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Electronic Product Information Leaflet (ePIL): Opportunities, Challenges, and Future Directions

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Abstract

The purpose of EPILs, the electronic version of the leaflets placed in pharmaceutical packaging, is to enhance patient understanding and information access. ePILs present a chance to optimize patient safety, engagement, and adherence as digital health continues to grow. The evidence that currently exists on patient preference, eHealth literacy, and ePIL adoption is examined in the following paper together with the positive aspects, difficulties, and potential implementation strategies. A qualitative examination of research from various nations shows that while ePILs improve accessibility and user satisfaction, issues with digital literacy, user interface, and trust still exist. There is consideration of the implications both for implementation in healthcare systems and futureresearch.

Conclusion: Electronic product information leaflets, or ePILs, give patients a better understanding of their medications and boost their confidence when taking them. However, problems like workflow integration and low digital literacy can limit their efficacy. Future studies should concentrate on vulnerable populations, long-term effects, and explicit regulations. When used appropriately, ePILs can enhance health literacy, safety, and adherence.

Keywords: medication adherence, eHealth literacy, patient education, electronic product information leaflets, or ePILs

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1. Introduction

Effective patient education is the foundation of safe and successful healthcare. Treatment outcomes, compliance, and overall patient safety are directly affected by patients' comprehension of their pharmaceuticals, including appropriate dosage, possibility of side effects, drug interactions, and contraindications. Paper-based patient information leaflets (PILs), which have been given with prescription medications, have been the conventional approach. Despite being widely distributed, research indicates that most people do not fully understand these leaflets, particularly those who are elderly, have low health literacy, or have complicated schedules of medication to follow. (1,2)

There is now more room for improving patient information's effectiveness and accessibility because of the rapid advancement of digital technologies in healthcare. The electronic versions of conventional PILs, identified as Electronic Product Information Leaflets (ePILs), are accessible via computers, tablets, and smartphones. Unlike static paper leaflets, technological patient information leaflets (ePILs) offer multimedia, interactive features, and the ability to update information in real-time, all of which can improve patient participation and knowledge. (3,4) Personalized information delivery, which includes reminders, drug interaction alerts, and condition-specific advice, is further facilitated by integration with electronic health records (EHRs) and e-prescribing systems.

Notwithstanding their promise, the deployment of ePILs is not without challenges. Digital literacy is inconsistent across populations, and older or underserved populations might face difficulties accessing or navigating digital content. In addition, healthcare professionals are central to ensuring understanding, because digital information is not likely to answer all patient questions or concerns. (2) The adoption and performance of ePILs also depend on regulatory guidelines, credibility in digital content, and technology infrastructure within various healthcare facilities.

This article synthesizes the existing literature on ePILs, summarizing evidence regarding patient preferences, benefits, challenges, and implementation strategies. Through a review of qualitative and quantitative research,

it underscores the therapeutic potential of ePILs for patient education, safety, and patient engagement, as well as opportunities and areas for future research and practice in eHealth communication.

3. Benefits of Electronic Product Information Leaflets (ePILs)

- Always updated – reduces risk of outdated info
- Accessible anywhere – phone/tablet/computer
- Eco-friendly – saves paper
- Patient-friendly–audio/video explanations possible
- Supports pharmacovigilance reporting

4.Barriers and Challenges

Although having benefits, ePILs also pose implementation challenges. Limited availability of internet, low digital literacy, and difficult user interfaces can make usability lower. (5) Besides, regulatory and standardization problems prevail across nations, as digital formats need to meet local pharmaceutical law. (6)

- Technical issues: app crashes, differences in device compatibility
- Trust barriers: patients may question the validity of online content
- Digital divide: not all have access to devices or the internet.
- Workflow issues: healthcare professionals require training and time to include ePILs in consultations

4.1 Regulatory and Legal Aspects

Electronic Product Information Leaflets are being regulated more and more to ensure harmonization, safety, and clarity. In Europe, ePILs are subject to the guidelines of the European Medicines Agency (EMA) and national eHealth laws so that all digital information meets the Summary of Product Characteristics (SmPC). (6) In the US, the FDA supports digital drug guides, but their application hinges on secure access, privacy concerns, and HIPAA compliance. (7) Compliance gives protection to patients and legitimacy.

- EMA: Rolling out ePIs across EU.
- FDA (US): Considering ePI as supplement to printed leaflets.
- ICH ePI initiative: Works on global harmonization.
- Japan & Singapore: Already implemented digital PILs with QR codes.

4.2 Integration with eHealth Systems

ePILs are optimally effective when built into electronic health records (EHRs), e-prescribing systems, and pharmacy management systems. (8) Integration provides automatic updating, tailoring of information (e.g., patient-specific dosing), and drug interaction alerts. Research in Sweden indicates that national-level e-prescribing systems improve patient satisfaction and medication safety. (9)

4.3 Technological Features and Innovations

Current ePILs may include:

- Interactive visual tools (videos demonstrating how to take medicine)
- Multilingual access for diverse populations
- Voice-guided reading for blind patients
- Searchable text for easy reference
- Hyperlinks to videos or clinical resources for in-depth understanding. (3,10)

These tools can dramatically enhance medication compliance and patient empowerment, particularly for disease management in chronic conditions.

4.4 Cross-Cultural and Age Considerations

Evidence indicates older people and those from disadvantaged groups experience particular difficulty with ePILs. (11,12) Solutions such as reduced complexity, increased font sizes, and caregiver-facilitated navigation enhance usability. Culturally responsive design (language, symbolism, and illustrations) is also essential to enable understanding across groups.

4.5 Role of Healthcare Professionals

Healthcare professionals are key in facilitating ePIL use. Pharmacists, nurses, and physicians can guide patients, clarify doubts, and reinforce safety messages. Studies indicate that even with digital leaflets, personal explanations enhance understanding, especially when patients have low health literacy. (2)

4.6. Advantages over Paper Leaflets

- •Environmentally friendly: reduces paper use
- •Cost-effective: eliminates printing costs, easy to update
- Real-time updates: drug warnings or recalls can be immediately conveyed
- Analytics potential: usage data can inform enhanced patient education methods

4.6 (A) Advantages of Introducing Electronic Product Information

Implementation of electronic product information (ePI) is a lot of clear advantages that directly impact both regulatory processes related to product information and patient care. First of all, ePI makes sure that its data is always current and reflects the most recent product information that was approved by the Health Authority. In order to improve health literacy and improve the understanding and accessibility of product information according to patient needs, it permits the use of various media formats, such as interactive elements and videos, as well as search functionality and the ability to change font sizes. In addition, ePI allows possible to deliver content with more impact and to provide patients and healthcare professionals (HCPs) with personalized content, which may increase patient engagement and improve health outcomes.

4.6 (B) Advantages of removing the paper package leaflet

The efficiency and sustainability of pharmaceutical distribution and utilization are directly affected by the removal of paper package leaflets. By ensuring that the most recent recommendations are always followed, transitioning from paper leaflets to computerized patient information (ePI) minimizes the chance that consumers and medical professionals will rely on outdated versions of

medicinal information, especially when it comes to safety updates. Additionally, the availability of prescription drugs could be enhanced, especially through making it easier to reallocate packs among Member States and facilitate multi-country/multi-language packs. This method ensures that patients can access the product information even if the pack is written in an additional language, supports more efficient packaging procedures, and lessens the logistical burden of producing and sending out various leaflets for different markets. a language they are not fluent in. Environmental benefits are another key advantage, as decreasing the use of paper and ink directly contributes to decreased waste and resource consumption, which falls in line with more general sustainability objectives.

4.7 Prospective Paths

There are some multiple approaches to increase the effectiveness of ePILs, according to research:

- •AI-powered personalization: tailoring content to patients' levels of literacy and conditions
- Gamification: enhancing the involvement of interactive tests or reminders
- Cross-border standardization: ensuring ePILs are compatible with various rules and regulations.

5. information for nearly all EU citizens

Figures 1 and 2 show the described trends with regard to internet access and basic digital skills.

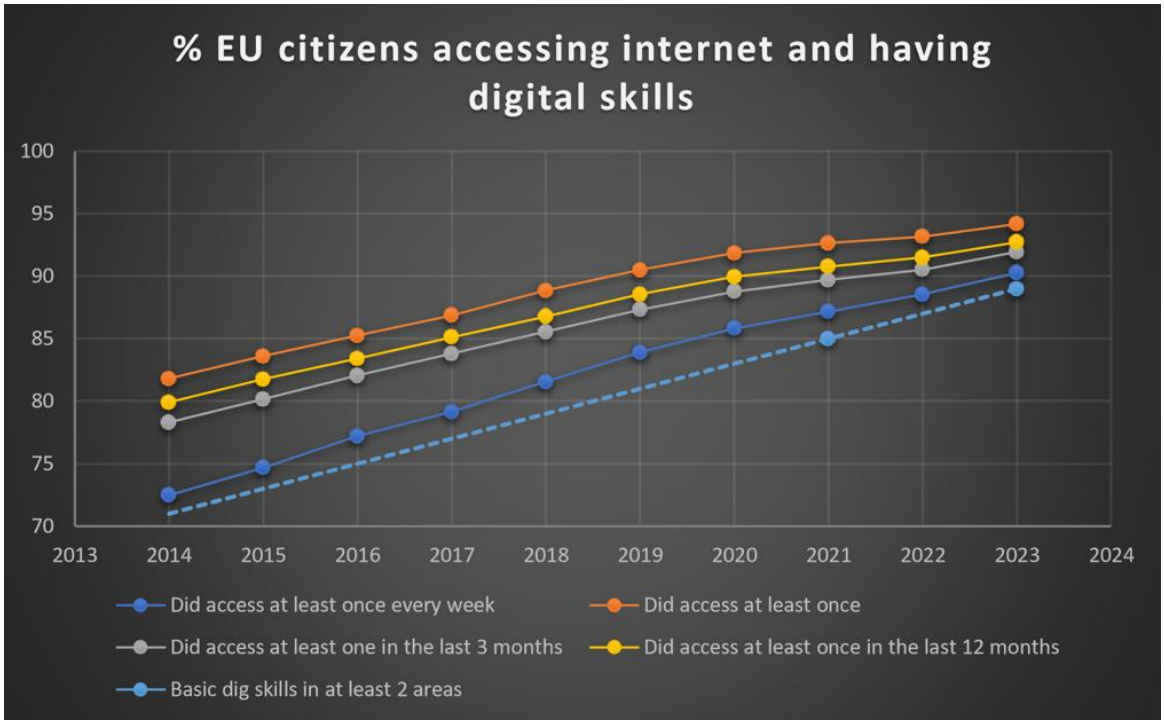

Figure 1. Internet access (at least once a week) is at 90% and is rapidly increasing.

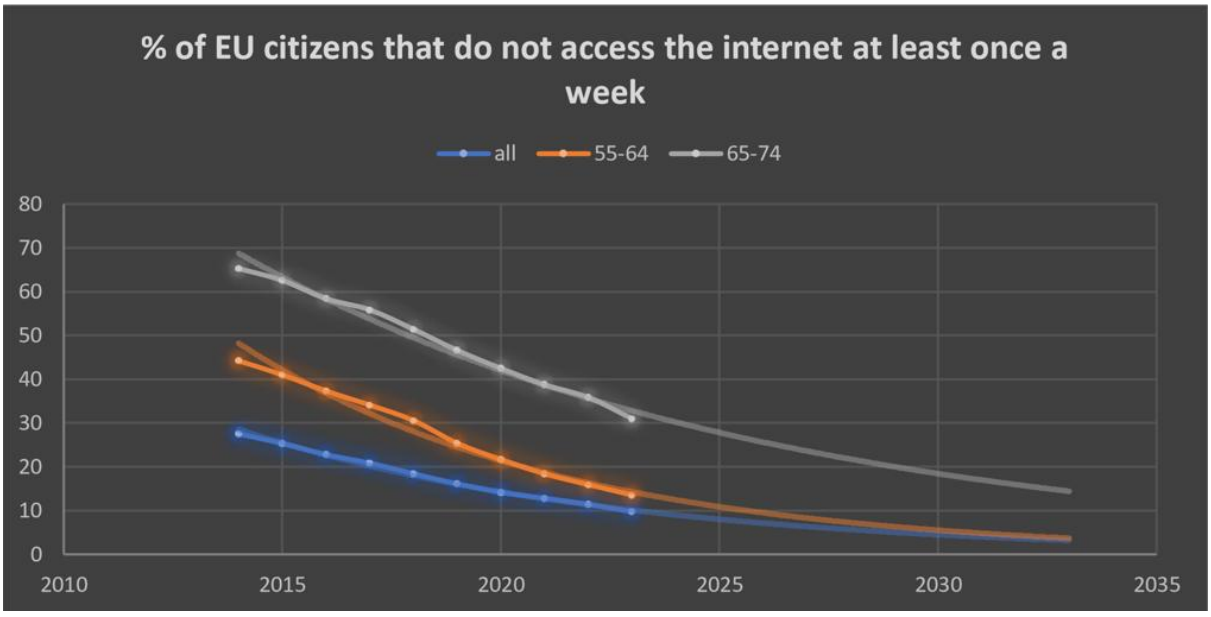

Figure 2. In 10 years from now (2034), the % of EU citizens that do not regularly access the internet will have dropped to 3% (all), 3% (55-64), and 13% (65-74).

Is the paper package leaflet still required, and are EU citizens interested to use electronic product information? Effective Eurostat data, which show that 90% of EU citizens had internet access (at least once a week) in 2023 (compared to 72% in 2014) and continues to increase, support the preparations of EU citizens for the adoption of electronic Product Information (ePI). The percentage of EU citizens who regularly access the internet is expected to grow to 97% overall and 87% among those aged 65-74 by 2034, indicating a significant increase in this trend in the years that follow. In in addition to internet access, Eurostat data indicates that nearly 90% of EU citizens had at least two basic digital skills in 2023, and all Member States with low internet access rates in 2014 are rapidly catching up (for example, Romania's percentage of citizens using the internet at least once a week increased from 48% in 2014 to 88% in 2023). These projections highlight the rapidly closing digital divide and the developing viability of ePI as the primary source for healthcare

5.1) Campaign for education and awareness

IATF demonstrates that the complete elimination of paper package leaflets should occur after the phase-in of ePI, which is already happening. Before ePI is completely available on the EMA/HMA portal intended as the ePI repository, some of the current ePI platforms, among them the National Competent Authority and industry websites and compendia, could be implemented as solutions for beginning the transition.

5.2) Campaign for education and awareness

The execution of an awareness and education campaign at the EU level is a crucial component of the proposal. In order to ensure a seamless transition for everybody involved, this campaign would inform EU citizens, patients, and healthcare professionals about the introduction of ePI and its benefits. To address specific requirements of each member state and its citizens, this campaign could incorporate national specifics and preferences. By demonstrating ePI in the best and most effective way, we hope to improve digital health literacy.

Figure 3: EMA published 10 principles for ePI

5.3) Integration and implementation across the European Union

Dissemination strategies, like apps and websites, may differ nationally to take local preferences to be considered even though the standard and portal would remain identical. This proposal is in in line with the EU Parliament's position, recommending for the general introduction of ePI, the formulation of a harmonized standard for ePI within a year of the revised pharmaceutical legislation becoming effect, and the founding by the EMA of a platform that will host all EU ePI within two years of the legislation becoming into effect.

6.ePI: changing circumstances

Legislative and regulatory changes

although they are at different stages of this transition, many nations are developing legislative and regulatory steps to permit electronic formats of pharmaceutical information. While certain nations, like the SmPC, concentrate solely on replacing the prescribing information, others aim to replace all product information with electronic versions. Additionally, certain countries are only considering ePI as a supplemental tool to paper formats, while others are considering legislation to totally replace paper-based information. The trend toward digital platforms comes obvious and unavoidable, nevertheless though the rate of change varies substantially between countries.

Table 1. ePI regulatory landscape in different countries/regions

COUNTRY/ REGION	HEALTH AUTHORITY	REGULATION/LEGISLATION
EU	European Commission (EC) European Medicines Agency (EMA)	The EC and EMA's stance, based on detailed consultations, is that ePI refers to the provision of electronic versions of product information without any content modifications. (13)
Japan	Pharmaceuticals and Medical Devices Agency (PMDA)	In 2021, the government mandated that the all patient information leaflets be uploaded to the PMDA website and updated with electronic patient information (ePI). (14)
Singapore	Health Sciences Authority (HSA)	In 2021, the HSA approved a full switch to digital formats for product information that could be accessed through URLs or QR codes, so there was no need to use paper copies. (15)
US	US Food and Drug Administration (FDA)	The FDA suggested changing the rule in 2014 that prescribing information should mostly be sent by mail. (16) There is political and legislative opposition to this, but a version of the bill is currently (December 2023) in the House of Representatives and has been sent to the Subcommittee on Health. (17)
Australia	Therapeutic Goods Administration	For a long time, the government has supported ePI as a way to get information about all oral and topical medicines. (19) In Australia, information about paper products is optional, and pharmacists help patients who need it in paper form. People still use ePI a lot to get information about drugs and products. (18)
Brazil	Brazilian Health Regulatory Agency (ANVISA)	The resolution that passed in 2022 allows the use of full ePI with QR codes and paper product information. (19) In November 2023, a proposed law called for centralized ePI databases that used structured and interoperable data. This opened the door for digital-first solutions. (20)
China	National Medical Products Administration (NMPA)	Laws about e-labeling are still in their early stages. But as of 2024, there is an ePI pilot program that uses QR codes. (21)

7. Case Study 1. Rapid implementation of ePI solutions for refugees from the Ukraine

As a result, the displaced Ukrainians in Poland and other European nations had simple, fast, and cost-free access to vital product information about their prescribed drugs, all in their native tongue through their cell phones. (6)

7.1 A vision for an integrated implementation across the EU

The IATF demonstrates the importance of proceeding to a pan-EU implementation of ePI because it recognizes the difficulties and inefficiencies that could result from a fragmented approach. The European Commission's proposed delegated act, which envisions a possible unified implementation 18 months after five years (6.15 years) from the legislation's entry into force, could help with this. However, the IATF promotes a faster timeline for a pan-EU strategy—18 months after one year (a total of 2.15 years) from entry into force. However, the IATF proposes a quicker timeline for a pan-EU strategy—18 months after one year (a total of 2.15 years) from entry into force. IATF also stresses that any implementation strategy should aim for simplicity and be prepared in accordance with industry, whether it is implemented by individual member states or through an act delegated by the European Commission. Timelines for implementation, for example. may vary based on patient access routes, but they shouldn't comprise unnecessary complicating criteria that might hamper the transition's performance and ultimate goals.

Table 2. Annex: Article 63 of the Directive—General principles on package leaflet 1. Package leaflets shall be mandatory for medicinal products**.**

European Commission proposal [AESGP]	European Parliament Position [EFPIA]	IATF proposed changes to the European Commission proposal. [MEDICINES FOR EU]
Member States can choose to make the package leaflet available in paper form, electronically, or both. If there are no specific rules in a Member State, the packaging of a medicine must include a paper package leaflet. If the package leaflet is only available online,	Member States may decide that for individual medicinal products, categories of medicinal products, or all medicinal products, the package leaflet shall be made available both in paper format and electronically or electronically only. In the latter case, the decision shall be made only following a consultation of patients,	Member States may decide that the package leaflet shall be made available in paper format or electronically, or both. In the absence of such specific rules in a Member State, a package leaflet in paper format shall be included in the packaging of a medicinal product. If a

patients should be able to get a printed copy of it for free if they ask for one. Also, the digital information should be easy for all patients to find.	carers, and other relevant stakeholders. In the absence of such specific rules in a Member State, a package leaflet shall be made available electronically and be included in paper format in the packaging of a medicinal product. If the package leaflet is only made available electronically, the patient's right to a printed copy of the package leaflet should be guaranteed upon request and free of charge, and it should be ensured that the information in digital format is easily accessible to all patients and written and designed in a clear and understandable way.	Member State decides that the package leaflet shall be only made available electronically, it shall not preclude the marketing authorization holder from providing the package leaflet in paper format in addition to the electronic format on a voluntary basis. If the package leaflet is only made available electronically, the patient's right to a printed copy of the package leaflet should be guaranteed upon request and free of charge, and it should be ensured that the information in digital format is easily accessible to all patients.
The Commission is empowered to adopt delegated acts in accordance with Article 215 to amend paragraph 3 by making mandatory the electronic version of the package leaflet. That delegated act shall also establish the patient's right to a printed copy of the package leaflet upon request and free of charge. The delegation of powers shall apply as of [OP please insert the date = five years following 18 months after the date of entering into force of this Directive].	When accessing the package leaflet electronically, the individual right to privacy shall be ensured. Any technology giving access to the information shall ensure the protection of personal data in accordance with Regulation (EU) 2016/679 and Directive 2002/58/EC and shall not allow the identification, profiling, or tracking of individuals, nor shall it be used for commercial purposes, including	The Commission is empowered to adopt delegated acts in accordance with Article 215 to amend paragraph 3 by making mandatory the electronic version of the package leaflet and removing the obligation to include a package leaflet in paper format in the package. That delegated act shall also establish the patient's right to a printed copy of the package leaflet upon request and free of charge. The delegation of powers shall apply as of [OP please insert the date = one year following 18 months after the date of entering into force of this Directive].

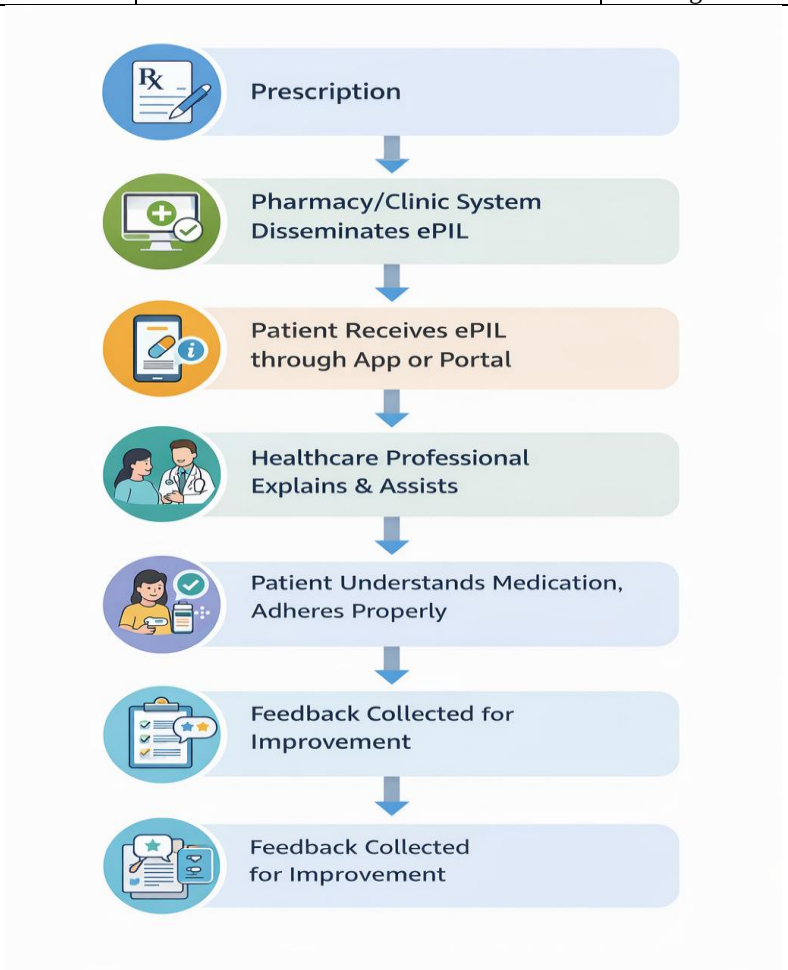

Figure 4: ePIL Use Workflow in Healthcare System

Table 3: Key Features of ePILs

Feature	Purpose/Benefit
Interactive Visuals	Searchable Content
Improve understanding of dosage and administration.	Quick reference for specific drug information
Text-to-Speech	Hyperlinks to Videos/Resources
Support visually impaired patients.	Provide additional education.
Multi-language Options	Real-time Updates
Increase accessibility for diverse populations.	Ensure safety and reflect the latest guidance.

Table 4. Key Findings from Reviewed Studies on ePILs

Study	Population	ePIL Benefits	Barriers	Outcome
Robben et al., 2012	Frail older adults	Clear info delivery	Digital literacy	High satisfaction
Hammar et al., 2011	Swedish patients	Nationwide ePrescribing access	None reported	Improved engagement
Mosa et al., 2012	Smartphone users	Multimedia explanations	Limited app use	Better comprehension
Chesser et al., 2016	Underserved US populations	Access to info	Digital divide	Variable usability
Hamrosi et al., 2014	Pharmacists & GPs	Support patient education.	Workflow issues	Moderate adoption

8.Discussion

The synthesis demonstrates that electronic Product Information Leaflets (ePILs) are a unique and innovative tool for improving patient education, especially when used in combination with spoken counseling by healthcare providers. A more informed and present patient population is made possible by their digital, interactive, and accessible nature, which makes it possible for the flexible release of medication information. In fact, a number of studies indicate that ePILs enhance patients' general understanding of their drugs, including how to use them, any side effects, and protection evaluations, thereby improving patient satisfaction and medication adherence. (2)

Multimedia tools like infographics, text-to-speech, and video demonstrations help make medication information simpler to comprehend for a variety of people, including those with low literacy. In addition, the capacity for real-time updates ensures that patients receive safety communications, recalls, and regulatory changes swiftly-a field in which paper leaflets are fundamentally inferior. (3)

Even though over 90% of people in Europe and other advanced nations have access to the internet, some categories-such as older adults, those who live in rural areas, and those who are socioeconomically disadvantaged-are at risk of digital exclusion. In addition, these groups can find it challenging to navigate the ePILs, which might increase already-existing health inequalities. Therefore, a user-centered and inclusive approach should be considered when designing ePIL systems, with a concentration on simplicity, accessibility, and multilingual capability.

To succeed in closing the digital divide, health professionals are essential. Doctors, nurses, and pharmacists can help patients access the ePILs, explain the information to them, and make sure they comprehend it. This cooperative strategy strengthens verbal consultations and guarantees trust in digital health information. In addition, training medical personnel on ePILs placed within EHRs and prescribing workflows increases standardization and efficiency. (11)

The harmonization and standardization of guidelines is another crucial aspect. The need for uniform guidelines on the content, format, and data security of ePILs has also been acknowledged by the EMA and other authorities (EMA, 2023). Today's disparities in national regulations render them difficult to implement and give pharmaceutical companies uncertainty. The interoperability of digital health systems would be enabled by a unified EU-wide strategy, enabling patients to receive consistent and trustworthy information across national boundaries. (6) From a technical point of view, ePILs are supposed to work with patient portals and e-prescribing systems. AI-driven personalization, in which data is customized based on the patient's literacy level or customized.

ePILs might become dynamic, adaptive learning tools through the utilization of medical profiles. Particularly for younger or more competent in technology patients, gamification and interactive modules may further boost engagement. Furthermore, information security and trust are crucial. The acceptance of digital health information may be undermined by privacy, data tracking, and the commercial use of patient behavioral data. (9) Clear policies must ensure that systems are compliant with GDPR or comparable requirements and that ePIL access doesn't compromise the privacy of patients.

ePILs provide system-level advantages in terms of cost-effectiveness and environmental sustainability in addition to patient education. Reducing paper inserts assists in accomplishing environmental objectives, which are becoming more and more crucial in pharmaceutical supply chains, and lowers printing and distribution costs. (6) The opportunity for user interaction analysis also leads to ongoing quality improvement; for example, understanding which leaflet sections are most frequently accessed and where users come across confusion may be helpful for enhancing the content.

In conclusion, multilevel strategies addressing technology, regulation, and user competence must be implemented for ePILs to be effective, even though they promise improvements in medication literacy, safety, and patient

engagement. Implementing a hybrid phase-in approach could guarantee inclusivity by keeping paper documents along with digital ones until everybody is knowledgeable about technology. In order to assess how ePIL use influences changes in medication adherence, adverse event reporting, and patient outcomes over time, longitudinal studies are also recommended. In the end, ePILs represent a new paradigm for interactive and patient-centered communication in healthcare; they are beyond just an electronic version of leaflets that exist currently on paper. ePILs have the potential to play an important part in ensuring the availability of contemporary, equitable, and sustainable patient information when combined with an expanded eHealth infrastructure and accompanied by strong instructional, accessibility, and regulatory frameworks.

9. Summaries

A qualitative synthesis of reviewed papers from 2000 to 2024 is used in this review. Relevance to patient information leaflets, digital health interventions, eHealth literacy, and patient engagement were taken into consideration when identifying the studies. The data was implemented to extract information about the study design, population, interventions, outcomes, and patient perspectives. Graneheim and Lundman's content analysis method was used to identify significant concepts and developments. The responses that specified ongoing ePI projects were subsequently given to a quantitative textual analysis by EMA. This achieved by compiling concise, uniform summaries of every project and categorizing them using (17) the following specifications:

- the stakeholder group responsible for of the project;
- covered content (PL/SmPC/);
- the ePI initiative's target audience;
- the specific type of electronic platform;
- geographic location; sector (private or public);
- the platform of the project (planning, ongoing, pilot, established);
- integrating components connected to accessibility;
- the specific type of standard in use;
- collaboration (yes/no);
- proactively multilingual (yes/no)

10.Conclusion

An essential next step in patient-focused medication education is the development of electronic product information leaflets. The data demonstrates that ePILs increase understanding, happiness, and participation; however, problems with digital literacy and workflow implementation must be addressed. Future studies ought to examine into long-term results, interventions for people with vulnerabilities, and the development of uniform frameworks for governing the implementation of ePILs. Healthcare systems can enhance patient safety, adherence, and general health literacy by carefully applying digital technologies.

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Conflict of Interest

The authors declare that there is no conflict of interest regarding the publication of this article.

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