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EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Medical Products and Innovation
Medicines: Policy, Authorisation and Monitoring

Brussels
SANTE.D.1/KS/am(2026)11531097

Subject: Request for the continued implementation of the electronic package leaflet project in Estonia, Latvia and Lithuania

Dear Dr Kiisk, Ms Dreika and Ms Marcinkė,

Thank you for your joint letter of 7 October 2026 concerning the electronic package leaflet (ePL) project in Estonia, Latvia and Lithuania, and for the constructive cooperation of your authorities in the implementation of this initiative since its launch on 1 January 2022 and its subsequent extension from 1 January 2024.

The Commission takes note of the positive experience reported by the Baltic medicines agencies and of your assessment that the project has delivered practical benefits in terms of the availability of medicinal products, reduced administrative and operational burden, improved access to the most up-to-date authorised product information for healthcare professionals, and environmental advantages through the reduced use of printed package leaflets.

The experience gathered through this project is of clear interest in the broader context of the ongoing digital transformation of product information in the Union. In particular, the practical lessons derived from the implementation in the Baltic States may usefully contribute to future reflections on electronic product information when implementing the new EU Pharmaceutical Directive in the Member States and at Union level.

In light of the information provided and the positive practical experience accumulated since 2022, the Commission agrees that the project may continue in Estonia, Latvia and Lithuania to gain more experience and continue learning from it. The pilot will provide an opportunity to better prepare for the transposition and implementation of new requirements for electronic package leaflets into national legislation until the new EU Pharmaceutical

Mrs Katrin Kiisk
Director-General State Agency of Medicines Estonia
Mrs Indra Dreika
Director Head of Administrative Department State Agency of Medicines Latvia
Mrs Dovilė Marcinkė
Director State Medicines Control Agency Lithuania

Directive becomes applicable. Therefore, the pilot should run without interruption until the new Pharmaceutical Directive is implemented into national law and becomes applicable.

The Commission would be grateful if the participating authorities could continue to keep DG SANTE informed of the implementation of the project, including any significant developments, operational issues identified, or lessons learned that may be relevant for broader regulatory considerations at Union level.

Thank you again for your letter and for your continued engagement on this matter.

Yours sincerely,

Electronically signed

Olga SOLOMON
Head of Unit

Electronically signed on 09/11/2026 23:36 (UTC+01) in accordance with Article 11 of Commission Decision (EU) 2021/2121