Medaxes
Association for accessible medicines

e-PIL pilot project
in Belgium & Luxembourg

Third Call for Candidates

August 2022

CALL FOR CANDIDATES

Second call for candidates to participate open from 17 August 2022 up to 17 November 2022

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 – approval for the conduct of the pilot until the 1st of August 2025 received from the European and the National Competent Authorities.

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 the end of this document for a summary of the results) observed in both intermediate analysis (after 12 months and after 24 months) of the pilot project, the project was first extended in 2020 with two years. However, according to the steering committee of the pilot project, more data is needed to confirm the results observed so far and to ensure the sample of products is sufficiently representative. Therefore, the Belgian and Luxembourg's authorities agreed to request a second extension of the project to the European authorities, which has been approved for a period of 36 months (until 01 August 2025) and for the 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 third call for candidates can be released without any paper PIL. There is no deadline as of when the batches must be released without paper leaflet.

The pilot project will be closed for analyses of the results, on 01 August 2025 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 2025.

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:
  - NL: https://geneesmiddelendatabank.be/menselijk-gebruik
  - FR: https://basededonneesdesmedicaments.be/usage-humain
  - EN: https://medicinesdatabase.be/human-use
- 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 and 24 months and a survey is now open after 48 months for a third intermediate analysis to evaluate the access, the use and reading of the electronic PILs. Another intermediate survey will be organized at t=70 months and a final survey at the end of the project (t=84months).
- A survey in participating pharma companies was conducted after 12 and 24 months and is now open after 48 months for a third intermediate analysis of the project to evaluate the questions received due to the absence of paper PIL in the packaging of the concerned medicines. Another intermediate survey will be organized at t=70 months and a final survey at the end of the project (t=84 months)

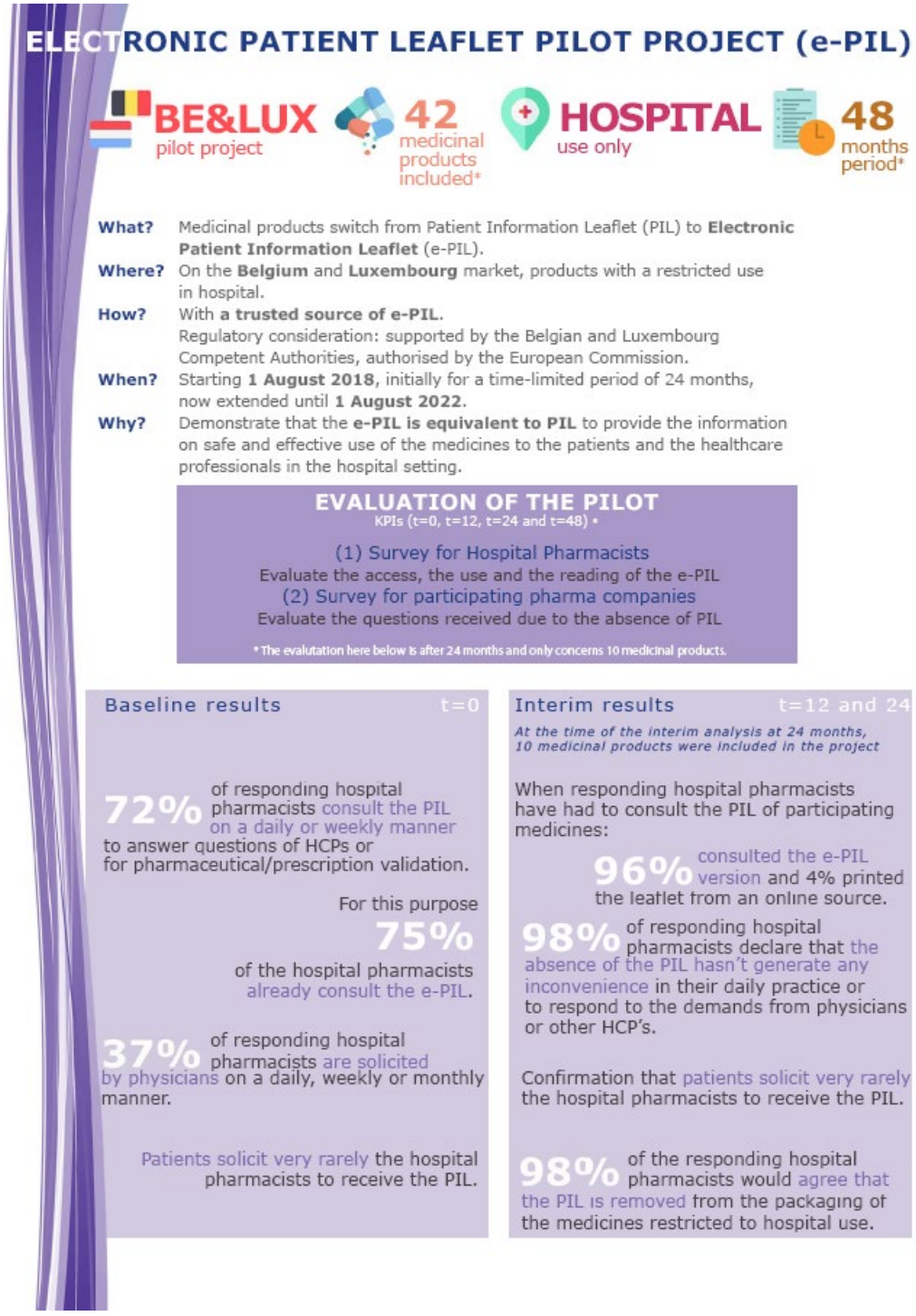
2. Medicinal products to be included in the pilot & call for candidates

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. Products in all therapeutic areas can be proposed. It would be of high interest for the project that also products are included for which the hospital pharmacist frequently needs to consult the patient leaflet in its daily work (e.g. new medicines, medicines in orphan diseases, medicines for which a preparation is needed etc.)

If you wish to participate to this pilot project, or if you have any other questions, please send your candidature or questions to ad@medaxes.be by 17 11 2022 the latest with the proposed medicine(s) to be included in the pilot project : name, common name, pharmaceutical form, strength, packsize, and type of container together with the name of one contact person for the pilot project per marketing authorization holder (one contact person for the project for authorities/associations and, if different, one contact person/mail address for HCPs in case of questions about the project).

The list of received medicinal products as candidates for the pilot project and fulfilling the above criteria will be 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. Once validated, the MAH will be informed via email (beginning of 2023).

Annex: e-PIl pilot project summary intermediate results




Advantages - Disadvantages
(t=0, t=12 and t=24)
Easy access, rapid sharing of the info, tailored use, most recent info & reducing waste
The absence of the paper patient leaflet in the packaging has had no impact on the daily process of pharmacists or even facilitated this proces
Access to internet not always easy & available for patients, change of habits to be accompanied by education
Interim results
Participating pharma companies
• Aggregated total of ± 409 511 sold units during these first 24 months
• Only 6 questions related to the absence of PIL submitted by the healthcare professionals to the participating pharma companies
What are the next steps?
Based on the positive results, the European commission agreed
• To extend the project duration until 1 August 2022
• To include new medicinal products in the project
Since December 2020, a total of 42 products restricted to hospital use from 18 pharmaceutical companies are included in the e-PIL pilot project.
Participating companies (not exhaustive)
Roche
CSL Behring
SANOFI
HUCLEIS
Boehringer Ingelheim
aspen
janssen
abbvie
gsk
Baxter
NOVARTIS
Takeda
Bayer
Pfizer
Bristol Myers Squibb
SERVIER
MSD
Questions ?
pharma.be
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Marie VANDE GINSTE
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Sonia FRANCK
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pharma.be vzw | asbl
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T 02 661 91 14 | F 02 661 91 99 | M 0499 37 54 59 | www.pharma.be | info@pharma.be |
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