REPUBLIC OF ESTONIA
AGENCY OF MEDICINES

State Agency
of Medicines
Republic of Latvia

STATE MEDICINES CONTROL AGENCY OF LITHUANIA

European Commission
Directorate-General for Health and Food
Safety (DG SANTE)
Unit D.1 – Medicines: policy, authorisation
and monitoring

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SANTE-PHARMA-POLICY@ec.europa.eu

Subject: Request for the continued implementation of the electronic package leaflet (ePL) project in Estonia, Latvia and Lithuania without a predefined end date

Dear Ms Olga Solomon,

We, the Heads of the Estonian, Latvian and Lithuanian medicines agencies, would like to express our appreciation for the European Commission's continued support for the pilot project on electronic package leaflets (ePL) for medicinal products used in healthcare institutions in the Baltic States.

The project was launched on 1 January 2022 and subsequently extended from 1 January 2024. Over the course of its implementation, the project has evolved from a pilot initiative into an established and functioning approach to the provision of product information for medicinal products administered by healthcare professionals.

Based on the practical experience gained in Estonia, Latvia and Lithuania, we consider that the project has demonstrated clear benefits for healthcare systems, pharmaceutical companies and the availability of medicinal products, particularly in small markets.

First, the use of electronic package leaflets contributes to improving the availability of medicinal products. The Baltic States represent relatively small pharmaceutical markets, where

country-specific packaging and printed package leaflet requirements may create an additional administrative and logistical burden for marketing authorisation holders.
The possibility to supply medicinal products without a printed package leaflet, where the medicinal product is administered by a healthcare professional and the relevant product information remains readily available electronically, provides additional flexibility in the supply chain and may facilitate the introduction and continued availability of medicinal products in smaller markets.
Second, the project reduces unnecessary administrative and operational burden. Electronic provision of package leaflet information reduces the need to manage country-specific printed leaflets and allows changes to product information to be implemented without creating avoidable complexity related to already printed packaging materials. This is particularly relevant where product information is updated frequently or where production volumes for individual markets are limited.
Third, electronic product information facilitates access to the most up-to-date authorised information. Healthcare professionals can access the current version of the package leaflet electronically rather than relying solely on a printed leaflet produced at the time of manufacture. This supports the availability of accurate and current information at the point of use and reduces the risk of outdated printed information remaining in circulation.

The experience of the Baltic States has also demonstrated that the absence of a printed package leaflet does not compromise access to the information necessary for the safe use of the medicinal product in the healthcare setting. The medicinal products included in the project are administered by healthcare professionals, who have access to authorised product information through the electronic sources maintained by the competent authorities.

Furthermore, the project supports the broader transition towards digital product information in the European Union and provides practical experience that can contribute to the future implementation of electronic product information at European level.
The project also offers environmental benefits by reducing the use, production, transport and disposal of printed package leaflets, particularly where printed materials have to be replaced following updates to authorised product information.

Considering the positive practical experience accumulated since 2022 and the benefits demonstrated during the implementation of the project, we believe that the continuation of the ePL approach should no longer be dependent on a predetermined pilot end date.

We therefore kindly request the European Commission's agreement to **continue the electronic package leaflet project in Estonia, Latvia and Lithuania without a predefined end date**, while maintaining the possibility for the participating competent authorities[1] and the European Commission to periodically review its implementation and, where necessary, adapt its conditions in light of regulatory developments and practical experience.

We also propose to maintain the possibility of applying the approach to medicinal products administered by healthcare professionals, in accordance with the applicable national regulatory arrangements and subject to the assessment of the respective national competent authority.

We believe that maintaining this approach will support the availability of medicinal products, reduce unnecessary regulatory and operational burden, facilitate access to up-to-date product

[1] A list of medicinal products distributed in Estonia: Paperless Package Leaflet (ePIL) Pilot Project | Ravimiamet
A list of medicinal products distributed in Latvia with an electronic package leaflet: Pilot project for Electronic Package Information Leaflets (e-PIL) | State Agency of Medicines of5 the Republic of Latvia
A list of medicinal products distributed in Lithuania with an electronic package leaflet: e-PL project - State Medicines Control Agency under the Ministry of Health of the Republic of Lithuania

information and contribute to the digitalisation and sustainability objectives of the European pharmaceutical regulatory network.

We would appreciate the European Commission's favourable consideration of this request and remain available to provide further information on the implementation and experience of the project in the Baltic States.

Yours sincerely,

Katrin Kiisk	Indra Dreika	Dovilė Marcinkė
(digitally signed)	(digitally signed)	(digitally signed)
Director General State Agency of Medicines Estonia	Director State Agency of Medicines Latvia	Director State Medicines Control Agency Lithuania