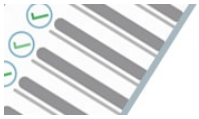
State Agency
of Medicines
Republic of Latvia


(/zvais/zalu-registrs/?lang=en)

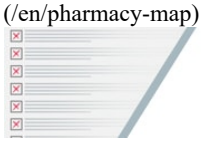
MEDICINAL PRODUCT REGISTER


(/en/report-adverse-drug-reactions-and-incidents-medical-devices-0)

REPORT ADVERSE DRUG REACTIONS AND INCIDENTS WITH MEDICAL DEVICES


(/en/pharmacy-map)

PHARMACY MAP


(/en/report-medicines-shortages)

MEDICINES SHORTAGES

PATIENTS AND PUBLIC
(/en/patients-and-public)

HEALTHCARE PROFESSIONALS AND INSTITUTIONS
(/en/healthcare-professionals-and-institutions)

INDUSTRY
(/en/industry)

BALTIC REGULATORY AGENCIES ANNOUNCE THE EPIL PROJECT FOR HOSPITAL USE MEDICINES

22.07.2021.

The Baltic regulatory agencies (Estonian, Latvian, Lithuanian) invite marketing authorisation holders to participate in a pilot project on implementation of electronic package leaflets (e-PILs) for medicinal products restricted to hospital use.

The aim of the project is to evaluate whether the use of e-PILs ensures safe use of medicinal products and whether the use of ePIL could improve the availability of hospital products.

The project is solely intended for medicines restricted for hospital use administered by a healthcare professional only.

The scope of the project is to provide e-PILs, instead of printed leaflets, for medicines used only in hospitals. ePILs are available in drug registers:

- Estonia
- Latvia (http://www.zva.gov.lv/zvais/zalu-registrs/?&lang=en)
- Lithuania

The medicines must have a valid marketing authorisation (national, DCP/MRP, centralised) and the package with Estonian Latvian and/or Lithuanian labelling.

Project duration is 2 years.

The outcome will be evaluated at the end of the project.

The Estonian State Agency of Medicines coordinates the participation of multilingual packages on behalf of other Baltic agencies.

Requests for participation shall be sent to the following e-mails by September 15, 2021:
Multilanguage packages:

- labelling@ravimiamet.ee (labelling@ravimiamet.ee)

Monolanguage packages:

- Estonia: labelling@ravimiamet.ee (labelling@ravimiamet.ee)
- Latvia: info@zva.gov.lv (info@zva.gov.lv)
- Lithuania: vvkt@vvkt.lt (vvkt@vvkt.lt)

Please indicate “ePIL pilotproject” in the subject line.

Request for participation shall contain the following information:

- Product name, strength, pharmaceutical form, active ingredients(s),
- Package size(s), labelling language(s)
- Contact person of the MAH.

List of participating products will be published on the agencies’ webpages.

For medicines authorised after the above deadline the applications can be submitted during the lifespan of the project.

05.07.2021. 13:12 | https://www.zva.gov.lv/en/news-and-publications/news/baltic-regulatory-agencies-announce-epil-project-hospital-use-medicines