

# Electronic leaflet pilot in Belgium and Luxembourg hospitals

## AUTHORS

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pharma.be is an umbrella association of the innovative pharmaceutical industry in Belgium, and represents more than 130 (bio)pharmaceutical companies.

## KEYWORDS

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## ABSTRACT

The e-PIL Pilot was set-up in Belgium and Luxembourg with the objective to demonstrate the equivalence between the paper patient information leaflet and the electronic patient information leaflet in providing information on the safe and effective use of medicines in hospital setting. The first results of the Pilot are promising and tend to demonstrate this equivalence. Furthermore, the absence of the paper leaflet appears to have a positive impact on the pharmacies waste management and does not result in any inconvenience in their daily work. Most of the respondent hospital pharmacists would agree to the removal of the paper leaflet from all hospital-only medicines. More data is needed to confirm these results and to support a potential change in European legislation.

## The electronic patient information leaflet: fast, efficient and environmentally friendly

In the EU, every medicine package must contain the patient information leaflet (PIL), which contains regulated and scientifically approved information to ensure the proper use of the medicine<sup>1,2</sup>. Furthermore, the latest approved leaflet text can be found on the regulator's website.

The electronic PIL offers new opportunities and possibilities compared to the traditional paper based PIL. It provides patients and healthcare professional (HCPs) with immediate access to the latest product information, made available by the market authorisation holders (MAHs) and the regulators responsible for the jurisdiction where marketed. Both patients and HCPs could so have the option to consult product information (PI) tailored to their needs (e.g., language of choice, electronically searchable topics of interest), which helps them to make informed decisions.

Moreover, replacing the paper PIL with an electronic version could have a positive impact on medicine shortages. This is because it would make it unnecessary to recall products to update the product information in the paper PIL. The use of electronic PILs would also facilitate imports between countries in Europe. Furthermore, this situation would have a positive impact on the environment, since adding the paper PIL in the packaging requires many additional resources such as paper, ink, larger packaging, and consequently more space and weight for transport and storage.

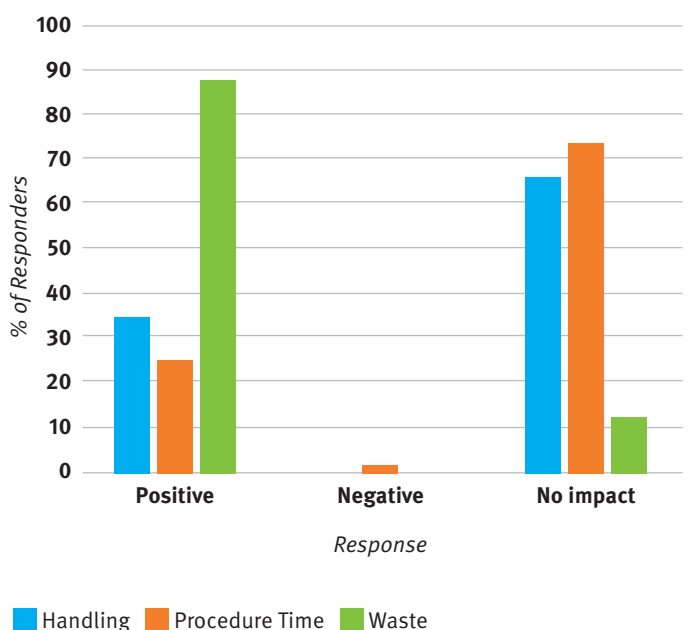
When considering the replacement of the inserted paper PIL in the packaging by the e-PIL, the e-PIL must be at least the same as the paper PIL in providing patients and HCPs with information on the safe and effective use of the medicine. In 2018, the e-PIL Pilot was implemented to demonstrate this equivalence, in a stepwise approach starting in hospitals in Belgium and Luxembourg.

## The Belgian and Luxembourg e-PIL Pilot

The e-PIL Hospital Pilot was proposed and designed by the associations of

the (bio)pharmaceutical industry in Belgium (pharma.be) and Luxembourg (IML). It had the support and collaboration of the Federal Agency of Medicines and Health Product (FAMHP) in Belgium and the Direction de la Santé (Ministry of Health) in Luxembourg, and the agreement of the European Commission. This Pilot is supported by the professional associations of hospital pharmacies in Belgium (BVZA-ABPH) and Luxembourg (APHL) and since 2020 by Medaxes, the association for generic and biosimilar medicines.

**Figure 1** How the removal of paper leaflets impacted pharmacists (t=24months)



### The concept and objective of the e-PIL Pilot

The e-PIL Pilot trials the switch from paper PILs to e-PILs in selected hospital-only medicinal products that are available on the Belgium and/ or Luxembourg market. The paper PIL is no longer required to be inserted in the medicines packaging. Instead, HCPs are referred to the e-PIL, which is available on various trusted reference sources. The medicines used in the Pilot represented different therapeutic areas for restricted hospital use. Moreover, the medicines were proposed on a voluntary basis by the MAHs, and their participation was validated by both national competent authorities (NCAs). By default, all hospitals in Belgium and Luxembourg participated in this Pilot, to avoid complexity from a MAH perspective to release different hospital-depending batches (with/without paper PIL inserted in the packaging).

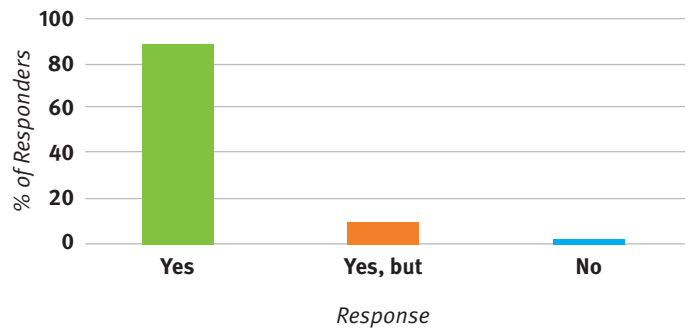
The objective is to demonstrate that the e-PIL is at least equivalent to its paper version, in providing information on the safe and effective use of medicines, to patients and HCPs within a hospital setting.

To conduct this Pilot, a specific derogation regarding the legal obligation of inserting the paper PIL, was requested and obtained from the Commission. It was initially given for two years starting in August 2018; however, based on positive interim results, the Pilot has been extended for an additional two years and will now run until August 2022.

### Methodology of the e-PIL Pilot

In June 2018, a dedicated steering committee, consisting of representatives of the NCAs, the hospital pharmacy associations and the pharmaceutical industry, was created to define and validate the key performance indicators (KPIs) of the Pilot. The steering committee would also monitor the Pilot and analyse the KPI results.

Figure 2 Do you agree that the paper leaflet should be removed? (t=24 months)?



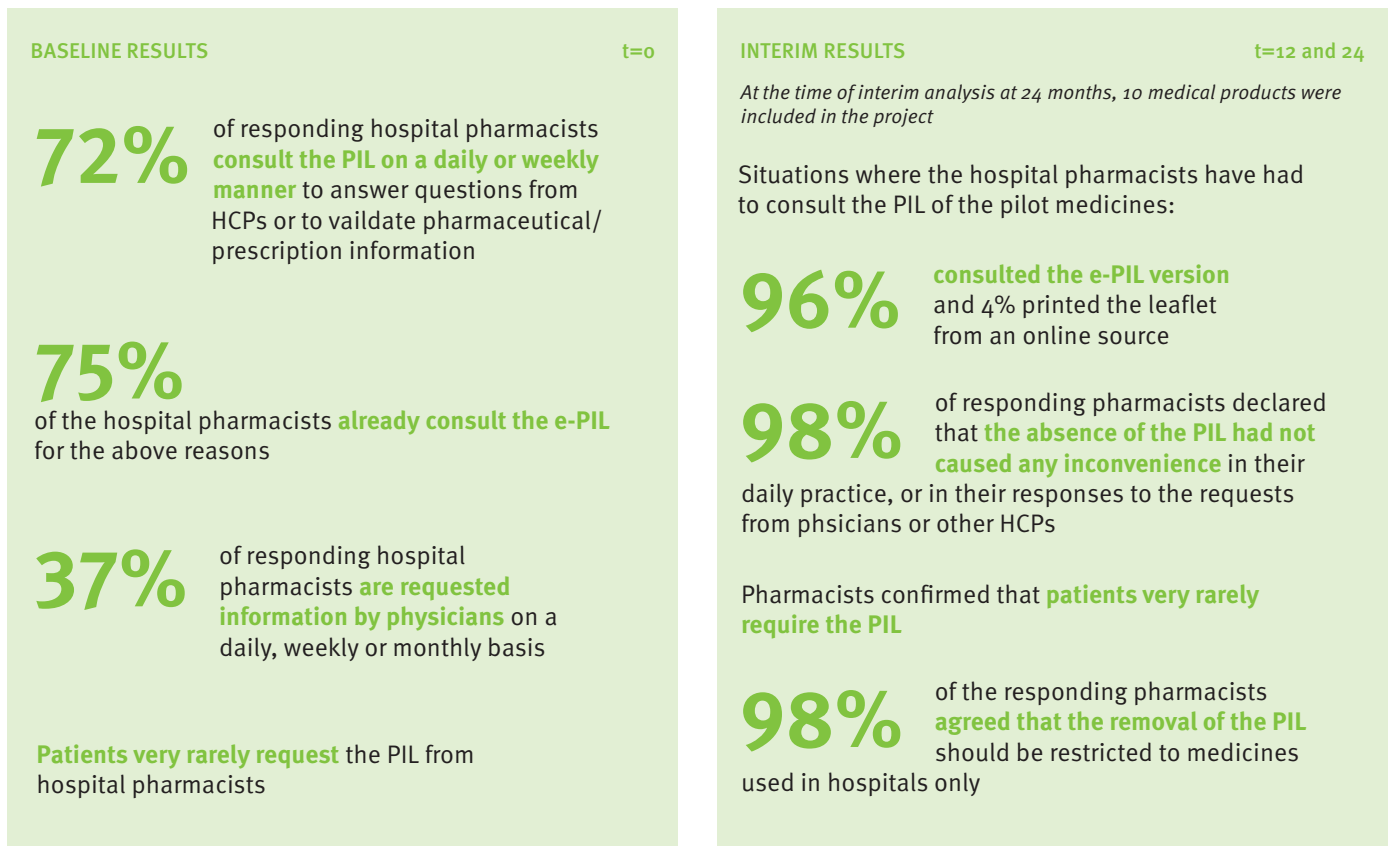
The following KPIs were chosen:

- Conduct a survey at specific times (at the start, after 12 months, after 24 months and at the end of the Pilot after 48 months) of participating hospital pharmacists (but also capturing the feedback of other HCPs in hospitals) to evaluate the access, usage and reading of the e-PILs
- Conduct a survey at specific times (after 12 months, after 24 months and at the end of the Pilot after 48 months) of the participating pharmaceutical companies, to evaluate any questions received due to the absence of the paper PIL within the concerned medicines.

### The first results of the e-PIL Pilot

In 2018, 12 medicines from 10 different pharmaceutical companies were validated by the authorities to take part in the Pilot. This number was increased after the second call for candidates launched in 2020. Since

Figure 3 Baseline and interim results of the e-PIL pilot



the end of November 2020, a total of 42 products from 17 pharmaceutical companies are now participating in the Pilot.

The questions of the survey have been drafted under the supervision of the steering committee of the Pilot. The surveys for hospital pharmacists and for participating pharmaceutical companies has each time been distributed electronically via the hospital pharmacist associations, and via the pharmaceutical industry associations respectively. The questions are further explained in the results section below. The evaluation of the results of the survey was done under the supervision of the steering committee.

### The baseline results (t=0)

The first survey was conducted at the beginning of the Pilot in 2018, in sought the experiences and views of participating hospital pharmacists. to create a reference baseline for the access, usage and reading of the already available e-PILs via existing trusted online sources.

The survey revealed that 72% of hospital pharmacists consult PILs in their daily practice on a daily or weekly manner, regardless of whether paper or electronic. It was determined that primarily, PILs were used to answer questions from HCPs (physicians, nurses and other pharmacists) or hospital departments, to check the posology (e.g., in case of pregnancy), the indication, the instructions for the preparation or administration, interactions with other medicines, adverse events and storage conditions. This is especially important for new medicines or medicines for rare diseases. 75% of hospital pharmacists will consult the e-PIL either daily or weekly. Moreover 78% of hospital pharmacists indicated that their rate of consulting the paper based PIL had fallen to less frequently than every 6 months or not at all.

The baseline survey also revealed that 91% of hospital pharmacists are either never or less frequently than every 6 months, asked by patients to receive the PIL of their medicines administered in hospitals. In these rare situations, the patients are provided with either the paper PIL (52%) or a printout of the e-PIL (37%).

### The interim results (after 12 and 24 months)

#### Survey in hospital pharmacies (t=12months<sup>6</sup> and t=24months<sup>9</sup>)

The Pilot surveys established that when the respondent pharmacists had to consult the e-PIL, 96% of them viewed the e-PIL online, with only 4% requiring a printout from the online source. Furthermore, for 98% of the respondent pharmacists, the absence of the paper PIL did not result in any inconveniences in their daily practice, or in their duty to respond to questions from physician or other HCPs.<sup>6</sup>

The absence of the paper PIL either had no impact (66%) or a positive impact (34%) on the handling of the medicine by the respondent hospital pharmacists. It had either no impact (73%) or a positive impact (25%) on the respondent pharmacists' procedure time, and indeed it was reported to have a positive impact on the pharmacies' waste management for 88% of the respondent pharmacists.<sup>7</sup>

The results confirm that patients very rarely request their medicine's PIL; with 98% of pharmacists in the Pilot having never or no more frequently than every 6 months, been asked by patients for the PIL.

Consequently, 98% of the respondent hospital pharmacists would agree to the removal of the paper PIL from all hospital-only medicines, with 11% (t=24) declaring that it should be limited to medicines restricted to hospital setting only, outside ambulatory setting.

### Pharmaceutical companies (t=12months<sup>8</sup> and t=24months<sup>9</sup>)

After 24 months, pharmaceutical companies only received six questions from hospital pharmacists. Five of them were related to the presence of

a blank leaflet inserted in the packaging of some included medicines; the latter was an intentional measure to bulk-out the relatively fragile vial in the packaging.<sup>10</sup> The other query was related to the Pilot in general, in which it was asked what was expected from the pharmacists, and whether the physicians (specialists) were also informed about the Pilot.

### A total of 409 511 units of medicines that did not contain a paper PIL in their packaging, were delivered during the first 24 months of the Pilot.

#### Discussion and conclusion

The interim analysis combined with the baseline information demonstrated that in a hospital setting, the e-PIL is just as effective as paper leaflets in providing information about the safe and effective use of medicines to HCPs.

The Pilot demonstrates that, in the daily practice of the hospital pharmacists, the e-PIL is consulted online, without the need to obtain a printout. Moreover, the absence of the paper PIL had either no- or even a positive impact on the respondent pharmacists' handling of the medicine. It had either no or even a positive impact on the pharmacists' procedure time. Furthermore, it had a positive impact on the pharmacies' waste management. Overall, the results illustrate that the absence of the paper PIL in the packaging of the medicines did not result in any inconvenience in the daily work of the pharmacist. In fact, the removal of the paper leaflet was found to facilitate the pharmacists' daily work.

The results also demonstrated that direct requests from patients to consult the PIL for their medications in hospital setting PIL were very rare.

### Next steps of the e-PIL Pilot

The Commission is closely following the progress of the Pilot and has been informed about the interim results. The next, and for now final, evaluation of the Pilot is planned in August 2022. However, the steering committee has recently decided that it would like to obtain more data to confirm the results obtained so far. They would also like to ensure a sufficient representation of the sample of medicines, to support a potential change in European legislation. Therefore, there will be another request to the Commission, to extend the Pilot and to include more products.

Postscript: the e-PIL Pilot in Belgium and Luxembourg has been a successful pioneering Pilot in Europe, and since it was launched, similar initiatives have been started in other Member States, such as Spain and the Baltic countries. The results of all these initiatives could be used collectively to support the recognition of the electronic product information and its use in the stepwise phasing out of the paper leaflets in hospital medicines. ■

### References

1. The legal requirement to include the PL in the packaging is laid down in Article 58 of the Directive 2001/83/EC
2. The content of the SmPC, labelling and PL is laid down in Articles 11, 54, 55 and 59 of Directive 2001/83/EC
3. Response rate of 100% in Luxembourg and 92% in Belgium (1 response per pharmacy per hospital was requested)
4. T=12months - Response rate of 60% in Luxembourg, 50% in Belgium (1 response per pharmacy per hospital was requested)
5. T=24months - Response rate of 60 in Luxembourg, 53% In Belgium (1 response per pharmacy per hospital was requested)
6. These results were exactly the same for both analysis
7. Results of the second interim analysis
8. T=12 - Response rate of 90%
9. T=24 - Response rate of 100%
10. It should be noted that the blank leaflet is added to ensure the stability of the vial in the carton of some of the medicines included in the Pilot as temporary solution. In a long-term situation (not a temporary Pilot), an adaptation of the packaging will be considered to avoid this blank leaflet.