IRIS GEUSSENS, *pharm D /Head of the Marketing Authorisation Division (variations and renewals) in the Federal Agency for Medicines and Health Products (Belgium)*, who treats all files concerning variations and renewal of national marketing authorisations for medicines for human use as well as all submissions for authorisations for parallel import.

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The national competent authorities of Belgium and Luxembourg share their views about the e-PIL Pilot

BY NATHALIE LAMBOT, pharma.be and
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Q: Why do the authorities support the e-PIL Pilot and why do you think it is important?

A: *Iris Geussens:* Digitalisation is the future, and the pharmaceutical sector cannot stay behind. The advantage of an electronic package leaflet is that you always have access to the most up-to-date information. Most changes to a patient information leaflet have to do with the safety of the product.

When the FAMHP administratively closes a change (variation) the adapted leaflets are available on our website the following week. This means that healthcare professionals quickly have the most recent information at their disposal, which is particularly useful for the safe and correct use of the medicine. A company has six months to implement the approved changes in the field. Therefore, updating the paper version takes much more time. Through the e-PIL Pilot, healthcare professionals are further encouraged to look up the information online and thus access the most recent information.

The first survey of hospital pharmacists carried out by pharma.be (the Belgian general association of the pharmaceutical industry) also showed that the paper version is often not used and is almost immediately discarded. So, from an environmental point of view, this Pilot also has an added value.

Dr. Anna Chioti: The Pilot is in line with the publication of an action plan by the European Medicines Agency in November 2017, aiming at improving SmPCs and patient information leaflets, including a move towards electronic information.

Throughout 2018, a series of initiatives have led to identifying actions that meet the needs of healthcare professionals and patients, such as enhancing readability, improving patient input, promoting best practices and developing an electronic format.

We, as regulators, were open to collaborating with other relevant stakeholders towards making ePIs a reality, because of the potential benefits of this format for public health. However, it was necessary to test these assumptions, as well as the feasibility of the approach in a real-life setting, and make sure that it could still be compliant with regulatory requirements.

This is why we at the Division of Pharmacy and Medicines of Luxembourg, decided to join our colleagues from the Belgian Federal Agency for Medicines and Health Products in August 2018, in collaborating with the industry associations on the e-PIL Pilot. After two years, we reiterated our support to expand the list of concerned medicines from 10 to 40 products and to continue the Pilot until August 2022. By doing so, this could further demonstrate the equivalence of an electronic leaflet with the paper version and confirm its value in providing up-to-date information on the safe and effective use of medicines by healthcare professionals and patients in hospitals.

Q: What are the benefits for patients and healthcare professionals?

A: *Iris Geussens:* The e-PIL Pilot only includes medicines that are exclusively used in a hospital. Thus, they do not directly reach the hands of the patient. The surveys carried out by pharma.be also show that patients rarely ask for the patient information leaflet. When they do, a printed version of the patient information leaflet can be supplied. This can be done in the patient's language only, and also in a more readable format.

The advantage for the healthcare professional is, as already indicated, having the most up-to-date information on the medicine quickly at hand.

Dr. Anna Chioti: There is a wide range of potential benefits for both patients and healthcare professionals. For instance, the use of e-PIL provides timely access to the latest information on a medicine's safety, benefits and conditions of use.

In the hospital-based setting of the e-PIL Pilot, it allows better delivery of information, so that the right information is available to the right HCP and patient at the point of need. In addition, the electronic PILs that are within the scope of the Pilot are available on our official website[1] as trustworthy and freely accessible open data.

Q: How do you see this within the context of environmental challenges?

A: *Iris Geussens:* In the day-to-day practice within a hospital, the paper version of the patient information leaflet proves to be superfluous. The presence of the paper patient information leaflet in the packaging creates a mountain of paper within the hospital that is not needed. When a paper version is no longer needed in these packages, this will reduce the environmental footprint.

Dr. Anna Chioti: Going 100% electronic to reduce waste and the environmental footprint of paper package leaflets is appealing but not conceivable. Although the e-PIL would be a recommended digital source of information, it is complementary to the paper leaflet. The current pharmaceutical legislation[2] requires the inclusion of a PIL in the packaging of all medicines, or directly conveying all information required[3] on the outer or immediate packaging. Therefore, each medicine that is included in the Pilot has received a special derogation for going from paper PIL to electronic.

One must not forget that providing access to the paper PL is still particularly important for patients with low digital literacy, or low ability to use digital devices effectively, or limited internet access. Nevertheless, only 4% of hospital pharmacists reported printing the leaflet of the medicines included in the Pilot from an online source. Furthermore, the preliminary results of our Pilot, confirm that patients very rarely request from the hospital pharmacists the printed PIL of these medicines.

> **The results of the e-PIL Pilot are positive for the pharmacists themselves. They quickly find the information that they are looking for**

Q: What are the main challenges and learnings so far from the Pilot?

A: *Iris Geussens:* The results of the e-PIL Pilot are positive for the pharmacists themselves. They quickly find the information that they are looking for. The absence of the patient information leaflet in the box did not have a negative impact; instead, it even facilitated their daily routine. However, the initial number of participating products was rather limited.

When the Pilot was extended, the number substantially increased. Therefore, we are curious to see whether the results of the survey after four years will yield the same positive results. Will including a larger number of products have a different impact on their routine? Are the right products included in the Pilot, namely those that generate a lot of questions/research?

Companies also need some time to adapt their production chain to this change. After all, in some cases the patient information leaflet is also used as a stabiliser for, for example, for a vial in the packaging.

Dr. Anna Chioti: The main challenge from our side was the need to set up a common framework that is compliant with the legal and regulatory requirements in guaranteeing patient safety. This meant granting national derogations for exempting each concerned product from its paper leaflet. Once this aspect was approved, the collaboration with the different stakeholders was very straightforward and efficient. After the initial period, the approach was deemed feasible and could be expanded to a wider range of products across therapeutic areas.

The Pilot has demonstrated that the advantages of the e-PIL, such as fast and easy access to up-to-date information, as well as reduced waste, far outweigh the potential inconvenience related to digital literacy and internet access. Indeed, very few patients solicited the hospital pharmacists to receive the printed PIL. We have also learned that education, awareness campaigns and information about e-PILs helps increase their use.

Q: How do you see the Pilot evolving in the future?

A: *Iris Geussens:* To date, legislation states that every package that is placed on the market must be accompanied by a patient information leaflet. Therefore, to make the removal of a patient

information leaflet in this category of medicines permanent, an amendment to the legislation is necessary. This is all the more important as the European Commission is planning a review of the legislation on medicines in the next few years. It would therefore be a good idea to extend this pilot once again and to run it in parallel with the review of the legislation, so that the results of the Pilot can be taken into account if necessary. We should also consider what the provision of the leaflet in digital form could mean for the nurse at the time of administering the medicine to the patient. Also, we could also look further into the way in which the digital patient information leaflet could be made available, for example via a QR code on the packaging or via XML format instead of via a PDF.

Dr. Anna Chioti : The current limitation of the Pilot is that the concerned medicines are mostly injectable formulations, which are dispensed in a hospital setting. Although patients very rarely ask the hospital pharmacists for the printed PIL of these medicines, this might not necessarily be the case for oral formulations or in the ambulatory setting and would need to be tested.

The Pilot illustrates the regulatory and operational feasibility, as well as the user-acceptance of replacing paper leaflets with e-PILs. Its results will serve as a basis for informing future initiatives. For instance, a next step could be to test the e-PIL for other types of products or products dispensed by community pharmacies. The e-PILs would be available on a trusted website with a good mobile interface and a printout would be available upon request at the local pharmacy if needed. Additional features related to the use of e-PILs could then be evaluated, such as the ease of access to information through key word searches, the use of "text-to-speech software" for the visually impaired or automatic translation to serve smaller markets.

The Pilot illustrates the regulatory and operational feasibility, as well as the user-acceptance of replacing paper leaflets with e-PILs

Finally, I see the development and wider use of e-PILs as an important bridging element with other ongoing digital initiatives at the national and EU level. ■

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