## Where is the Q and A document located?

The 'master' Q&A document is in English, located on each National Competent Authority's website.

The national language versions of the Q&A document are on respective NHA website.

## What is the scope of the pilot project?

The scope of the project is to skip printed leaflets, for medicines used only in hospitals. PILs are available electronically in drug registers of each country (NCA website)

## Why are Baltics conducting this pilot project? What are the Key Performance Indicators (KPIs)?

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.

We plan to conduct a feedback survey amongst hospital pharmacists, pharmacists from institutions that were involved in the pilot project firstly at 6 months after the start of the pilot.

In general, it is expected that abandoning the paper-PIL increases availability and flexibility, contributes to sustainability and efficiency, supports experimentation, simplification and digitalisation.

## What products are in scope of the pilot?

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

All pack sizes of the listed products are included, unless stipulated differently in the application/NCA decision/participating product list.

## What are the grounds not to accept a product/a pack size into the pilot?

The products can only be induced if the safe use without printed PIL is ensured.

Examples of reasons of potential rejection from joining:

- product is used in emergency care settings and the PIL includes relevant instructions for Health Care Professionals (HCP).

- the product could be used at home /care homes

- the Risk Minimisation Measures foresees the printed PIL and it cannot be otherwise distributed

## Where is the product list published?

The list of products, which packages are accepted to have no paper-PIL in the package, is published for each country on the respective NHA website.

## How to join the pilot project?

MAH shall send application to participate by e-mail in free format with following information:

* Product name, strength, pharmaceutical form, active ingredients(s),
* Package size(s), labelling language(s)
* Contact person of the MAH
* Contact e-mail and phone No.

The list of products shared via APME, SIFFA and IFPA, is being reviewed and no separate application is required for these products, NCA will get in touch with the representatives.

## Whom to address the application in case a product is not authorized in one of the Baltic states but has a multilingual package for two other countries?

For multilingual packages please contact Estonian State Agency of Medicines (labelling@ravimiamet.ee) EE coordinates it further within Baltic countries.

In case the product package is monolingual, please send the application to respective NCA.

## Can MAH apply for joining the pilot project after start of the pilot? Can MAH ask to remove the products from the list?

The applications to join can be submitted throughout the lifespan of the project, irrespective of the registration time.

For voluntary withdrawal from the pilot project please contact the authority whom you submitted the application.

## What kind of formal permit will be issued for the product acceptance into the pilot? How does it reach the MAH?

Estonia: administrative decision will be issued with digital signature and sent by e-mail to the applicant.

Latvia: no separate decisions will be issued, the list of accepted products will be published on the Agency’s website

Lithuania: no separate decisions will be issued, the list of accepted products will be published on the Agency’s website

## When can MAH expect the permits?

The list of accepted products will be published and/or the national decisions issued after the common agreement.

## When will the pilot project start and how long will the project last?

The start of the project is expected January 1, 2022. The pilot project duration is 2 years.

## The EC permit for the pilot in Baltics is given for 2 years. What will happen after these 2 years?

Depending on the course of the project, the NCAs may decide on the need for the prolongation,

Baltic NCAs will align on the continuation options in due time.

## How long can the batches released during the 2 years be on the market?

No difference compared to ordinary situation. The batches that are released during the exemption period, can be on the market until expiry date. Exception would be an urgent safety restriction.

## Who and how will track information/data about the batches released without paper-PIL?

MAH is expected to inform the NCA upon placing the batch without PIL on the market. As the dates may be different the respective NCA has to be informed.

- name of the product, strength, pharmaceutical form

- package size

- MA No

-date of batch release;

- batch no.;

- expiry date

- batch size

- estimated time of delivery to country.

## Who and whom shall MAH inform about the missing paper-PIL? How shall MAH share information about an updated PIL?

EE: The NCAs inform the hospital pharmacies about the project, there is no need for the MAHs to distribute any additional information.

LT The SMCA of Lithuania will inform the involved institutions about the project, there is no need for the MAHs to distribute any additional information.

LV: The SAM of Latvia will inform the involved institutions about the project, there is no need for the MAHs to distribute any additional information.

## Is QR code required on the outer pack?

PIL is electronically publicly available in latest version, no QR code required on the packages.

It is allowed to add voluntarily QR code, linking to PIL/NCA website drug register.

Adding a QR code on outer package is subject for an appropriate variation/ notification in marketing authorisation documentation.

## Are there additional requirements for outer package of the products participating in the pilot?

There are no additional requirements for outer package.

## Is it allowed to add empty paper instead of printed PIL into the package, e.g. in case it is technically needed to keep the inner package from moving around?

Yes, this would be the QP decision. Outer package is not part of the MA dossier, no notification is applicable.

## Who will compose, distribute and analyse the results of the survey towards pharmacists from involved institutions?

The results including interim reports will be prepared in co-operation with NCAs, MAHs and hospital pharmacies.

## Can all hospitals/hospital pharmacies/healthcare centres participate in the project?

One of the aims of the project is to increase availability of hospital medicines. No licensed healthcare institution shall be excluded from receiving a product that has been accepted into the pilot project.

## What information will be published on NHA websites?

* Q&A document in English and national language;
* list of products participating

Exact location of this information will be communicated on NHA website in due time.