



e-PIL pilot project
in Belgium & Luxembourg

november 2020

1. Description of the pilot project for Belgium & Luxembourg

Concept of the pilot

The pilot project proposes a **switch** from paper PIL to e-PIL in the packaging

- of selected approved (via centralized, mutual recognition, decentralized, or national procedure) medicinal products available on the Belgium and/or Luxembourg market but restricted to hospital use as per their legal status mentioned in the annex IIb of the marketing authorization and in line with the SmPC.
- using as reference a trusted source of electronic PILs for medicines approved in Belgium
- during a time limited period of 24 months (project initially started on 01 August 2018), now extended to 48 months (until 01 August 2022)

Objective of the pilot

This pilot aims at demonstrating that the electronic PIL is equivalent to the paper PIL to provide the information on safe and effective use of the medicines to the patients and the healthcare professionals in the hospital setting.

Outline of the organization of the pilot

The e-PIL pilot project has been launched on August 1, 2018, for initially a period of 24 months.

The hospitals were informed on the general principles of this pilot and its organization and conduct in Belgium and Luxembourg via their responsible hospital pharmacist. A general communication was sent to the attention of hospital pharmacists to explain the pilot project (including regulatory considerations) and to list in annex the participating medicinal products as validated by the authorities (name, common name, pharmaceutical form, strength, packsize, and type of container) with one contact person for each marketing authorization holder in case of questions. The communication also provided the references of the national trusted source(s) that can be used to access the electronic version of the PIL in the context of this pilot.

The batches of the included medicinal products are since the starting date of the project (August 1, 2018) released by the qualified person for manufacturing without any paper PIL inserted in the packaging and are distributed to the hospitals in Belgium and Luxembourg by the marketing authorization holder. A letter is sent together with each batch of the medicines concerned by the pilot to the attention of the pharmacists to confirm the inclusion in the pilot. The respective National Competent Authorities are informed of all the batch numbers and release dates concerned by the pilot for each selected product by the contact person nominated by the marketing authorization holder.

Thanks to the positive results (see annex for a summary of the results) observed in the intermediate analysis of the pilot project, the Belgian and Luxembourg's authorities agreed to request an extend of the project to the European authorities, which has been approved for again a period of 24 months (until 01 August 2022) and for inclusion of more products.

Once validated by the National Competent Authorities in Belgium (FAMHP) and in Luxembourg (Health Directorate), the batches of the additional medicines newly included in the pilot after this second call for candidates can be released without any paper PIL.

The pilot project will be closed after 48 months for analyses of the results, on 01 August 2022 which means that the last release of the batches of the medicines without any paper PIL in the packaging should thus happen before 01 August 2022.

A communication will be sent to the attention of the hospital pharmacists to inform them about the extension of the pilot project and provide them the list with all medicines included.

Source of electronic PIL for the pilot

Based on the information collected in a survey conducted in hospital pharmacists (*see annex below*), the following trusted reference sources are proposed to be communicated in the context of the pilot:

- Famhp website: <http://bijsluiters.fagg-afmps.be/?localeValue=fr>
- CBIP/BCFI website: <http://www.cbip.be/fr/start>
- Website of the government of Luxembourg: <http://www.sante.public.lu/fr/index.php>
- e-notice: <http://www.e-compendium.be/> (for Pharma.be members)

It is advised to propose the different sources for the best convenience of the hospitals.

KPIs for evaluation of the pilot

The following KPIs are proposed

- A survey for hospital pharmacists (which also captures the feedback of the healthcare professionals in hospitals) was conducted at the beginning (t=0) of the project for the baseline, after 12 months for a first intermediate analysis and a survey is now open after 24 months for a second intermediate analysis to evaluate the access, the use and reading of the electronic PILs. A final survey will be organized at the end of the project (t=48 months).
- A survey in participating pharma companies was conducted after 12 months for a first intermediate analysis of the project and is now open after 24 months for a second intermediate analysis of the project to evaluate the questions received due to the absence of paper PIL in the packaging of the concerned medicines. A final survey will be organized at the end of the project (t=48 months)

2. Medicinal products to be included in the pilot & call for candidates

A limited number of medicinal products approved (via centralized, mutual recognition, decentralized or national procedure) and available on the Belgium and/or Luxembourg market can be part of the pilot project. Only medicinal products **restricted to hospital use** as per their legal status mentioned in the annex IIb of their marketing authorization and in line with the information in the SmPC can enter the pilot project. There may be **no direct delivery** of the concerned medicinal products to the patient by the hospital pharmacy. Multi-country packs (except Be-Lux packs) and packs used for exportation may not be included.

The list of received medicinal products as candidates for the pilot project and fulfilling the above criteria will be further provided to the Federal Agency of Medicines and Health Products in Belgium and the Competent Authorities in Luxembourg for further validation and confirmation of participation before inclusion in the pilot project.

Annex: e-PIL pilot project summary intermediate results (after 12 months)

Electronic patient leaflet pilot project (e-PIL)– What's next ?

What? Medical products switch from paper patient leaflet to electronic patient leaflet.
Where? On the Belgium and Luxembourg market, products with a restricted use in hospital.
How? With a trusted source of electronic patient leaflets.
Regulatory consideration: supported by the Belgian and Luxembourg Competent Authorities, authorised by the European Commission
When? Starting the 1st August 2018, for a time-limited period of 24 months.
Why? Demonstrate that electronic version of the patient leaflet is equivalent to the paper version of the patient leaflet to provide the information on safe and effective use of the medicines to the patients and the healthcare professionals in the hospital setting.



Evaluation of the pilot KPIs (t=0, t=12 & t=24)

- (1) Survey for Hospital Pharmacists
 → Evaluate the access, the use and the reading of the electronic patient leaflet
- (2) Survey for participating pharma companies
 → Evaluate the questions received due to the absence of paper patient leaflet

Baseline Results (t=0)



72%

Of responding hospital pharmacists consult the patient leaflet on a **daily** of weekly manner, to answer HCPs questions or for pharmaceutical/prescription validation.

for this purpose

75% of the hospital pharmacist already consult the electronic version.



37%

Of responding hospital pharmacists are solicited by physicians on a **daily, weekly** or monthly manner

Patients solicit **very rarely** the hospital pharmacists to receive the patient information leaflet.

Advantages / Disadvantages



Easy access, rapid sharing of the info, tailored use, most recent info & reducing waste



Access to internet not always easy & available for patients, change of habits to be accompanied by education



Interim Results (t=12)

When responding pharmacists have had to consult the patient leaflet of participating medicines:

96% have consulted the electronic version and 4% have printed the leaflet from online source.

98% of responding hospital pharmacists declare that the absence of paper version **hasn't generate any inconvenience** in their daily practice or to respond to the demands from physicians or other HCP's.

Confirmation that patients solicit **very rarely** the hospital pharmacists to receive the patient information leaflet.

98%

Of the responding pharmacists would agree that paper leaflet is removed from the packaging of the medicines restricted to hospital use.



Advantages / Disadvantages

The absence of the paper patient leaflet in the packaging has had **no impact on the daily process** of pharmacists or even has facilitated this process.

Electronic patient leaflet pilot project (e-PIL)– What’s next ?

Interim results - participating pharma companies



- ✓ Aggregated total of ± 69000 sold units during these first 12 months
- ✓ **Only 4 questions** related to the absence of paper leaflet submitted by the healthcare professionals to the participating pharma companies



What’s the next steps?

The steering committee of the project agrees

- ✓ With the positive results
- ✓ That it is asked to the competent authorities in Belgium and in Luxemburg
 - To inform the European Commission about the interim results of the patient leaflet
 - To request the European Commission to extent the derogation for the pilot



DURATION of the pilot



inclusion of **NEW MEDICINAL PRODUCTS**

Questions ?



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