

# Electronic patient leaflet pilot project (e-PIL)– What’s next ?

**What?** Medical products switch from paper patient leaflet to electronic patient leaflet.

**Where?** On the Belgium and Luxembourg market, products with a restricted use in hospital.

**How?** With a trusted source of electronic patient leaflets.

**Regulatory consideration:** supported by the Belgian and Luxembourg Competent Authorities, authorised by the European Commission

**When?** Starting the 1<sup>st</sup> August 2018, for a time-limited period of 24 months.

**Why?** Demonstrate that electronic version of the patient leaflet is equivalent to the paper version of the patient leaflet to provide the information on safe and effective use of the medicines to the patients and the healthcare professionals in the hospital setting.

**10**  
Medicinals  
products  
included



**24**  
months  
period

**BE & LUX**  
pilot project



**HOSPITAL**  
**USE**  
only



## Evaluation of the pilot

KPIs (t=0, t=12 & t=24)

### (1) Survey for Hospital Pharmacists

→ Evaluate the access, the use and the reading of the electronic patient leaflet

### (2) Survey for participating pharma companies

→ Evaluate the questions received due to the absence of paper patient leaflet

## Baseline Results

(t=0)

  
**72%**

Of responding hospital pharmacists consult the patient leaflet on a **daily** of **weekly** manner, to answer HCPs questions or for pharmaceutical/prescription validation.

for this  
purpose

**75%** of the hospital pharmacist already consult the electronic version.

**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 patient information leaflet.

### Advantages / Disadvantages



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



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

## Interim Results

(t=12)

When responding pharmacists have had to **consult the patient leaflet of participating medicines**:

**96%** have consulted the electronic version and 4% have printed the leaflet from online source.

**98%** of responding hospital pharmacists declare that the absence of paper version **hasn't** generate any **inconvenience** in their daily practice or to respond to the demands from physicians or other HCP's.

Confirmation that patients solicit **very rarely** the hospital pharmacists to receive the patient information leaflet.

**98%**

Of the responding pharmacists would agree that paper leaflet is removed from the packaging of the medicines restricted to hospital use.



### Advantages / Disadvantages

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

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## 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 ?



### Project contacts

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