

BE&amp;LUX

HOSPITAL  
USE ONLY84  
MONTHS129 MEDICINAL  
PRODUCTS INCLUDED

- WHY** To demonstrate that the **e-PIL is equivalent to the paper PIL** in providing information on safe and effective use of the medicines to the patients and healthcare professionals (HCPs) in **hospital setting**.
- HOW** The e-PIL is available on several **trusted sources online**. The project is supported by the Belgian and Luxembourg Competent Authorities and authorised by the European Commission
- WHAT** Medicinal products switch from paper Patient Information Leaflet (PIL) to **Electronic Patient Information Leaflet (e-PIL)**.
- WHERE** On the **Belgium and Luxembourg** market, products with a restricted use in hospital.
- WHEN** Starting **1 August 2018**, initially for a time-limited period of 24 months, now extended until **1 August 2025**.

## Evaluation of the pilot

### (1) Survey for hospital pharmacists to evaluate the access, the use and the reading of the e-PIL

#### Baseline results (2018) t=0m

- 72 % of responding hospital pharmacists consult the PIL on a daily or weekly manner to answer questions of HCPs or for pharmaceutical/prescription validation.
- For this purpose: 75 % of the hospital pharmacists already consult the e-PIL.
- 37 % of responding hospital pharmacists are solicited by physicians on a daily, weekly or monthly manner.
- Patients very rarely solicit the hospital pharmacists to receive the PIL.

#### Latest interim results (2022) t=48m

When responding hospital pharmacists have had to consult the PIL of participating medicines:

- **98 % consulted the e-PIL version** and 2 % printed the leaflet from an online source.
- **97 %** of the responding hospital pharmacists declare that the **absence of the paper PIL in the packaging has not caused any inconvenience** in their daily practice. Moreover, according to **100 %** of the hospital pharmacists, the absence did not cause any inconvenience to physicians and for **93 %** of the hospital pharmacists, the absence did not cause any inconvenience to nurses.

Confirmation that patients **solicit very rarely** the hospital pharmacists to receive the PIL.

- **95 %** of the responding hospital pharmacists would **agree that the PIL is removed** from the packaging of the medicines restricted to hospital use.

## (2) Survey for participating pharma companies to evaluate the questions received due to the absence of the paper PIL

### Latest interim results (2022) t=48m

- Aggregated total of **± 1,079,523 sold units** during the first 48 months
- Only **9 questions** related to the absence of the paper PIL submitted by the healthcare professionals to the participating pharma companies

### What are the NEXT STEPS?

- Following a third call for candidates organised by the Belgian and Luxembourg competent authorities, **88 additional medicinal products were approved** to be included in the project.
- Since June 2023, a total of 129 products restricted to hospital use from **27 pharmaceutical companies** are included in the e-PIL pilot project. Batches can be released without paper PIL in the packaging until **1 August 2025**.
- A **next interim** evaluation of the project is planned for **2024**.
- The results of this pilot can be used to support the **change in EU pharmaceutical legislation regarding the transition from paper PIL to e-PIL, implemented through a step-wise approach, starting in the hospital.**

### PARTICIPATING COMPANIES (NON-EXHAUSTIVE)



pharma.be

iml  
Dedicated to Life

Medaxes  
Association for accessible medicines

famhph  
federal agency for medicines and health products

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