

# ELECTRONIC PATIENT LEAFLET PILOT PROJECT (e-PIL)



**42**  
medicinal  
products  
included



**Hospital**  
use only



**84**  
months  
period

- What?** Medicinal products switch from 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.
- How?** With **a trusted source of e-PIL**. Regulatory consideration: supported by the Belgian and Luxembourg Competent Authorities, authorised by the European Commission.
- When?** Starting **1 August 2018**, initially for a time-limited period of 24 months, extended until **1 August 2025**.
- Why?** Demonstrate that the **e-PIL is equivalent to PIL** 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=0m, t=12m, t=24m, t=48m, t=70m and t=84m)

### (1) Survey for hospital pharmacists

Evaluate the access, the use and the reading of the e-PIL

### (2) Survey for participating pharma companies

Evaluate the questions received due to the absence of 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 solicit very rarely 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 4% 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 pharmacists, the absence did not cause any inconvenience to physicians and for 93% of the 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.

## Advantages - Disadvantages of the e-PIL (baseline and interim results)



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

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



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

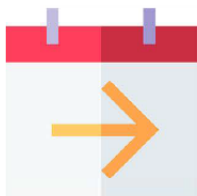
## Latest interim results of survey in participating companies (2022)

- Aggregated total of  $\pm$  1 079 523 sold units during these first 48 months
- Only 9 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 2025**
- 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.

The competent national authorities are currently validating new products to enter the project, following a **third call for candidates** that was open from August 2022-November 2022.

### Participating companies (not exhaustive)



CSL Behring  
Biotherapies for Life™

SANOFI

MUCLEIS  
RADIOFARMACÉUTIQUES

Boehringer  
Ingelheim

abbvie

aspen

janssen | JOHNSON & JOHNSON

gsk

Baxter

Pfizer

NOVARTIS

Takeda

Bayer

Bristol Myers Squibb™

SERVIER

MSD  
INVENTING FOR LIFE

### Questions?

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Association for  
accessible medicines

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