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ASSOCIATION GÉNÉRALE DE L'INDUSTRIE DU MÉDICAMENT
ALGEMENE VERENIGING VAN DE GENEESMIDDELENINDUSTRIE

afmps fagg
agence fédérale des médicaments et des produits de santé
federaal agentschap voor geneesmiddelen en gezondheidsproducten

E-PIL
Belgium & Luxembourg
Pioneer Pilot Project

London, the 28th of November

APL
Association Pharmaceutique Luxembourgeoise

LE GOUVERNEMENT
DU GRAND-DUCHÉ DE LUXEMBOURG
Ministère de la Santé

Direction de la santé

Why such a pilot project in Belgium and Luxembourg?

Convenience of electronic Patient Information Leaflet

- Continued access to the most recent information
- Personalised and user-friendly information

- Supporting the mission of Public Health
- Quick access and dissemination of the most recent information
- Personalised and user-friendly information
- Flexibility in update of the information, reducing product recalls
- Reducing environmental impact (paper and production)

A specific context in Europe

- 2015: recommendations in Nivel Report
- European Commission report on improvement of product information

A specific context in Belgium and Luxembourg

- internet access up to 85%* in Be and to 97% in Lux**.
- use of social media (69%)*

2014: a survey in hospital pharmacists showed a wide use of electronic support for patient information

- 90% pro switch paper version to electronic version
- 44% use both the paper and the electronic version
- 55% only the electronic version

Source:
**https://economie.fgov.be/fr/themes/line/les-tic-en-belgique/le-tic-en-chiffres*
*** Lux Figures in 2015*
****Survey conducted in 2014 with the help of pharma.be and the hospital pharmacists association; survey filled out by 199 respondents.*

Objectives and outline of the pilot

The **package leaflet** for a selection of centrally approved medicinal products restricted to hospital use and marketed in Belgium and/or Luxembourg is **no longer included in their paper version but** is **available via online consultation of trusted websites**

CONCEPT

1

To demonstrate **e-PIL is equivalent to paper PIL** to provide information on safe and effective use of medicines to healthcare professionals and patients in the context of hospital used medicines

OBJECTIVE

2

- Only for a **selection of medicines** ± 15 medicines in different therapeutics areas
- Hospital-only
- NO ambulatory
- Central products only

SCOPE

3

Time-limited project of 24 months

Roadmap

Regulatory considerations

No more paper product information leaflet inserted in the package
⇒ Not in line with article 58 of EU Directive 2001/83/CE (implemented in Belgian and Luxembourg legislation)

***2016-2017**: Consultation and engagement of association hospital pharmacists*

October 2017 –December 2017:

***Request of Derogation to article 58** prepared by the BE & LUX authorities and submitted to EU commission*

Conditions: limited number of medicines restricted to hospital setting; time limited project

Obtained in December 2017

April 2018 – June 2018:

***Call for candidates** supported by the BE & LUX authorities*
***Validation by the BE & LUX authorities** of each proposed medicine as candidate*

Practical setting and methodology

Operational setting

01 Aug 2018: Batch release and distribution of batches without paper PIL inserted

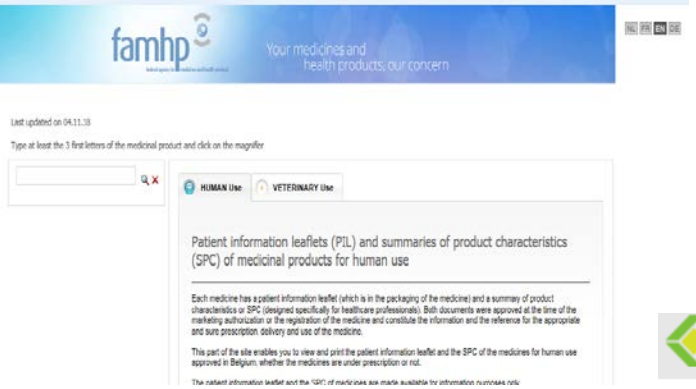
Communication to pharmacists together with each batch of concerned medicines

Inform National Competent Authorities of the batch numbers and release dates of concerned batches

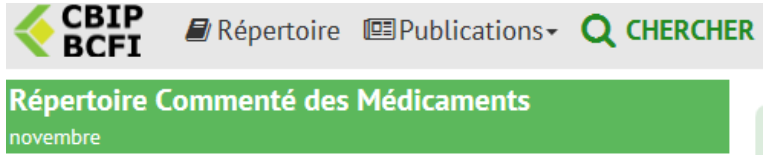
21 months QP batch release

24 months for KPI analyses

Online consultation of product information

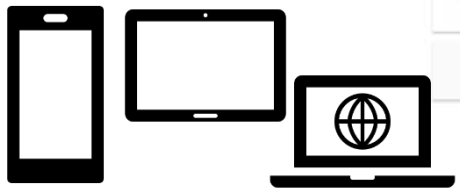


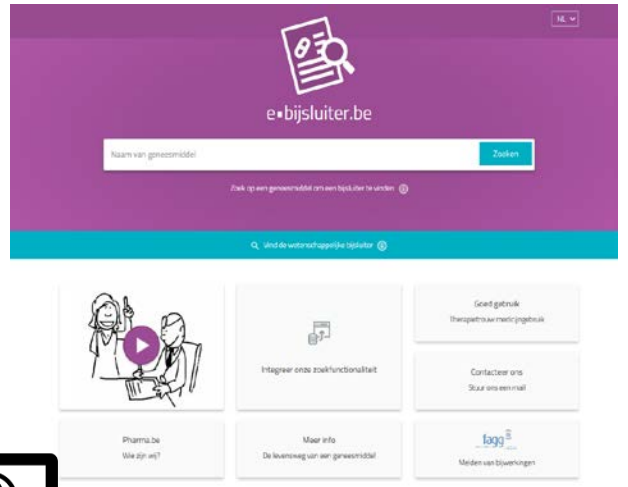
Via Competent Authorities website & official commented list of medicines (CBIP-BCFI)



Via pharma.be e-notice

- *Adaptive site*
- *Search engine*
- *Xml layout*
- *Chapter by chapter*





Key performance indicators and follow-up of the pilot project

Steering committee:
- pharma industry representatives
- hospital pharmacists
- BE & LU competent authorities

KPIs

- Defined and monitored by the steering committee
- Survey in hospital pharmacists (t=0=baseline; t=12months; t=24months) to evaluate **the access, the use and the reading of electronic PILs** during the pilot project
  - Incl. capture of the feedback for the healthcare professionals in hospitals (nurses, physicians)
  - Baseline survey during summer 2018: response rate: 100% Lux, 92% Be - Results under analysis
- Survey for participating pharma companies (t=12months; t=24months) to evaluate the questions due to the absence of paper patient information leaflet in the packaging.

⇒ **key outcomes to demonstrate:**

- allow to provide sufficient, adequate and tailored (e.g. language) information to healthcare professionals and patients with no need to print the patient information
- positive impact on daily practice of hospital pharmacists

Thank you!

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