

Alternative ways of providing the printed package leaflet of medicinal products

Recommendations of the Inter-Association Task Torce (IATF) for electronic Product Information (ePI) (AESGP, EFPIA and Medicines for Europe)

Context

The European Commission's (EC) draft proposal for a new pharmaceutical directive¹ introduces a new requirement for providing package leaflets *electronically*. Further it opens up the possibility for package leaflets to be provided *electronically only* in future², 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 proposal³. 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.⁴

Considering these legislative developments, this paper aims to explore and evaluate possible practical ways to fulfill 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.

¹ Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC (COM/2023/192)

² 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.*

³ 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)

⁴ 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.*

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 analyzed 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 softwares, 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 analyzing 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 analyzed 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 table below compares 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 table below aims to describe the potential positive and negative aspects of each method and offers some additional reflections and considerations for implementation.

Method	Positive aspects	Negative aspects	Additional considerations for implementation
<p>Printing by medicinal product dispenser/seller or care provider</p> <p>Description: Printing by a professional such as the medicinal product dispenser/seller, or other care provider including health centres, patient or elderly care facilities.</p>	<p>Patient gets immediate access to the printed package leaflet together with the medicinal product at the point of dispensing or sale.</p> <p>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.</p> <p>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.</p> <p>A specific language or large print could be selected for printing depending on the patient's needs.</p>	<p>Additional workload for medicinal product dispenser/seller/care provider to print the leaflet.</p> <p>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.</p>	<p>Agreements to be made on compensation for initial set-up and consumable costs of printing.</p> <p>Seamless integration of printing into prescribing/dispensing/retail software will support service.</p> <p>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.</p> <p>Best practice for provision of printed copies of package leaflets needs to be developed considering initiation of new treatments, long-term treatments.</p> <p>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.</p>

Method	Positive aspects	Negative aspects	Additional considerations for implementation
<p>Self-service printing kiosk</p> <p>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.</p>	<p>Able patient/users can print the leaflet themselves. Dispenser/seller/care provider can utilise their time for other services.</p> <p>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).</p> <p>Dispensers/sellers/care providers would be nearby to direct patients/customers to the kiosk and offer support or instruction to users if needed.</p> <p>Users could self-select their preferred language out of available options and font size for printing.</p> <p>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.</p>	<p>This additional printing kiosk would need an initial investment and maintenance (IT, paper, toner, etc).</p> <p>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.</p> <p>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.</p> <p>Demand in printing can be expected to decrease over time as uptake of electronic package leaflet increases. Risk of kiosks becoming obsolete over time.</p>	<p>Agreements to be made on compensation for initial set-up and consumable costs of printing as well as management of maintenance and regular servicing.</p> <p>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.</p>

Method	Positive aspects	Negative aspects	Additional considerations for implementation
<p>Self-service community printing hub</p> <p>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.</p>	<p>Able patient/consumers can print the leaflet themselves. Dispenser/seller/care provider can utilise their time for other services.</p> <p>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).</p> <p>Users could self-select their preferred language out of available options and font size for printing.</p> <p>Similar to self-service kiosks used in other sectors (e.g. banking, travel, retail) making it a relatively intuitive/familiar solution for many users.</p> <p>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.</p>	<p>Requires patient/consumer to visit another premises.</p> <p>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.</p> <p>Requires buy-in from suitable locations in the community. This additional printing kiosk would need an initial investment and maintenance (IT, paper, toner, etc).</p> <p>Demand in printing can be expected to decrease over time as uptake of electronic package leaflet increases. Risk of kiosks becoming obsolete over time.</p>	<p>Agreements to be made on compensation for initial set-up and consumable costs of printing as well as management of maintenance and regular servicing.</p> <p>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.</p> <p>Opportunity for multi-functional printing kiosks – other uses by other sectors.</p> <p>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.</p>