadvantaged or with limited digital literacy as they are not required to print the leaflet themselves. ▪ A specific language or large print could be selected for printing depending on the patient's needs.
Negative aspects	▪ Additional workload for medicinal product dispenser/seller/care provider to print the leaflet. ▪ May undermine adoption of electronic package leaflets. If patients can request a printed copy, they might request one every time rather than learning to access the electronic package leaflet themselves.
Additional considerations	▪ Agreements to be made on compensation for initial set-up and consumable costs of printing. ▪ Seamless integration of printing into prescribing/dispensing/retail software will support service. ▪ Balance the need to ensure those with low digital literacy or limited internet access receive printed leaflets, while also encouraging wide-spread adoption of electronic package leaflet amongst those not facing these challenges. ▪ Public awareness campaigns will be needed to explain to patients how to use electronic labelling. ▪ Best practice for provision of printed copies of package leaflets needs to be developed considering initiation of new treatments, long-term treatments. ▪ Consideration of all dispensing scenarios including the use of robotic dispensers/vending machines where there is no face-to-face interaction with the pharmacist as well as general sale category where there is no interaction with a healthcare professional.

Method 2	SELF-SERVICE PRINTING KIOSK
Description	Printing by the patient/consumer at a self-service kiosk or printing station located within a pharmacy, retail outlet, health centre or hospital. Comparable to the likes of an ATM, self-check in kiosk at airports, or a retail self-checkout kiosk, but which allows users to print package leaflets.
Positive aspects	▪ Able patient/users can print the leaflet themselves. Dispenser/seller/care provider can utilise their time for other services. ▪ While not at the immediate point of dispensing/sale, the patient/consumer gets quick, almost immediate, access to the package leaflet (i.e within the building/vicinity of dispensing/sale/care). ▪ Dispensers/sellers/care providers would be nearby to direct patients/customers to the kiosk and offer support or instruction to users if needed. ▪ Users could self-select their preferred language out of available options and font size for printing. ▪ Similar to self-service kiosks used in other sectors (e.g. banking, travel, retail) making it a relatively intuitive and familiar solution for many users.
Negative aspects	▪ This additional printing kiosk would need an initial investment and maintenance (IT, paper, toner, etc). ▪ Due to the cost associated, most appropriate as an option for outlets serving a larger population – e.g urban pharmacies, retail chains, large retail centres, and large health centres; less practical for smaller pharmacies, retail outlets, or health centres outside of large urban areas. ▪ More burdensome for the patient/consumer than receiving the leaflet directly from the dispenser/seller/care provider. Some patients may find it difficult or may prefer not to use a self-service kiosk. ▪ Demand in printing can be expected to decrease over time as uptake of electronic package leaflet increases. Risk of kiosks becoming obsolete over time.
Additional considerations	▪ Agreements to be made on compensation for initial set-up and consumable costs of printing as well as management of maintenance and regular servicing. ▪ A simple, intuitive interface with user-friendly instructions would have to be provided. It can be expected that assistance from personnel would be needed, particularly in the beginning of implementation. Training would be required for dispenser/seller/care providers who may need to assist users with the kiosk.

Method 3	SELF-SERVICE COMMUNITY PRINTING HUB
Description	Printing by the patient or consumer at a self-service kiosk or printing station located in a suitable public location within the community. Comparable to the likes of an ATM, self-check in kiosk at airports, or a retail self-checkout kiosk , but which allows users to print package leaflets
Positive aspects	▪ Able patient/consumers can print the leaflet themselves. Dispenser/seller/care provider can utilise their time for other services. ▪ While not at the immediate point of dispensing/sale, the patient gets quick access to the package leaflet (at a nearby public location within their community). ▪ Users could self-select their preferred language out of available options and font size for printing. ▪ Similar to self-service kiosks used in other sectors (e.g. banking, travel, retail) making it a relatively intuitive/familiar solution for many users. ▪ Placement in locations within the community would allow one kiosk to serve a larger number of patients/consumers compared to placement in each health centre, pharmacy or retail outlet.
Negative aspects	▪ Requires patient/consumer to visit another premises. ▪ Potential increased risk that the patient/consumer doesn't print out their leaflet compared to when printing facilities are located at or near to the dispenser/seller/care provider. ▪ Requires buy-in from suitable locations in the community. This additional printing kiosk would need an initial investment and maintenance (IT, paper, toner, etc). ▪ Demand in printing can be expected to decrease over time as uptake of electronic package leaflet increases. Risk of kiosks becoming obsolete over time.
Additional considerations	▪ Agreements to be made on compensation for initial set-up and consumable costs of printing as well as management of maintenance and regular servicing. ▪ A simple, intuitive interface with user-friendly instructions would have to be provided. It can be expected that assistance from personnel would be needed, particularly in the beginning of implementation. Training would be needed for personnel who may need to assist users with the kiosk. ▪ Opportunity for multi-functional printing kiosks – other uses by other sectors. ▪ Appropriate locations need to be identified but considerations could be post offices, citizens advice centres, town halls, libraries, community hubs. This choice may be different depending on country.

“Key Information Section” in the Package leaflet

Position Paper

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"Key Information Section" in the Package leaflet

Recommendation

An additional Key Information Section should **not** be introduced in the package leaflets.

This position is based on the following considerations:

Current absence of legal basis for the proposal

Any form of guidance developed must be compliant with the pharmaceutical legislation and must not go beyond any applicable legal requirement as set out in the legislation.

Introducing the Key Information Section or - in other words – a new requirement with which MAHs are expected to comply in practice and for which there is no legal provision would undermine legal certainty.

Challenges for the selection of the content of the Key Information Section

- Who will decide on what is key to include in this section and what should be considered key safety messages? Every patient needs the information that is relevant for him/her, so what is key for one person may be irrelevant for another (e.g. different information sought by a young pregnant woman versus an older man with multiple medications and renal dysfunction). Also, what is not key for most patients might be highly important for a small number of patients. So, providing adequate and relevant key information for all patients and users is challenging. When it comes to safety information such as contraindication or warnings and precautions, making a selection could be life-threatening for patients not reading the full leaflet. In addition, with the listing of side effects, the notion of severity (and what actions to take if they occur) or frequency would be lost. Making a selection among side effects could imply that some events are to be considered less important than others, while some of these common events may be "precursors" of very serious reactions. For products having more than one indication, the complexity would be even increased, as it would be very difficult to selecting the "main goal" treatment among many indications. All in all, the Key Information Section would be an even more disproportionate representation of benefit and risk. It is still unclear and questionable how this will be of general benefit for the patient, nor will it improve the observance issue.

- If safety information is updated (for example following PRAC recommendation), who decides what the impact for the Key Information Section is?
- It would be difficult to keep the Key Information Section to a summary format (small size), especially for complicated/specialised products, and to maintain balance between benefit/safety/risk for compliance.
- Patients may only rely upon this Key Information Section, therefore not reading the full leaflet and potentially missing important information relevant to them. A disclaimer would be needed, even prolonging the text more. Not having information in the KIS may also imply that the information is of lesser importance which is not actually the case (e.g. storage conditions)
- There is a risk of liability issues as it might give a false reassurance to patients that reading the Key Information Section is sufficient for the safe use of medicines.

Concern for increase of leaflet size

- Adding a Key Information Section will increase the size of the leaflet, while many patients already indicate that the leaflet is too long. It will thereby counteract our objective to shorten the leaflet.
- There would be redundancy between information in the Key Information Section and the rest of the leaflet, meaning patients could become overwhelmed as they would need to read more information if expected to still refer to the complete leaflet (i.e. the overall length of the leaflet increases).
- Cartons/boxes may not be able to accommodate a longer leaflet, especially for very small packaging, and this can have impact on supply chain and manufacture (packing lines and processes). Additionally, we have to take the environmental aspect into account.
- Alternatively longer leaflets (especially multilingual leaflets) may also require smaller font sizes, which is not possible as it would impair reading.

Leaflets with multiple languages and multi-country packs

The requirement for multiple languages is already a huge challenge for most products, as there is a limit for the size of a paper leaflet. Adding the Key Information Section to any leaflet in multiple languages will increase this challenge.

Many efforts are done by the regulators to support multi-country packs with the aim to increase availability of medicines, mostly by shortening the information to be included in the leaflet or by applying language exemptions. The requirement of having a Key Information section will significantly increase the amount of information to be included in the leaflet and therefore jeopardize these efforts, as the physical

leaflet will likely be too long to accommodate the multi-country pack. Decreasing font size is not a solution and would be necessary beyond any reasonable and acceptable limits.

Regulatory Burden

- Adding this new section would require regulatory assessment of all new leaflets, which will increase the workload for both industry and regulatory authorities. As authorities already identified there is a problem of resources to handle the current workload, there is a concern that need for assessment of the addition of a Key Information Section to all leaflets will result in extended assessment timelines due to lack of resources to deal with this.
- Implementation timelines as well as defining the submission type through which this new section needs to be introduced will be an additional challenge. For example, a PRAC recommendation may lead to a 're-discussion' on the content of the Key Information Section and hence would become a type IB and not a type IA.
- In addition, this summary would need to be 'reviewed' with every change of the leaflet, which may add another level of complexity. A review of the data at each update of the leaflet as well as ensuring consistency and accuracy of this section will be time-consuming and resource intensive.
- The task of maintaining version control and ensuring content accuracy throughout all sections of the leaflet is considerably heightened with the inclusion of a separate section, introducing challenges to the overall integrity of information presented.
- Harmonisation of safety information is currently an issue; this will be further enhanced with the Key Information Section. Indeed, same medicinal products (same substance or combination) - with different MAHs - have different leaflets. At this stage core leaflets were established for very few medicinal products (i.e. Hormone Replacement Therapy). Thus, the Key Information Section for the same medicinal product will be different from one MAH to another. There are uncertainties on whether the regulators will coordinate the content of the Key Information Section, especially for the same medicinal products.
- The readability testing process will be impacted as all pharmaceutical companies would require a user testing with the addition of this section. There is concern that readability user testing companies may be overwhelmed and unable to cope with the workload required to perform this exercise in a timely manner.
- Education of the public on this new section: is it foreseen to educate the public on this new section? Would this be done by Industry or Health Authorities? There will be an impact on healthcare professionals who may receive more queries from patients and carers; healthcare professionals might therefore require support. The potential need for educational material, which would need to be assessed, would be an additional step/workload and burden to consider.

Patients and Future potential solutions

We can understand the fact that some patients may find the idea of a summary very appealing and to read only a subset of the information. However, it is considered that this new section would create an inconsistency of Key Information Section available for medicinal products on the market containing the same substance (or substance class), which would be confusing, especially for identical medicinal products with the same indications. Further confusion would arise if information previously present in the Key Information Section is removed to be replaced by more serious information and give the impression that what was previously included is no longer applicable. This could create anxiety in chronic patients. Interchanging medicinal products with different Key Information Sections could also be destabilising for patients and carers.

The inconsistency of the Key Information Section in package leaflet is considered detrimental as it could lead to misinterpretation of the safety and efficacy profile of medicinal products by patients, carers, and healthcare professionals. – especially in the case the patient reads only the Key Information Section.

As work is ongoing to shorten the leaflet within the current legal framework, we are concerned that patients will base their opinion on the leaflet as they know it today; whereas the content of the leaflet of tomorrow should be shorter, more patient-centric and further taking into account patients' needs. We believe it will be very difficult to implement a Key Information Section and overall, there are more downsides than advantages.

The main criticism of the leaflet is that they are too long, and this problem should be solved instead of adding more content to the leaflet. Proposals have been made already in cooperation with stakeholders and are under evaluation.

The transition to digital versions will also support navigation and give a better overview, search functions for example will additionally increase usability of the leaflet.

Case study 1

MAH A and MAH B both own marketing authorisations of Medicinol 500mg : Medicinol A, 500mg and Medicinol B 500mg.

Below steps are considered to be taken by MAHs to include this new section:

- Assessment, drafting, and review of information to generate a Key Information Section,
- Liaising with artwork, packaging to evaluate the new size of the package leaflet,
- Readability testing,
- Submission and assessment by Health Authorities,

- Update of the package leaflet based on the implementation timelines provided and the lifecycle of the medicinal product.

Both MAHs perform this exercise and provide different Key Information Sections. MAH A only market its product in one country with a single language and the packaging is not impacted by the new section. MAH B markets its product in Belgium where 3 languages need to be included; the packaging needs to be adapted to fit the longer leaflet which has an impact on timeline and availability.

MAH A and MAH B submit to different Health Authorities who make adjustment to the proposed wordings, this further enhances the differences between this section for the same medicinal product with the same indications. Moreover, due to the varying lifecycle of the medicinal products, MAH A and MAH B have their information updated with a gap of 1 year.

Case study 2

MAH A and MAH B both own marketing authorisations of Medicinol 200mg: Medicinol A 200mg and Medicinol B 200mg.

Medicinol A 200mg is a CAP whilst Medicinol B 200mg is a NAP. As above, MAH A and MAH B submit to different Health Authorities and the resulting Key Information Section is different.

Let's consider a patient who usually purchases Medicinol A but only gets a hold of Medicinol B. Upon reading the Key Information Section, which is different, considers the product to not be equivalent and refuses to use the medicine.

Conclusion

These case studies highlight that it will be inevitable to have varying information across Key Information Sections, which could lead to misinterpretation and misunderstanding of the safety and efficacy of medicinal products. As the Key Information Section is given so much prominence, this will be the main section considered by some readers, and the rest of the package leaflet might not be read. Moreover, as key information is subjective and different based on the individual reading the leaflet, this new section will not be beneficial to all readers.

This section will create tremendous workload, additional resources will be required on both industry and Health Authorities side. It will add complexity to the current process, lengthen the package leaflet, complicate multi-country packs and changes to packaging at the very least.

As such, from an industry perspective, we consider the introduction of a Key Information Section more disruptive than beneficial for understanding and interpreting the safe and effective use of medicinal products.

The *European Parliament Position on the General Pharmaceutical Legislation Review refers to* **a Key Information Section in Amendment 336 Proposal for a Directive - Annex VI – paragraph 1 – point 2 a (new).**

Removal of the name and address of the manufacturer in the PIL

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Removal of the name and address of the manufacturer in the PIL

Recommendation

The name and address of the manufacturer should be **deleted** in the package leaflets.

Current situation

- According to Article 59f of Directive 2001/83, the package leaflet shall include, among other things, the name and address of the marketing authorisation holder and the name and address of the manufacturer. The annotated QRD template particularises it by stating that this should be the manufacturer responsible for batch release.
- If the marketing authorisation holder and the manufacturer are the same, the name and the address have to be stated just once under the general heading "Marketing Authorisation Holder and Manufacturer".

Considerations for removal of manufacturer in the PIL:

Reduction of complexity for patients

- At the moment it is not clear and confusing for the patient whom to contact if there is a quality or safety issue, namely the MAH or the Manufacturer.

  Usually the MAH is located in the country where the patient has gotten the medicinal product, whereas the manufacturer is usually located somewhere in the EU. Most likely, the patient will get in touch with the entity that is located in the home country anyway. Therefore, the likelihood that the manufacturer will ever be contacted tends towards zero.
- There is no added value for the patient in having both in the PIL, MAH and the manufacturer.
- Section 4 of the PIL, includes additional contact information for the patients where they should report any side effects they may experience.
- The removal of the manufacturer would make it much clearer and less confusing for the patient. Consequently, there would be two points of contact for the patient.

Reduction the amount of text in the PIL

- In the NIVEL report and from patient feedback from various user tests the length of the PIL was identified as the main issue. Efforts must be made to shorten the PIL wherever possible.
- In workshops with User Testing companies "manufacturer" was mentioned most often to be deleted
- Remove details that are not relevant to make space for more patient relevant safety information.

Streamlining the packaging process

- Consumers perceive the manufacturer as the company that has physically produced the medicinal product, which is in reality not often the case. Basically, it is the final step in manufacturing acting as the batch release site within the EU which could also be done just by signature.

  It is of no added value for the patient to have the address of the batch release site stated in the PIL.
- When a product has multiple release sites registered, it creates the need for different versions of the package leaflet, leading to increased complexity.

Liability[7,8]

- From a legal perspective the overall responsibility for a medicinal product lies with the MAH (Article 6 of Directive 2001/83). Throughout the life of a medicinal product, the MAH is responsible for the product which is placed on the market (Notice to Applicants volume 2A chapter 1)
- As indicated in Annex 16 of the GMP Guide[9], the ultimate responsibility for the performance of a medicinal product over its lifetime, its safety, quality and efficacy, lies with the MAH.
- According to the reflection paper on Good Manufacturing Practice and Marketing Authorisation Holders[8], the GMP guide also does not provide for reduced MAH responsibilities (or for the delegation of responsibilities) in situations where the MAH and the manufacturer belong to the same overall group of companies but where the two companies are different legal entities. There is no difference

[7] EudraLex Volume 4 EU Guidelines for Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use

[8] Reflection paper on Good Manufacturing Practice and Marketing Authorisation Holders (EMA/419571/2021, 10 January 2022, Version 2)

[9] EudraLex Volume 4 EU Guidelines for Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use - Annex 16: Certification by a Qualified Person and Batch Release

in the responsibilities that apply to the MAH in this situation relative to when the MAH and the manufacturer are from separate and unrelated companies

- According to chapter 7 of the GMP Guide[10] appropriate arrangements should be in place where the marketing authorisation holder and the manufacturer are not the same.

[10] EudraLex Volume 4 EU Guidelines for Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use - Chapter 7 - Outsourced activities

Adding Disposal Information on the Labelling of Medicinal Products

Position Paper

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Adding Disposal Information on the Labelling of Medicinal Products

Recommendation

The IATF supports the current requirements concerning labelling disposal information on medicinal products. It is against change because the current system works well and national disposal system (and their respective logos) used at national level are known by users.

Should the EP proposal become the final legal text, we recommend adding a common EU logo on the outer packaging and linking it to the corresponding EU website in the package leaflet.

Problem Statement

The current European Commission (EC) requirements concerning the addition of disposal information on the label (secondary packaging or immediate packaging where there is no secondary packaging) and on the Summary of Product Characteristics (SmPC) are proposed to be made obligatory by the European Parliament (EP) in its report due to the removal of the case-by-case approach. The requirement concerning the leaflet is left unchanged but making it mandatory on the SmPC will have a direct impact on the leaflet content.

Current legislation	EC proposal	EP proposal
TITLE V LABELLING AND PACKAGE LEAFLET Article 54 The following particulars shall appear on the outer packaging of medicinal products or, where there is no outer packaging, on the immediate packaging: *4 (j) specific precautions relating to the disposal of unused medicinal products or waste derived from medicinal products, where appropriate, as well as reference to any appropriate collection system in place;*	**Annex IV, paragraph 1, point j (outer packaging)** The following particulars shall appear on the outer packaging of medicinal products or, where there is no outer packaging, on the immediate packaging: *[…] specific precautions relating to the disposal of unused medicinal products or waste derived from medicinal products, **where appropriate**, as well as reference to any appropriate collection system in place;*	*(j) Specific precautions relating to the disposal of unused medicinal products or waste derived from medicinal products as well as reference to any appropriate collection system in place*
Article 11 6.6. special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product, if appropriate.	**Annex V, paragraph 1, point 6, point f (SmPC)** […] special precautions **for** disposal of **a used** medicinal product or waste materials derived from **such** medicinal **product**, **if appropriate**.	(f) Specific precautions relating to the disposal of unused medicinal products or waste derived from medicinal products as well as reference to any appropriate collection system in place

According to Article 127b of Directive 2001/83/EC as amended, Member States shall ensure that appropriate collection systems are in place for unused or expired medicinal products. The take-back schemes have been implemented throughout the EU, but the specific dispositions may vary between Member States.

Industry supports efforts to foster and promote correct disposal of medicines. However, the differences in implementation of the take back scheme requirements across the EU mean that the disposal statement on the product packaging may differ from one country to the other.

Thus, mandating the specific precautions related to the disposal of unused or expired medicinal products on the packaging is of particular concern in case of:

- limited packaging size; and/or
- multi-country packaging (provided the disposal between neighbouring countries is different).

Adding this information may be challenging for small packs or packaging that already contains many statutory requirements (e.g. instructions on use). Increasing the size of packaging to fit all information would also be contrary to the general EU objective to limit waste and reduce packaging sizes promoted in the Green Deal.

Proposed Solution

First and foremost, we advocate in favour of keeping the current wording as proposed by the European Commission which is risk-based and has proven effective in its implementation.

If the requirement is made mandatory according to the EP proposal, then we propose the following:

According to the EC proposal Article 73:

> *"the outer packaging and the package leaflet may include symbols or pictograms designed to clarify certain information set out in Articles 64(1) and 65 and other information compatible with the summary of product characteristics that is useful for the patient, to the exclusion of any element of a promotional nature".*

Instead of adding a reference to the local disposal system (take-back scheme), we suggest adopting a common EU logo and website that would centralise disposal information for all EU countries. This common EU logo could be added on the outer packaging of the medicinal product, referring to the website, and the link to the EU website could be added to the package leaflet.

If a common EU logo is affixed to the packaging of medicines, communication should be organised at a national level to make people aware of the correct way to dispose of medicines consulting the website for further information.

We believe that the use of a common EU logo and website will ensure access to up-to-date information for the benefit of all. It will also enable patients traveling or moving abroad to know how to dispose of their medicines correctly in their destination country. It will enable effective communication and avoid confusion between the different national logos that could be used for multi-country packaging.

The proposed solution is in line with the objectives of the Green Deal and packaging reforms in Europe because it does not contribute to increased packaging.

We recommend adopting a common EU logo on the outer packaging and linking it to a corresponding EU website in the package leaflet.

NOTE: We agree to list product-specific warnings where appropriate as it is already the case today (e.g., insulin pen) but the concern has to do with the general information on disposal of medicinal products.

Case Study

MedsDisposal is a European campaign to raise awareness on how to dispose of unused or expired medicines appropriately in Europe, bringing information on current disposal schemes in European countries to one place. It is a joint initiative between healthcare professionals, industry, and pharmacist student associations.

The MedsDisposal websites features an interactive map of Europe which, when a user clicks on a given country, provides a summary of the requirements for the disposal of medicines, with links to national website. The website is regularly updated with the latest recommendations on the disposal of medicines in the countries covered.

The logo has been designed combining the well-known recycling arrows and medicinal products symbolised by pills.

The MedsDisposal initiative was recognised among good practices by the OECD's Environment Directorate in their 2021 report on the Management of pharmaceutical household waste: Guidance for efficient management of unused or expired medicine.

This initiative, including the website and logo, could be adopted after further adaptation for official use in the EU.

Facilitating Medicines Availability and Environmental Benefits through Language Exemptions and Electronic Product Information (ePI)

Position Paper

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Facilitating Medicines Availability and Environmental Benefits through Language Exemptions and Electronic Product Information (ePI)

Executive Summary

The Inter Association Task Force (IATF) on Electronic Product Information (AESGP, EFPIA and Medicines for Europe) advocates for the strategic facilitation of Multi-country packs (MCPs)[11] through language exemptions, with electronic Product Information (ePI) serving as a pivotal tool in this process. Multi-country packs stand to significantly enhance the availability of medicines across the European Union (EU), especially benefiting smaller markets and small volume products with the opportunity to enhance patient access to medicines. However, the implementation of multi-country packs using multiple languages on the pack and the Patient Information Leaflet by creating multi-language packs (MLPs) has encountered numerous challenges, including regulatory complexities, packaging constraints, and environmental concerns.

The IATF advocates for language exemptions as a direct solution to these issues, with ePI providing the necessary flexibility and accessibility to all language versions to support this approach. This position paper outlines the advantages of multi-country packs, the challenges encountered with multi-language packs, and presents a comprehensive case for the adoption of language exemptions facilitated by ePI.

For HCP-administered products, a custom language exemption allowing the use of a single appropriate language is proposed, supported by the high level of internet access among healthcare professionals (HCP). For self-administered products, language exemptions could be granted either through a general

[11] Multi country packs are defined as medicine packs that can be used in multiple countries either by using language exemptions or by including multiple languages on the pack. Multi language packs are defined as packs containing multiple languages and are one possibility to create packs that can be used in several countries.

exemption by the Member State or through case-by-case approvals upon reasoned request by the Marketing Authorization Holder (MAH).

These language exemptions should be made possible through the currently ongoing revision of the pharmaceutical legislation and should be facilitated by collaborative efforts among industry stakeholders, regulatory bodies, and Member States to establish clear guidelines and frameworks to support this transition, aiming to streamline the pharmaceutical supply chain and enhance its sustainability.

The Advantages of Multi-Country Packs

Throughout the document multi country packs are defined as medicine packs that can be used in multiple countries either by using language exemptions or by including multiple languages on the pack. Multi language packs are defined as packs containing multiple languages and are one possibility to create packs that can be used in several countries.

Multi-country packs, enabled by language exemptions, provide several key benefits:

1. **Enhanced Medicine Availability**: By simplifying packaging requirements, multi-country packs can be more easily reallocated across Member States, addressing shortages and ensuring wider access to medicines for consumers/patients.
2. **Supply Chain and Logistics Flexibility:** The ability to produce larger batches for multi-country packs improves supply chain flexibility, crucial for responding to unprecedented events and fluctuating market demands and ensuring the availability of medicines, especially benefiting smaller markets and small volume products such as orphan medicines.
3. **Environmental Sustainability:** Language exemptions, by reducing the need for multi-language packaging and multi-language package inserts, can significantly decrease the environmental footprint of pharmaceutical products.

Despite these advantages, the current approach to using multi-lingual approaches to stimulate multi-country packs has faced substantial barriers related to the inclusion of multiple languages on the pack and in the package leaflet.

Challenges with Multi-Language Packs (MLPs)

Several commendable attempts and efforts have been made (e g by CMDh) to stimulate the use of multi-language packs. The relatively limited use in some countries is probably caused by the many hurdles related to the implementation of these multi language packs, as listed below:

- The use of a large number of languages on the pack and in the patient information leaflet can cause confusion amongst patients.
- The additional complexity introduced by different national requirements in terms of approval and implementation timelines, HA labelling requirements, etc. This can lead to significant delays for MLPs compared to mono-lingual packs.
- Lack of space for the EU (reduced) harmonized labelling text in the applicable languages.

- Lack of space for the different blue boxes as some member states require a significant amount of information in the blue box, for example non-harmonized waste directive requirements or symbols such as warning triangle and warning sentences regarding driving vehicles and handling machines.
- The need for larger boxes and larger Patient Information Leaflets (PILs) which has a negative environmental impact and which also may lead to the introduction of larger boxes. This could also lead to space issues at pharmacy level.

The Case for Language Exemptions and ePI

Contrary to the implementation of multi-language packs, the use of language exemptions is linked with few hurdles and offers a solution to the implementation of multi-country packs, facilitating medicines availability and environmental benefits.

A distinction must be made between two categories of medicinal products based on their mode of administration. On one hand, we have products administered by healthcare professionals (HCP-administered products), and on the other hand, products intended for self-administration by patients. This distinction is pivotal because it necessitates different approaches towards the implementation of language exemptions and the transition to Electronic Product Information (ePI).

HCP-Administered Products

For HCP-administered products, multi country packs could be stimulated in countries that share the same route of administration by a custom language exemption. HCP-administered products – independent from whether they are dispensed in a hospital pharmacy or community pharmacy - are exclusively administered to the patient by healthcare professionals who, due to their high level of education and professional requirements, possess the ability to understand and communicate in several European Union (EU) languages[12]. Moreover, healthcare professionals typically have ready access to the internet, enabling them to easily access detailed information about medicines, including Electronic Product Information (ePI), online. Eurostat data shows that the level of internet access by highly educated individuals (tertiary education) is currently at 98% throughout the EU.

Given these factors, a complete and custom language exemption can be applied to HCP-administered products, allowing for the use of a single, pre-approved and appropriate language upon notification of the Health Authority by the Marketing Authorization Holder (MAH).

[12] Foreign language skills statistics - Statistics Explained (europa.eu)

In alignment with the recent plenary vote within the EU Parliament on the revision of the EU Pharma Legislation, the paper Patient Information Leaflet (PIL) for these products could be removed immediately following the enactment of the new pharmaceutical legislation. This possibility is supported by several currently ongoing pilots in the EU that show the feasibility of removing the paper leaflet for HCP administered products. This move towards digital, making PIL and packaging information available in all relevant languages through the European Medicines Agency (EMA) repository, reflects a broader recognition of the digital proficiency and professional context of healthcare providers.

Products for Self-Administration

The approach towards language exemptions for products intended for self-administration by patients requires more careful consideration of the specifics of the medicinal product (such as for example therapeutic class and chronic or acute use) as well as the patients' access to digital resources and digital and linguistic capabilities.

Internet Access (at least once a week) is at 90% in the general EU population and is rapidly increasing. In 10 years from now (2034) the percentage of EU citizens that regularly accesses the internet will have increased to 97% (all ages), 97% (aged 55-64) and 87% (aged 65-74)[13]. Making Electronic Product Information available in the patient's native language is critically important in this case as the general patient population may not be fluent in multiple EU languages.

As such, IATF would advocate for an approach in which language exemptions for self-administered products can be facilitated in two ways: either through **a general exemption for all products based on a decision by the Member State or through case-by-case approvals of exemptions upon a reasoned request by the MAH.**

Strategic Recommendations

To successfully leverage the advantages of multi-country packs, the IATF recommends that language exemptions should (1) be made possible through the currently ongoing revision of the pharmaceutical legislation and (2) should be further facilitated by clear guidelines and frameworks to support the harmonized implementation of these language exemptions and sufficient collaboration between member states.

[13] Statistics | Eurostat (europa.eu)

Required legal changes

Regarding the legislative measures needed to make the appropriate language exemptions possible, IATF proposes the following changes to the new directive proposal (replacing EC/2001/83) by the European Commission.

Article 74.4:

> "The competent authorities of the Member State may also grant a full or partial exemption**, on reasoned request and through a coordinated procedure,** to the obligation that the labelling and the package leaflet must be in an official language or official languages of the Member State where the medicinal product is placed on the market, as specified, for the purposes of this Directive, by that Member State. For the purpose of multi-language **country** packages, **the competent authorities of** the Member States may allow the use on the labelling and package leaflet of an official language of the Union that is commonly understood in the Member States where the multi-language country package is marketed."

Article 74.4a (New):

> **"The official language obligation as mentioned in Article 74.1 shall not apply for the labelling and the package leaflet when the product is not intended to be delivered to the patient for self-administration. In this case a single appropriate language can be used."**

Moreover, IATF would like to reintroduce the current provision in the legislation regarding certain orphan medicinal products.

Art 74.5 (Reintroduced):

> **"In the case of certain orphan medicinal products, the particulars listed in Article 54 may, on reasoned request, appear in only one of the official languages of the Community."**

Required frameworks and guidelines

In order to facilitate the practical implementation of language exemptions, IATF advocates for the introduction of a harmonized framework for language exemptions across the EU, supported by comprehensive guidelines. The approval processes of these language exemptions and the guidelines that describe these processes should be implemented across all European procedures (CP, MRP/DCP) and should preferably take place before or at the start of the assessment procedures.

Proposals to Support Multi Country Packs and Simplify Supply Chain

Position Paper

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Proposals to Support Multi Country Packs and Simplify Supply Chain

Background

When creating packs of medicinal products which can be used for multiple countries, companies often run into issues caused by disharmonisation of requirements set at member state level or limited space on the immediate or outer packaging. For example, the terminology used for the expiry date and batch number and the language used for the INN.

The European Commission proposal for the Directive replacing Directive 2001/83 includes also the requirements for labelling of pharmaceutical products.

The below proposals for changes to the Directive and its Annex IV will solve the issues mentioned above and will result in benefits like simplifying packaging processes or ensuring effective use of limited space on the packaging.

Recommendations

In this paper we have only included proposals to the articles and sub articles that we propose to change in relation to the topic of multi country packs and simplification of supply chain. Articles/sub articles that are not included in this paper are discussed in other papers or are proposed to be kept as in EC proposal.

EC proposal	IATF-ePI proposal	Reasoning
Article 66 *Labelling of blister packs or small immediate packaging* *2. The following particulars at least shall appear on immediate packagings that take the form of blister packs and are placed in an outer packaging that complies with the requirements laid down in Articles 65 and 73.* *[…]* *(c) the expiry date* *(d) the batch number.*	Article 66 *Labelling of blister packs or small immediate packaging* *2. The following particulars at least shall appear on immediate packagings that take the form of blister packs and are placed in an outer packaging that complies with the requirements laid down in Articles 65 and 73.* *[…]* *(c) the expiry date* ***in clear terms (month/year), without need for any words or abbreviation****;* *(d) the batch number****, without need for any words or abbreviation****.*	To harmonise the countries and to prevent from introducing abbreviations in the national implementation it is proposed to specify this is not a requirement. Based on the text of the Directive an abbreviation should not be necessary. However, this is not the current experience in all countries, i.e. some countries seem to have an abbreviation on the blister. In QRD Appendix IV the following footnotes are included for some member states: [6] *For small immediate packaging and blisters, the batch number and the expiry date can be stated without any words or abbreviations* [7] *For blisters, the batch number and the expiry date can be stated without any words or abbreviations*

EC proposal	IATF-ePI proposal	Reasoning
Article 66 *Labelling of blister packs or small immediate packaging* 3. *The following particulars at least shall appear on small immediate packaging units on which the particulars laid down in Articles 65 and 73 cannot be displayed, shall include at least the following labelling particulars:* *(a) the name of the medicinal product and, if necessary,* ***the route of administration****;* *(b) the* ***method*** *of administration;*	Article 66 *Labelling of blister packs or small immediate packaging* *3. The following particulars at least shall appear on small immediate packaging units on which the particulars laid down in Articles 65 and 73 cannot be displayed, shall include at least the following labelling particulars:* *(a) the name of the medicinal product* ***and strength*** *and, if necessary,* ~~***the route of administration***~~ ***the pharmaceutical form. If the active substance is not part of the name, the marketing authorization holder is allowed to include the INN either in the local language or in Latin, or in EN*** *(b)* ***if necessary,*** *the* ***route*** ~~***method***~~ *of administration,*	The pharmaceutical form is not always necessary but should be added if there is a risk of confusion for the patient. Clear guidelines would therefore be required on how and when this would be determined and on what basis. Due to the limited space on small immediate packaging and blister packs, the route of administration would be more appropriate: the method of administration can be a long sentence, and this information is already present on the leaflet (and on the outer packaging) The route of administration should only be included if there is a risk of error.

EC proposal	IATF-ePI proposal	Reasoning
ANNEX IV *The following particulars shall appear on the outer packaging of medicinal products or, where there is no outer packaging, on the immediate packaging:* *(a) the name of the medicinal product, including in Braille, followed by its strength and pharmaceutical form, and, if appropriate, whether it is intended for babies, children or adults; where the medicinal product contains up to three active substances, the international non-proprietary name (INN) shall be included, or, if one does not exist, the common name;*	ANNEX IV *The following particulars shall appear on the outer packaging of medicinal products or, where there is no outer packaging, on the immediate packaging:* *(a) the name of the medicinal product, including in Braille, followed by its strength and pharmaceutical form, and, if appropriate, whether it is intended for babies, children or adults; where the medicinal product contains up to three active substances, the international non-proprietary name (INN) shall be included* ***in Latin or in EN or in the local language****, or, if one does not exist, the common name.* ***If the INN is part of the name of the medicinal product, it shall not be repeated***	Currently the members states are not aligned in the language that can be used for the INN, resulting in the requirement to have the INN in multiple languages on the pack in case of multi-country packs. By allowing the MAH to choose for the INN to be in Latin or EN or the local language, it will make it easier to combine countries and it will reduce the need for duplicating the information. If the INN is in the product name: To avoid duplication of text on the pack, and to efficiently use limited space on the pack, there should be no requirement anymore to repeat the INN.

EC proposal	IATF-ePI proposal	Reasoning
ANNEX IV *The following particulars shall appear on the outer packaging of medicinal products or, where there is no outer packaging, on the immediate packaging:* *[…]* *(h) the expiry date in clear terms (month/year);* *[…]* *(m) the manufacturer's batch number;*	*ANNEX IV* *The following particulars shall appear on the outer packaging of medicinal products or, where there is no outer packaging, on the immediate packaging:* *[…]* *(h) the expiry date in clear terms (month/year),* ***preceded by the abbreviation 'EXP';*** *[…]* *(m) the manufacturer's batch number****, preceded by the word 'Lot';***	Currently there is no harmonisation of terminology used, as this is set at MS level; harmonisation will support multi country packs and will increase readability in case of free movement of packs across EU. In addition, this will remove complexity in the packaging process.

Overview of potential obstacles for using multi-country packs caused by the proposals for the revised Pharmaceutical legislation

Position Paper

AESGP
VOICE OF EUROPEAN SELF-CARE INDUSTRY

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Overview of potential obstacles for using multi-country packs caused by the proposals for the revised Pharmaceutical legislation

Background

The use of multi-country packs is one of the important mechanisms to increase availability of medicines mainly in the smaller markets. The importance of this has also been recognized by regulators, resulting in definition of specific guidance for multi-country packs requiring multiple languages.

While the EU national competent authorities via the Co-ordination Group for Mutual Recognition and Decentralised procedures – Human (CMDh) have worked on a process to simplify the regulatory guidance for multi country packs, industry has identified challenges caused by proposals for the Directive replacing Directive 2001/83.

Several of the proposals made by the European Commission (EC) or in the European Parliament (EP) resolution may create obstacles for the creation of multi country packs.

In this paper we have provided an overview of the proposals which may cause obstacles for multi-country packs.

Antimicrobial Resistance (AMR)

According to **Article 69** of the EC proposal, an antimicrobial medicinal product will require an awareness card for patients, in addition to the established Summary of Product Characteristics (SmPC) and package leaflet.

The addition of another separate document, a paper card, inside the medicine packaging will make it more difficult to implement multi-country packs. The potential to establish a shared pack is limited by space constraints, dictated by the number of languages and country-specific information required on the packaging and/or package leaflet. In order to meet the requirement, there is a risk that either the "card" becomes large and cumbersome or will need to be printed in the minimum required font size, or on multiple cards, one for each language, neither of which are ideal for patients. In the worst case, the

size of the "card" will necessitate an increase in the size of the outer carton which is against the current environmental considerations.

While most package leaflets can be packed via an automated process, awareness cards generally need to be added to cartons manually. This is a labour-intensive process. The proposed paper awareness card as a separate document in the packaging of antimicrobials will have a direct and negative impact on the supply output of antimicrobial manufacturing lines.

The respective additional information intended to be communicated via the proposed awareness card should be included within the package leaflet, where part of the information is already included, to avoid redundancy. It also has the added benefit that the patient only has one document to look at and avoids confusion on the purpose of the separate documents.

As the package leaflet provides comprehensive information on how to take and store the medicine safely and effectively, the information intended to be communicated via an awareness card could be seamlessly integrated into the package leaflet.

In future, providing this information in an electronic package leaflet (ePI), would enable faster updates to information, including links to the most up-to-date information on local antimicrobial medicine waste disposal programs, and would support continued supply and supply chain flexibility for these critical medicines.

Disposal

In the proposal for **Annex IV, paragraph 1, point j (outer packaging)** and **Annex V, paragraph 1, point 6, point f (SmPC)**, the EP position concerning the addition of the information of the disposal system in place on the label (secondary packaging or immediate packaging where there is no secondary packaging) and in the Summary of Product Characteristics (SmPC) makes it obligatory by removing the case-by-case approach (unlike the current EC proposal). The current requirement concerning the leaflet is left unchanged, but it can be assumed that making it mandatory on the SmPC will also impact the leaflet content.

Industry supports keeping the status quo which has proven to work satisfactorily. If the EP proposal prevails, we fear that multi-country packs may be jeopardized. The differences in implementation of the take back scheme requirements across the EU mean that the disposal statement on the product packaging may differ from one country to the other and providing the specific precautions related to the disposal of unused or expired medicinal products on the packaging is of particular concern in case of multi-country packaging (provided the disposal between neighbouring countries is different).

Instead of adding a reference to the local disposal / take-back system, we suggest using a common EU logo and website that would centralise disposal information for all EU countries.

Single dose dispensation

The EP proposal of Article 66, which sees application of batch specific information on each single dose of the blister pack being included into EU law. The batch specific information is the batch number, expiry date, and a GS1 Data Matrix code containing these elements plus the GTIN.

This proposal will require much more information to be placed on the immediate packaging where space is already limited, especially blisters. Even for one language this will likely result in need for a bigger blister size, but for multiple languages it will be impossible to achieve this requirement without increasing the size of the blister. With a single dose of the blister pack, all particulars - product name, strength, pharmaceutical form, INN – need to be printed in each language per unit as languages cannot be alternated.

While regulatory authorities are looking for solutions to increase availability in all markets by supporting multi-country packs, these will become less feasible, and, maybe impossible in the case of blister foils due to the space restrictions in place over each pocket. Space constraints also impact the possibility to print a data matrix codes on each single dose.

Awareness Cards for Antimicrobials in the EU Pharmaceutical Reform

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Awareness Cards for Antimicrobials in the EU Pharmaceutical Reform

Background

Antimicrobial resistance (AMR) has been recognized as one of the most significant current health threats. It is a direct threat to the effectiveness of antimicrobial medicines, which are a critical part of our toolkit for treating infectious diseases.

In response to this, the proposed reform of the pharmaceutical legislation by the European Commission (EC) includes various legislative measures to address AMR.[i] These range from supporting innovation in new antimicrobial treatments, to preserving the effectiveness of existing antimicrobial therapies through prudent use and proper disposal.

One of the specific proposed measures is an "awareness card" which is to be included in the packaging of an antimicrobial medicinal product, in addition to the package leaflet.[ii] This awareness card is intended to inform patients of the risk of AMR as well as appropriate use and disposal of antimicrobial medicines and waste. Additional warnings should also be included in the existing package leaflet[iii], informing the patient that improper use and disposal of the medicinal product contributes to AMR.

The EC propose that each Member State may decide that the awareness card is provided in paper format inside the packaging of an antimicrobial, electronically, or both. In the absence of specific rules in a Member State, the awareness card must be provided in paper format.[iv] Whereas the European Parliament (EP) has proposed that the awareness card must always be provided in paper format, and may additionally be provided in electronic format in the Member States.[v]

Recommendation

The IATF fully supports the intention of the EC to address AMR and agrees with the EC's statement that Marketing Authorisation Holders (MAHs) and Member States together have a responsibility for building awareness of the appropriate use and disposal of antimicrobials.[vi] However, this should be done in the most efficient and sustainable manner, with careful consideration of the acute and long-term challenges faced in supplying antimicrobial medicines in the EU.

The IATF do not support the proposed requirement of separate paper awareness card for AMR in the packaging of antimicrobials. Instead, we support enhancing the existing package leaflet and making this the patient's key source for comprehensive information about an antimicrobial medicine. The IATF

proposes incorporating information on AMR into the package leaflet. A separate awareness card would therefore not be needed, and when electronic product information (ePI) is implemented, AMR information would also be available electronically within the package leaflet.

Below, we present the rationale for this position. We outline five key concerns with the proposed paper awareness card and detail our alternative solution for AMR awareness which recognizes the important role of the package leaflet together with national, EU, and international public awareness campaigns in the fight against AMR.

Concerns with the proposal in the EU pharmaceutical reform

Duplication of information reduces communication effectiveness

Under the EC proposal, in addition to the established package leaflet, all antimicrobial medicinal products will require an additional document - an awareness card for patients.

Introduction of this separate document, which by legislation needs to be aligned with the information in the package leaflet[vii], will likely lead to duplication of information, reducing the readability and effectiveness of the written information overall.

Specifically, inclusion of a separate paper awareness card in the medicine packaging introduces a risk that the full package leaflet, containing important information about dosing and interactions that can influence the effectiveness of the antimicrobial therapy, is not read by the patient.

Impracticality of additional card inside the medicine packaging

Under the EC proposal, the awareness card by default should be included in paper format inside the packaging of the antimicrobial medicinal product. Member States may decide that the awareness card is provided in paper format, electronically, or both. However, the EP's amendment removes the 'electronic only' choice for Member States and mandates, a card inside the medicine's packaging which may be additionally complemented by an electronic version. [viii]

It must be acknowledged that paper is not always the ideal or most preferred option for dissemination of information. This information is static, prone to becoming outdated, and cannot be updated quickly.

Additionally, it should be considered that many antimicrobial medicines are used in hospitals and supplied in bulk packages. A traditional paper card in a package would not be sufficient to hand to all patients treated. Similarly, in the case of certain antimicrobials with broad ranges of indications and dosing regimens, it may be necessary to divide a package of medicine between more than one patient to account for different courses of treatment, even outside of hospital settings. In such scenarios patients

and healthcare providers would greatly benefit from access to electronic package leaflets which could also be utilized to enable AMR awareness information to reach all patients in these scenarios.

Additional supply chain complexity risking availability of critical medicines

Inserting additional printed materials inside medicine packaging adds complexity and cost to the packaging process. The proposed paper awareness card as a separate document in the packaging of antimicrobials will impact the supply output of antimicrobial manufacturing lines.

Antimicrobial medicines and in particular antibiotics, are known to be vulnerable to supply issues and sudden unexpected increases in demand.[ix] To mitigate this, MAHs of key antibiotics are requested to implement proactive measures to increase production to prepare for extra demand on supply, particularly for the winter months.[x] Meanwhile these antibiotics run the risk of being taken off the market due to small volumes and consequently limited revenues.[xi]

The complexity introduced to the packing process by the paper awareness card is foreseen to lower the speed of packaging lines of these critical products, while increasing operating costs. This has a direct effect on the ability of manufacturers to increase production to cover seasonal demand and respond to unexpected fluctuations in demand, but also on the commercial viability of many antimicrobials and hence long-term availability on the market. In other words, this proposed requirement places additional burden on antimicrobial manufacturers at a time when critical issues of AMR, medicines availability, and access all need to be addressed together.

Constraints on multi-country packages utilised in small Member States

The addition of another separate document inside the medicine packaging will make it more difficult to implement multilingual, multi-country packs. In an effort to increase access in "smaller" Member States, and increase supply chain flexibilities, Member States, competent authorities and MAHs are increasingly facilitating multilingual, multi-country packages. Multi-country packages are used to facilitate re-distribution of medicines among Member States in response to local availability issues. The potential to establish a shared pack is limited by space constraints, dictated by the number of languages and country-specific information required on the packaging and/or in the package leaflet. Introducing a separate awareness card will introduce another limitation to establishing multilingual, multi-country packs, unless they can be provided via electronic means only.

In order to produce an awareness card for a multilingual, multi-country pack, it seems likely that the amount of text required on the "card" will lead to a large and cumbersome document format and/or will need to be printed in the minimum required font size, all of which is not ideal for patients. In the worst case, the size of the "card" will necessitate an increase in the size of the outer carton which has knock-

on efforts for storage and distribution. In these cases, there would be extended lead-times to allow for testing and packaging line validation, along with shipping validation studies.

Increased use of packaging materials and environmental impact

The proposed requirement of a paper "awareness card" in the packaging of antimicrobials will directly increase use of materials required to produce the cards such as paper and plastic laminate coatings – and consequently the carbon footprint of the product. It may also indirectly lead to increased use of other packaging materials as well as storage and distribution services if the addition of an awareness card leads to an increase in the size of some outer cartons.

This goes against the other key environmental ambitions of the pharmaceutical reform, and other cross-industry legislative reforms in Europe. In particular, the Packaging and Packaging Waste Regulation which aims to phase out unnecessary packaging and overpackaging, and to reduce packaging waste by 15% by 2040 per Member State per capita, compared to 2018.xii Industry is also working diligently to reduce packaging. Introducing an additional paper awareness card would work against these joint efforts.

Proposed solutions

Package leaflet as the patient's primary source of written information about antimicrobial medicines

The package leaflet is the most appropriate document for building awareness among patients about the risk of AMR and the appropriate use and disposal of a specific antimicrobial medicine. The respective information intended to be communicated via the proposed awareness card should therefore be included within the package leaflet itself.

As the package leaflet already provides comprehensive information on how to take and store the medicine safely and effectively, the information intended to be communicated via an awareness card could be seamlessly integrated into the package leaflet, avoiding any duplication and increasing the effectiveness of the communication.

Furthermore, as the package leaflet information is incorporated into most prescribing and dispensing software, healthcare professionals will be able to reference the full information in the package leaflet to use as discussion tools when counselling their patients about the correct use of an antimicrobial therapy.

Including the information on AMR within the existing package leaflet enables additional improvements to be explored. These could include emphasizing the AMR message with formatting styles such as boxed text sections and standard warning statements. When electronic product information (ePI) is implemented, providing the AMR information within the package leaflet in an electronic format would

introduce additional formatting possibilities, enable faster updates to information, including links to the most up-to-date information on local antimicrobial medicine waste disposal programmes, and would support continuing supply and supply chain flexibility for these critical medicines, as well as environmental sustainability goals.

Raising awareness of AMR: a joint responsibility to address systemic issues.

As outlined in the recitals of the proposed pharmaceutical reform, building awareness of AMR is a joint responsibility between MAHs and Member States. Joint action is needed.

Product-specific information provided by MAHs in package leaflets can support proper use and disposal of a prescribed antimicrobial treatment. In addition to this product-specific information, public awareness campaigns to encourage prudent prescriber and patient practices are sorely needed. Awareness campaigns by public institutions at Member State, EU and global levels would support general understanding of AMR, and encourage correct use and proper disposal of antimicrobial medicines. Public campaigns are considered key and may be more effective at raising awareness of the risks of misuse and overuse of antimicrobials than MAH materials alone.

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> *2. The marketing authorisation holder shall include in the packaging of antimicrobials a document that contains specific information about the medicinal product concerned and that is made available to the patient in addition to the product leaflet ("awareness card") with information on antimicrobial resistance and the appropriate use and disposal of antimicrobials.*
>
> *Member States may decide that the awareness card shall be made available in paper format or electronically, or both. In the absence of such specific rules in a Member State, an awareness card in paper format shall be included in the packaging of an antimicrobial.*
>
> *3. The text of the awareness card shall be aligned with Annex VI.*

https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52023PC0192

[iii] European Commission, *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*, 26 April 2023, annex VI Contents Of Package Leaflet,

> *8. for antimicrobials, a warning that improper use and disposal of the medicinal product contributes to antimicrobial resistance.*

https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52023PC0192

[iv] European Commission, *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*, 26 April 2023, Article 69, 2., Directive

> *The marketing authorisation holder shall include in the packaging of antimicrobials a document that contains specific information about the medicinal product concerned and that is made available to the patient in addition to the product leaflet ("awareness card") with information on antimicrobial resistance and the appropriate use and disposal of antimicrobials.*
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> *Member States may decide that the awareness card shall be made available in paper format or electronically, or both. In the absence of such specific rules in a Member State, an awareness card in paper format shall be included in the packaging of an antimicrobial.*

https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52023PC0192

[v] European Parliament, *legislative resolution of 10 April 2024 on the proposal for a directive of the European Parliament and of the Council on the Union code relating to medicinal products for human use*, Article 69, 2 Directive:

> "...Member States **shall ensure** that the awareness card **is** made available in paper format or **both** in paper format **and electronically** in the packaging of an antimicrobial."

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> *The provision of information to healthcare professionals and to patients on the appropriate use, storage and disposal of antimicrobials is a joint responsibility of marketing authorisation holders and of Member States should ensure appropriate collection system for all medicinal products.*

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[vii] European Commission, *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*, 26 April 2023, Article 69, 3,

> *The text of the awareness card shall be aligned with Annex VI.*

https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52023PC0192

[viii] European Parliament, *legislative resolution of 10 April 2024 on the proposal for a directive of the European Parliament and of the Council on the Union code relating to medicinal products for human use*, Article 69, 2 Directive:

> "...Member States **shall ensure** that the awareness card **is** made available in paper format or **both** in paper format **and electronically** in the packaging of an antimicrobial."

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