The Icelandic Medicines Agency (IMA) calls for candidates to participate in a pilot project on the use of electronic patient information leaflets (e-PILs) for human medicinal products

IMA seeks participation of marketing authorisation holders (MAHs) for a pilot project on implementation of e-PILs for medicinal products restricted to hospital use. The project is supported by the Ministry of Health.

Project description

- The scope of the project is to provide e-PILs only (the leaflets will be available online), instead of printed leaflets, for medicines used only in hospitals/healthcare facilities (i.e. medicines that have IMA's "H" categorisation).
- The medicines must have an Icelandic marketing authorisation (approved via centralised, mutual recognition, decentralised, or national procedure) but do not have to be currently on the market in Iceland, although medicinal products will have to be put on the market in order to participate.
- Project duration is three years.

For hospital products only

The project is solely intended for medicines restricted for hospital use ("H" categorised) in accordance with the Icelandic marketing authorisation. Administration must always be carried out by a healthcare professional and may under no circumstances be carried out by the patient.

Aim of the project

The aim of the project is to evaluate whether the use of e-PILs ensures safe medicinal treatments of patients. It will also be assessed whether the project will lead to an increase of hospital products on the Icelandic market.

Project plan

The concept of the project will be presented to the concerned healthcare professionals and marketing authorisation holders before its initiation.

The e-PILs will be available online at www.serlyfjaskra.is

Project evaluation

- A survey will be conducted amongst the participating healthcare professionals (pharmacists/nurses/doctors) at the beginning, during and at the end of the project's run. The survey will include questions on the access, use and reading e-PILs.
- A survey will be conducted amongst participating pharmaceutical companies, both at project start and end. There, potential downsides of not having printed PILs during the project will be evaluated.
- After the project has ended, a review will be performed to assess whether the availability of hospital medicinal products has increased on the Icelandic market.

A request for participation shall be sent to the e-mail e-PIL@lyfjastofnun.is. For medicinal products that are currently on the Icelandic market, a request shall be submitted before February 1st 2021. Requests for participation for new medicines can be submitted during the lifespan of the project.

Request for participation shall contain the following information: Product name, active ingredients(s), strength(s), pharmaceutical form(s) and package size(s) and a contact person for the product.

IMA will publish a list of participating products on its website.