EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Medical Products and Innovation
Medicines: Policy, Authorisation and Monitoring

Brussels
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Dear Director-Generals of the Baltic countries,

Thank you for your request to extend the duration of the electronic Patient Information Leaflet (e-PIL) pilot project for a period of three years starting from January 1, 2024 (until December 31, 2026) and for sharing the results since its inception on January 1, 2022.

Your letter was forwarded to me to reply.

You refer that the number of medicinal products included in the pilot was lower than expected due to implementation challenges particular to small markets. Nonetheless, I am pleased to receive the positive feedback from the stakeholders involved, and the strong commitment to take this e-PIL pilot forward.

In this regard, you intend to expand the project beyond hospital pharmacies. Grateful if you could clarify which settings shall be covered in addition to hospital pharmacies as the reference to *medicinal products administered by healthcare professionals* is quite broad.

Similarly with the approach taken when the e-PIL project was announced, we would be grateful if you could send the list of medicinal products to be included in the extended phase of the e-PIL project, and the therapeutic areas covered.

Mrs Katrin Kiisk
Director General
State Agency of Medicines Estonia

Mrs Indra Dreika
Director
Head of Administrative Department
State Agency of Medicines Latvia

Mr Gytis Andrulionis
Director
State Medicines Control Agency Lithuania

Welcoming your commitment to periodically inform the Commission on key milestones (e.g., impact on access to medicines, level of access to product information in electronic and paper format) and lessons learnt, I look forward to continuing learning from the e-PIL pilot project in the Baltic countries.

As you know, the Commission sees the experience acquired with this e-PIL pilot project as a valuable source of empirical evidence to support key EU initiatives in this area: the EMA-EC collaboration with the Heads of Medicines Agencies Better Use of Medicines Working Group in the development and implementation of electronic product information (ePI) and the recently adopted proposal for a revised pharmaceutical legislation.

I hereby confirm the European Commission's support for the envisioned pilot project for a period of three years. I wish you a successful implementation of the extended phase of this valuable initiative.

Yours faithfully,

Olga SOLOMON
Head of Unit

Electronically signed