# Informing and empowering patients through accessible and clear information on medicines

**February 2025**

The European Patients' Forum (EPF) strongly believes that all patients, regardless of their condition, background or nationality, have a **fundamental right to patient-centred care** that respects their needs, preferences and values. A cornerstone of this right is access to accurate, clear and comprehensive health information, particularly on diagnoses, treatment options, and disease management strategies. Such access is essential to uphold patients' rights and promote equity, empowering patients to take an active role in their healthcare, achieve better outcomes, improve their quality of life, and contribute to a more efficient healthcare system.

A key area for advancing health education is the **information patients receive about medicines**. Patients need accurate, user-friendly and accessible information about their medicines. More importantly, this information must enable patients and carers to use medicines safely and effectively. It supports adherence to prescribed treatments and encourages self-management. It also ensures safe use and detection of potential adverse effects and interactions, guiding patients to take appropriate action when necessary.

In many cases, the patient information leaflet (PIL) is the **primary source of information patients receive about their medicines,** along with oral advice from healthcare professionals, such as doctors, nurses or pharmacists. The PIL is therefore an essential resource for patient care and a key reference, which needs to be improved to address patients' information needs. In addition, a parallel reflection is needed on ways to ensure patient access to information about medicines they receive in hospitals or other healthcare settings to improve transparency and empower patients to take a more active role in their own care.

The format and content of the PIL are currently being discussed in several fora at European level. The European Union (EU) is currently revising its regulatory framework for medicines, including provisions to allow the expanded use of electronic product information (ePI). The format of the PIL is also being considered in the context of regulatory flexibilities to address medicines' shortages. In parallel, the European Medicines Agency (EMA) Working Group on Quality Review of Documents is revising product information templates, with input from various stakeholders, including patient organisations, to address gaps in patient understanding and use of the information provided. The European Medicines Regulatory Network (EMRN) also adopted a harmonised standard for ePI and conducted a one year pilot on creation and publication of ePI in regulatory procedures[1].

In light of these developments, EPF urges the EU to consider the following key aspects related to the inclusion of a key information section, electronic patient leaflets as a complement to paper leaflets, and a broader health literacy strategy.

[1] https://www.ema.europa.eu/en/human-regulatory-overview/marketing-authorisation/product-information-requirements/electronic-product-information-epi

## 1. Improving the content of the PIL to increase patient safety

The content of the PIL must be tailored to its primary audience: patients and carers. EPF advocates for the inclusion of a **key information section** in the leaflet to ensure that the most important information is easy to find and understand.

Studies have shown that the current format of the PIL is often inadequate, with issues such as poor readability and confusing presentation of information[2]. Studies have showed that few patients read the entire leaflet until the end and fully understand its content[3]. For example, the use of overly complex language and excessive medical jargon makes it difficult for a lay reader to understand the content. In addition, the listing of side effects and their causal relationship to the medicine can be unclear, making it difficult for both patients and healthcare professionals to understand the information and apply it to their own health status[4].

A key information section would improve legibility by providing an accessible summary of the most relevant information and the key messages for safe use of the product. A key information section would improve readability and facilitate informed decision-making. It is not meant to replace the full PIL but to enhance accessibility for patients as past efforts to simplify the body of the leaflet have not led to major improvements across countries. It should provide a clear, structured starting point while the full PIL remains available for more in-depth information.

Based on our findings and our members' input, the key information section should include the following elements:

- **Indication and use:** A description of the cases and conditions in which the medicine is used and for what purpose (ad hoc vs chronic use).
- **Dosage and administration:** Instructions on how to take or use the medicine, including the correct dosage, frequency, and any special instructions. To avoid discrepancies between the prescription and the PIL, information should focus on what the patient should not do (e.g. no more than 6 tablets a day, not without food, etc.).
- **Undesirable effects and adverse reactions:** A description of the most common adverse reactions that patients are most likely to experience, as well as serious side effects for which patients must identify warning signs and know what to do if they occur. Indicating the probability of the occurrence of a side effect helps put this information into context and alleviate patients' concerns.
- **Contraindications and warnings:** Information on any conditions or situations in which the medicine should not be used and any special warnings. This should include any interactions with other medicines, pre-existing medical conditions, or certain activities (e.g. driving), and any allergens that could trigger severe reactions.
- **Storage and disposal instructions:** Clear instructions on how to store the medicine (e.g. keep in a cool, dry place, away from children) and a simple message to ensure safe disposal of unused or expired medicines.
- Information about **use in specific populations** (e.g. pregnant or breastfeeding women, pediatric populations, etc.)

[2] European Commission (2017) "Report from the commission to the European Parliament and the Council in accordance with Article 59(4) of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the community code relating to medicinal products for human use"

[3] https://pmc.ncbi.nlm.nih.gov/articles/PMC8631714/#B9

[4] Mühlbauer V, Prinz R, Mühlhauser I, Wegwarth O. (2018) Alternative package leaflets improve people's understanding of drug side effects-A randomized controlled exploratory survey. PLoS One.

- **A disclaimer** that the patient should read the full leaflet for comprehensive information.

The key information section should be written in **lay language and avoid jargon.** To enhance readability, the section should feature **standout formatting**, such as bold text, bullet points, and colour coding. The use of pictograms where relevant could be considered, but research has shown that patients have to learn their meaning with each use, which impedes understanding and requires higher health literacy[5]. As a result, pictograms should mainly be used with accompanying text, which may be more suitable for the body of the leaflet.

## 2. Complementing paper-based information with ePI

To ensure equity and patient safety, basic access to paper-based safety information must continue to be guaranteed for all medicines. EPF strongly believes that the introduction of **electronic product information (ePI) should complement, not replace, the paper-based information** provided with medicine packages.

ePI should be part of a broader digital health strategy to ensure that all patients in the EU have access to comprehensive, high-quality, up-to-date and understandable information about their medicines. While digital formats hold promise for improved therapy management through searchable content and interactive features, always up-to-date information and rapid communication of critical updates, there are still many barriers to their practical implementation for all patient populations in all circumstances. These include challenges such as limited access to digital tools, insufficient digital literacy, and caregiver dependance. This is particularly critical for medicines used in emergencies, such as antihistamines, where immediate access to package leaflet information is essential. In such cases, relying solely on digital formats, which may be dependent on internet connectivity or device availability, is not an option.

To ensure the successful integration of ePI alongside paper formats, several key considerations must be addressed:

- **Accessibility**: ePI must accommodate different needs and adapt to people with disabilities, including accessibility features such as large fonts and audible formats.
- **Patient involvement**: Patients must be actively involved in the design and testing of ePI content and interfaces to ensure that they are fit for purpose, accessible and effective for patients of all ages, digital literacy levels and abilities. For example, the ePI should include tools that allow patients to report suspected adverse effects in a centralised way.
- **Linking printed and digital formats**: A QR code should be available on the paper leaflet, linking to the digital page.
- **Open access to regulator-approved information only:** Oversight from public regulatory authorities is crucial: they should manage the platforms enabling access to ePIs and remain responsible for the content, thereby ensuring accuracy, security, and impartiality. Third party contents and links, particularly promotional material, must be excluded to maintain sciences-based and publicly validated information and trust. Harmonised EU guidance, developed in consultation with patient organisations, should be provided regarding the content and format to facilitate equitable access to information across Member States.
- **Data protection**: ePI must not collect personal data or navigation information**.** If the package leaflet is made available electronically, the individual's right to privacy shall be respected. Individuals' identification or tracking must be prohibited and patients' browsing history must not

[5] https://english.cbg-meb.nl/topics/mah-medicine-pictograms

be used for commercial purposes**.** Public authorities' platforms providing access to ePI should ensure robust safeguards against unauthorised data collection or sharing.

- **Multilingual ePI**: it is essential that patients have access to information in their own language. ePI must be available in all official EU languages through certified translations. For nationally authorised products, EPF recommends that Member States also provide the ePI in English in addition to the official national languages, and link to all other available language versions.
- **Up-to-date information**: ePI must be updated in real-time to reflect the most recent information, such as safety updates, changes in instructions for use or newly identified risks. Clear processes should be in place to ensure timely updates, with regulatory oversight and publication of changes to ensure accuracy and transparency.

## 3. A comprehensive health literacy strategy

We should view PIL as part of a broader strategy to improve patients' health literacy, to support patient self-management to improve quality of life and increase trust in the medicines they use, but also to address broader public health challenges such as antimicrobial resistance, waste management and sustainability. In this context, EPF advocates for a **comprehensive, EU-wide health literacy strategy for EU citizens.** Health literacy is a societal challenge that requires coordinated action at all levels to strengthen prevention and improve all aspects of healthcare.

Well-informed patients are an asset to society. They take greater responsibility for their health and medical treatment, self-manage effectively, and contribute to better use of health resources. With ongoing challenges to the long-term sustainability of Europe's healthcare systems and rapid roll-out of digitalised tools across the healthcare sector, enhancing health and digital health literacy has never been more pressing.

EPF urges the European Commission and other EU institutions to work with stakeholders, in particular patient organisations, to improve patients' access to clear and understandable information on medicines. This should be achieved through the introduction of a more patient-centric PIL and the development of an ambitious EU health literacy strategy.

## ABOUT EPF

The European Patients' Forum (EPF) is an independent non-profit, non-governmental umbrella organisation of patient organisations across Europe and across disease areas. Our 80 members include disease-specific patient groups active at EU level and national coalitions of patients. To read about our vision, mission, and strategy, visit: www.eu-patient.eu