

BE&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, 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.

Final results (2024) t=72m

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

- **97 % consulted the e-PIL version** and 3 % printed the leaflet from an online source.
- **100 %** 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 **97 %** 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.

- **97 %** 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

Final results (2024) t=72m

- Aggregated total of **minimum 4 290 712 sold units** throughout the pilot project.
- Only **12 questions** related to the absence of the paper PIL submitted by the healthcare professionals to the participating pharma companies.

Conclusion & Next Steps

- 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**.
- The project demonstrated that, in hospital setting, the use of the e-PIL format only is **equivalent to the use of the paper PIL** to provide information on a safe and effective use of the medicines by the hospital pharmacists to the healthcare professionals in their daily practice.
- 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)



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