

Electronic Product Information | **Progress Report**

“What do patients say about ePI by PharmaLedger?”

By PharmaLedger Association members, Patients Expert Center, Innovative Medicines for Luxembourg, EUPATI Luxembourg, Pharma.be, and European Patients Forum.

June 2023



Introduction

In the healthcare industry ecosystem, patients are the most important stakeholder. A patient's correct use of a medicine, described in traditional paper leaflet inserts included in every medicine package, is imperative for effective treatment. However, many patients do not find the physical leaflet helpful, as it can be very long, hard to understand, and difficult to search for the information required. Many patients keep only the medication in its primary packaging, discarding the box and the paper leaflet.

To serve this unmet need, PharmaLedger has been working on developing an electronic Product Information leaflet (*ePI by PharmaLedger*) that provides the user with an enhanced experience, such as the ability to locate information quickly and manipulate the screen to see details more clearly, as well as additional features such as videos of how to use the product, scan history, batch recall notifications, and adverse event reporting. Besides the enhanced experience, through *ePI by PharmaLedger* the user has the guarantee of obtaining the latest approved information from the most reliable source, the manufacturer, in a format that cannot be tampered with.

The global movement toward digitizing medical product leaflets is gaining momentum across more than 40 countries. While these initiatives may have different names, like **e-leaflet**, **ePI**, **ePIL**, and **e-Label**, they all aim to create a digital alternative to the paper inserts found in regulated medical product packages. PharmaLedger's contribution to this endeavor is the open-source blockchain-enabled system called **ePI by PharmaLedger**. Developed in collaboration with patient input and feedback throughout the PharmaLedger project and now within the PharmaLedger Association, *ePI by PharmaLedger* tackles the diverse regulatory landscape on a global scale.

During different stages of development since 2020, multiple patient advocacy groups have been involved and provided patient input and feedback to the PharmaLedger ePI project with a gradual increase in the number of patients participating at each stage. This has given PharmaLedger the edge of direct end-user input and co-creation, and in return given patients the rare opportunity to influence the functionalities and the “look and feel” of the app.

For any digital product information solution to be effective, patients need to be willing and able to access a digital leaflet with their smartphone. *Are patients satisfied with this approach? What about patients who are not willing or unable because they are not used to managing their health matters digitally? What features would patients value the most?* These are some of the questions we have asked.

This progress report shows **“What do patients say about ePI by PharmaLedger?”** through feedback sessions organized in 2021-2023 in a collaborative effort between PharmaLedger Association members, Innovative Medicines Luxembourg (LU), Patient Expert Center (BE), European Patients Forum (BE), EUPATI (LU) and Pharma.be (BE).

The PharmaLedger Association would like to thank all involved people and organizations which collaborated with us in taking one more step forward into digitally enabled and patient-centric healthcare. We look forward to continued collaboration on increasing the number of patients involved as well as the frequency of these insightful interactions.

Progress Report Conclusion

- **Patients are strongly satisfied with the process of obtaining a medical leaflet via the PharmaLedger app.**
- For the majority, the process is simple, fast, and easy to understand.
- Patients are still used to paper, and in general they would like to have both options available. However, it is likely users will slowly move to a “paperless mindset” as they begin to see the benefits of digital solutions.
- Patients are aware of the advantages and features that the digital version brings.

Although the data shows ePI would be acceptable to patients based on prototypes, Real World Evidence (RWE) is the next stage of patient input and feedback collection. Thus, the next milestone is to conduct several pilots with marketed products in multiple geographies. PharmaLedger Association members are already working with pharmacists in Belgium and Luxembourg to assemble the first pilots and collect more feedback from users.



Feedback Results per Area | Patient Satisfaction*



100%
App Navigation



88%
App Design Interface



88%
App Ease of Understanding
(Language)

*Data collected from patient surveys where participants rated their satisfaction on a scale from 1 to 5

HIGH ACCEPTANCE LEVEL



92%

Patient satisfaction with Process to Obtain ePI

Figure 1&2: Summary results of surveys conducted in 2021 and 2023

Proof of Concept in Belgium



by **Stefan Gijssels – Patients Expert Center**

Contributors: **Amanda Muir (GSK) and Hynek Zalcik (MSD)**

In Belgium, the project was directly coordinated by the **Patient Expert Center**. To assess patient perspectives in a real-world setting, we sent “dummy” product boxes with both a QR and 2D Data matrix code to the patients’ homes through the mail, with only the instruction to use the QR code on the pack to get started. The objective was to evaluate how individual patients manage to work with the digital leaflet. After one week, we set up individual interviews with each patient to understand their experience, using an interview guide with the following key topics:

- description of how they proceeded to use the electronic product leaflet
- value of the digital leaflet
- ease-of-use and accessibility, including language, typeface, and visuals
- preference for digital versus paper leaflets and the advantages of each

The interviews were conducted in the native language of each participant. Participants represented several disease groups (rheumatoid arthritis, cancer, multiple sclerosis), age ranges, and languages (Dutch and French-speaking).

Results from Patient Expert Interviews in Belgium

Of the 10 patients, 9 managed to open the QR code and get access to the patient leaflet. One person did not have a camera on her phone and did not know how to proceed.

Of those who managed to get access, the majority were happy with the result, including the ease of use and the option to select different languages. They all distinguished between the product box with the valid date and the box with the expired date. The advantages they experienced with the digital leaflet were:

- ease of use
- option to increase the font size
- structure and organization of the leaflet with clear sections at the beginning
- possibility to search the document for specific keywords (e.g. pregnancy).

Other future options that were mentioned included: the integration of a search engine, the use of color for important warnings, the use of color to make visuals easier to understand, the possibility to keep the leaflet access as a “favorite” on their phone (guarantee of access), and more.

Despite all the positive responses, most participants still valued the paper document and would recommend having both formats alongside each other. A larger sample of the patient population would be needed to fully demonstrate the advantages of a digital leaflet vs a paper leaflet.

Proof of Concept in Luxembourg

By Elisa Dolci - Innovative Medicines for Luxembourg
Contributors: Amanda Muir (GSK) and Hynek Zalcik (MSD)

In Luxembourg, the project was directly coordinated by **Innovative Medicines for Luxembourg** (IML), the trade association representing the research-based pharmaceutical companies operating in the country.

In Luxembourg, the methodology applied was slightly different, as each patient was met in person to perform the test. This was possible in part thanks to the collaboration with **EUPATI Luxembourg**. The questionnaire was the same one used in Belgium in its English and French versions, according to the patient's preference. A total of 12 patients representing 9 nationalities were interviewed, and some of the patients spoke only English.

These interviews are valuable above all because of the qualitative data they provided. For this reason, it was considered important to spend time in discussion with the interviewees, both during and after the test.

Results from Patient Expert Interviews in Luxembourg

In total 12 patients were interviewed, and they all managed to access the e-leaflet, although some struggled more than others. The main difficulty was to find the 2D Data matrix on the box, to scan it. However, most of the respondents found the navigation intuitive and easy once they were in the PharmaLedger web space. On average, the rating given to this aspect of the application was 4.4 out of 5.

Concerning the clarity of the language used in the ePIL, unfortunately, three of the respondents could not answer because they did not speak any of the proposed languages. For the other nine, the clarity of the language used was positively rated (4.3 out of 5). With respect to the used languages, one comment that emerged in several interviews was the need to include English among the options. In Luxembourg, English is one of the languages most used by foreigners and it is also accepted by the public administration.

All participants appreciated that the application includes a feature that informs the patient if the product has expired. All but one participant considered it important that the e-leaflet was available even if the product had expired.

Among all respondents, the average satisfaction rating of the process of obtaining the digital leaflet through the PharmaLedger application was 4.1 out of 5.

Among the most cited reasons, patients appreciated the solution were:

- the certainty of the source
- the possibility of finding information more easily
- the ease of reading thanks to the possibility of enlarging the font
- the possibility of copying and pasting information in order to translate it and/or send it via chat

The most critical individual respondents emphasized the importance of still having the paper leaflet available alongside the digital one.

During the discussion of possible future developments, participants highly appreciated the idea of being able to use a search bar to quickly access information such as dosage, side effects, incompatibility with other substances and medicines, precautions in the case of pregnancy and breastfeeding, and indications for children.

Participants also very much appreciated the idea of using videos to make information even more interactive and more usable by people with special needs (e.g. people suffering from dyslexia).

As already highlighted, discussions with patients revealed that many would prefer to have access to the information leaflet in English, Portuguese, or other languages. This consideration might open a dialogue with the national authorities, as under current law the leaflet has to be in French or German.

With respect to the other advantages of the PharmaLedger app, some patients emphasized that the paper leaflet often gets lost or ruined, whereas this solution makes it very accessible through a smartphone. Some mentioned that the paper leaflet is printed in very small font characters, making it difficult to read.

PharmaLedger Project | Initial Patient interaction feedback



By Hannes Jarke – European Patients Forum

During the early development of the ePI by PharmaLedger app, patients were invited to provide feedback. In the summer of 2021, EPF (European Patients Forum) and EFGCP (European Forum for Good Clinical Practice) recruited eight patients (five women and three men) affected by different conditions and living in various countries across Europe for a workshop series together with PharmaLedger members.

To gain a more holistic understanding of needs, we started the workshop series by identifying how patients interacted with leaflets in general. We inquired about what information is relevant to them and how well they understand it, and learned more about their individual experiences with leaflets. Based on this general discussion and to help us gain a sense of priorities, we led a conversation about specific ideas and features the group would like to see in an ePI app. We then asked patients to vote on which five features were the most important to them and rank them by priority.

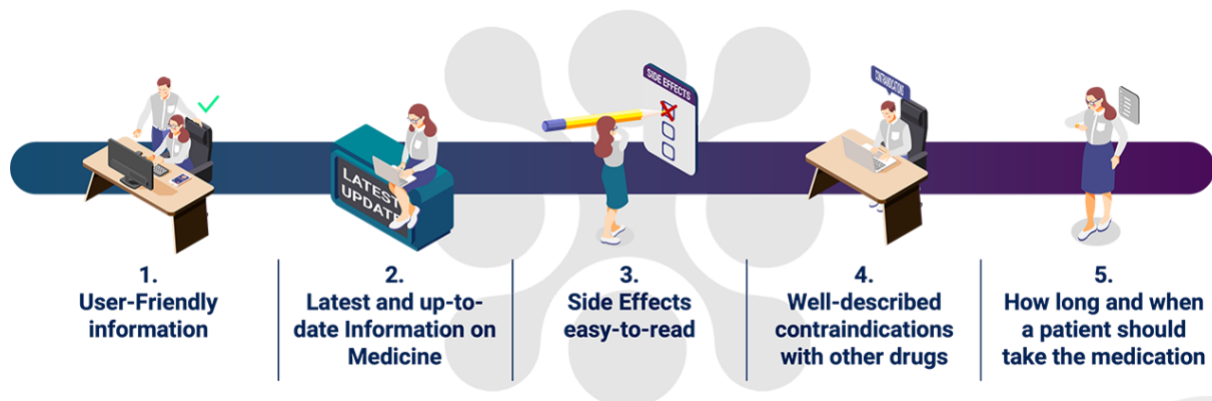


Figure 2: Five most important features that should be included according to the patient group. Features with no votes came up as a topic during Workshop 2, but were not voted for in the survey.

When asked to rate all features on a 5-Point Likert Scale from not important at all to very important, user-friendly information again emerged as the highest priority. This preference was later confirmed in an [open consultation at the Patient Engagement Open Forum](#).

In the third workshop, PharmaLedger partners provided a look and feel of the app with screenshots and took further input on the user experience. This input was taken into account in the fourth workshop and informed the lite version used in a fifth workshop—one year after the initial workshop—in which participants trialed the scanning process.

We found that shaky hands in particular can make scanning the 2D Code challenging and that the need to scan two codes did not make sense to some in the first interaction. Despite these challenges, however, users were able to navigate through the process.

Key Messages

- Involving patients early in the development process unveiled many considerations we might have missed otherwise
- Blockchain technology itself is not necessarily the most interesting part of the app for patients, but rather the interface they interact with and how the app functions
- One challenge will be to explain in layman's terms how data is stored (especially for the digital medicine cabinet) and communicate issues around data ownership
- While the people in our group are enthusiastic about digital, we will have to ensure that basic processes are easily accessible to all and account for groups who might be disadvantaged in the use of the app (e.g. people with hand tremors, or people unused to using apps commonly)
- There is great enthusiasm about a digital solution, but evaluating key concerns such as the presentation and user-friendliness of the information itself requires wider, system-level efforts with even more stakeholders
- Lastly, hear from the patients themselves in this [interview!](#)