1. Where is the Q and A document located?

The 'master' Q&A document is available in English, located on the websites of the participating National Competent Authority (NCAs).

2. What is the scope of the pilot project?

The scope of the project is to allow the omission of printed package leaflets for medicines used only in hospitals and/or administered by healthcare professionals, depending on national implementation.

In all cases, the PILs are available electronically in national medicines registers of each country (NCA website)

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

The aim of the project in Phase 1 was to evaluate whether the use of e-PILs ensures safe use of medicines and whether the use of ePIL could improve the availability of hospital products.

The experience gained from the initial phase (Phase 1) was limited and duration of 2 years was too short, considering manufacturing timelines and change management processes necessary to undertake by MAHs.

Phase 2 of the project has been extended until the end of 2026 and broadened to include medicines marketed in the general pharmacies and administered by HCP. Implementation of Phase 2 was not simultaneous across Estonia, Latvia and Lithuania.

The feedback surveys conducted amongst hospital pharmacists in each country, and further surveys are planned amongst pharmacists and HCPs from institutions that are involved in the pilot project.

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

Based on the experience gained during the pilot, the Baltic authorities are also considering extending the project beyond the current timeline.

4. What products are in scope of the pilot?

The pilot applies to medicines administered by healthcare professionals.

In Estonia and Lithuania, in addition, certain medicines that may be supplied to patients through community pharmacies but can only be administered by a qualified professional may also be considered in scope (e.g. vaccines or intrauterine systems).

All pack sizes of the listed products are included, unless stipulated differently in the application, NCA decision, participating product list. NCA permit for concrete product is prerequisite for participating in the pilot.

5. What are the grounds to accept a product/a pack size into the pilot?

The products can only be included in the list if the safe use without printed PIL is ensured.

Examples of circumstances subject to review:

- medicines are used in emergency care settings where the PIL includes relevant instructions for HCP;
- potential use outside healthcare institutions (e.g. at home or in care homes);
- medicines with Risk Minimisation Measures requiring distribution of a printed PIL

6. Where is the medicines list published?

The list of medicines, which packages are accepted to have no paper-PIL in the package, is published on each NCA's website. Baltic NCAs regularly exchange information and update data.

7. How to join the pilot project?

The application form is published on NCAs' websites. The single application form may be used for multiple products and multiple Baltic countries.

MAH shall send application to participate by e-mail to the relevant NCAs.

Contact details:
Estonia: labelling@ravimiamet.ee
Latvia: info@zva.gov.lv
Lithuania: vvkt@vvkt.lt

Submission instructions:

- If the application is **for a single country**: send the application via email to the respective NCA.
- If the application is **for two countries**: send a single email addressed to both NCAs.
- If the application is **for all NCAs**: send one email addressed to all three NCAs.

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

8. Can MAH apply for joining the pilot project after start of the pilot? Can MAH ask to remove the medicines 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.

9. What kind of formal permit will be issued for the medicine acceptance into the pilot? How does it reach the MAH?

Estonia: administrative decision for each accepted marketing authorisation 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 NCA website

Lithuania: administrative decision for each accepted marketing authorisation will be issued with confirmation email and will be published on the NCA website

10. When can MAH expect the permits?

The applications are reviewed within a month.

11. When will the pilot project start and how long will the project last? What happens thereafter?

Phase 1: January 1, 2022 – December 31, 2023 (duration 2 years)

Phase 2: January 1, 2023 – December 31, 2026 (duration 4 years)

The Baltic authorities are considering extending the project beyond the current timeline. Phase 3 of the project is planned to start on 1 January 2027 and is envisaged to continue without a predefined end date, subject to common agreement between the participating authorities. However, this approach is still under discussion and will require approval from the European Commission. The need for the prolongation depends on the course of the project. Baltic NCAs will align on the continuation options in due time.

12. How long can the batches released during pilot project 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.

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

MAH is expected to inform the NCA upon placing **the first batch or all batches** without paper-PIL on the market. As the dates may be different the respective NCA has to be informed.

Country-specific requirements:

- **Estonia and Lithuania:** the MAH should notify the NCA when **the first batch** without a paper PIL is placed on the market.
- **Latvia:** the MAH should notify the NCA about **all batches** placed on the market without a paper PIL.

Contact details:

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

14. Who and whom shall MAH inform about the absent paper-PIL? How shall MAH share information about an updated PIL?

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

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

16. Are there additional requirements for outer package of the medicines participating in the pilot?

There are no additional requirements for the outer package.

17. Is it allowed to include blank 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.

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

The analysis including interim reports will be prepared in co-operation with NCAs, MAHs and other stakeholders (e.g. hospital pharmacists, nurses, patient organisations).

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

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

20. What information is published on the NCA websites?

- General information about the pilot project;
- Q&A document;
- list of products accepted, including batch release/marketing start timeline.