Medaxes
Association for accessible medicines

e-PIL pilot project
in Belgium & Luxembourg

Second Call for Candidates

August 2020

CALL FOR CANDIDATES

Second call for candidates to participate open from 17 August 2020 up to 15 September 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)

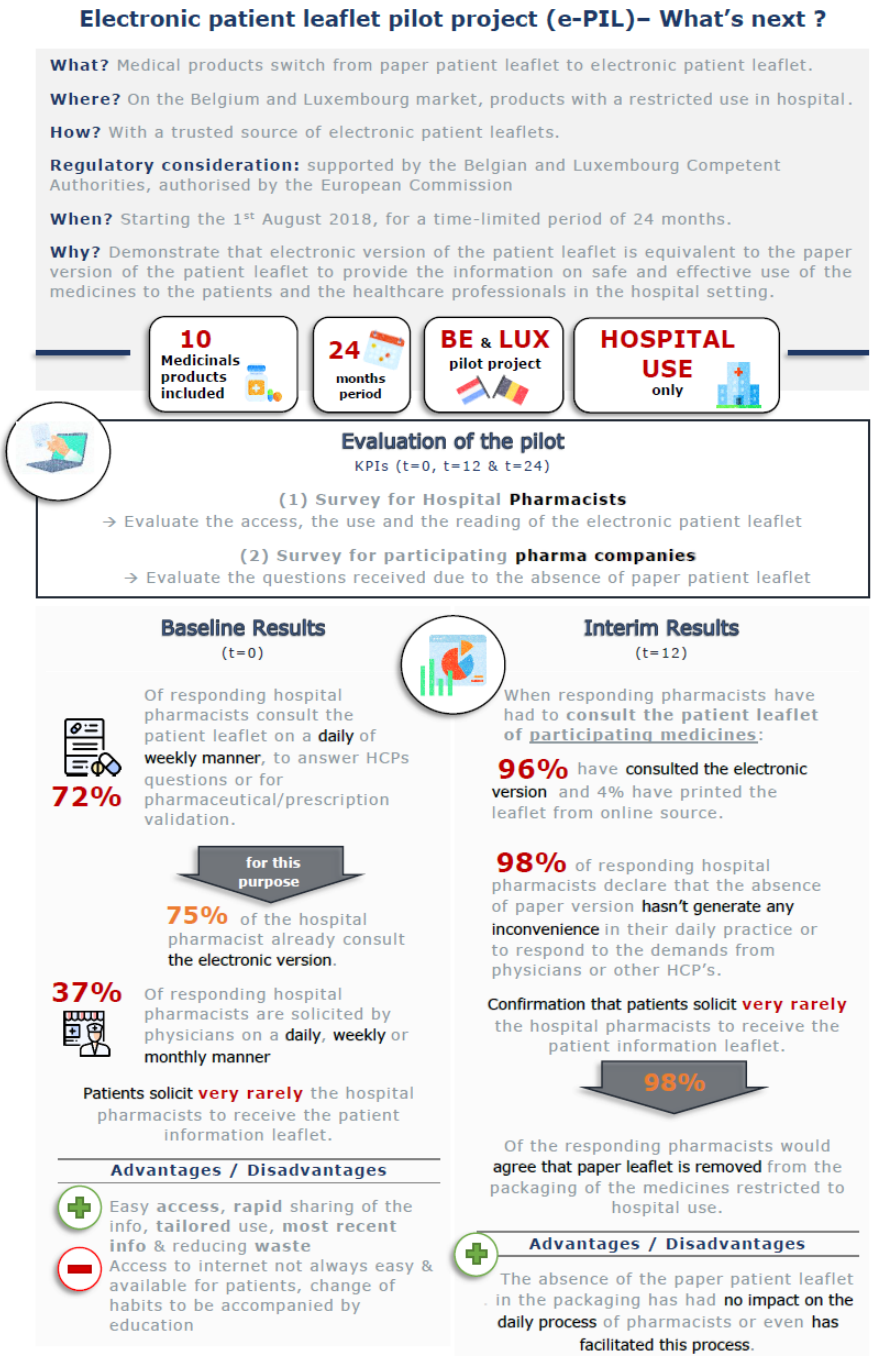
2. Medicinal products to be included in the pilot & call for candidates

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.

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 15 09 2020 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 medicine should be proposed as first choice with the possibility (*if you wish*) of more medicines preferably in another therapeutic area. Candidates will be included chronologically upon receipt of candidatures (when they fulfil the criteria mentioned hereabove).

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 inf the pilot project.

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



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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