REPUBLIC OF ESTONIA
AGENCY OF MEDICINES

State Agency
of Medicines
Republic of Latvia

Mrs Stella Kyriakides
European Commission
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BELGIUM

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Request for extension of the pilot project of electronic package leaflet for medicinal products used in hospitals in Estonia, Latvia and Lithuania

Dear Mrs Kyriakides,

According to your letter Ares(2021)3931471 – 16/06/2021 the European Commission's support for the envisioned e-PL pilot project for a period of two years will end in the Baltic States on the 31st of December, 2023.

The e-PL pilot project (hereafter – Project) started on the 1st of January, 2022. There are 18 medicinal products included in the list during the first phase of the Project. The first notification of the medicinal product release has been received in June 2022. About 30 % of the medicinal products involved are released without product information leaflet on paper to date. All the relevant information is published on the Agencies websites[1].

The feedback from the stakeholders on the initiative is positive, however due to the long production cycles for the small markets the implementation of the Project for pharmaceutical industry requires more than 6 months. According to the published results of the surveys[2] conducted at hospital pharmacies the pharmacists mostly use electronic package leaflets. It is noted that number of products released without paper leaflet was below expected during the Project but considering feedback from the main stakeholders the number of products released without paper leaflet are expected to increase over longer period of time. Therefore, referring also to the European Commission's Proposal[3] "the envisaged use of the electronic product

[1] LV: https://www.zva.gov.lv/en/healthcare-professionals-and-institutions/medicines/pilot-project-electronic-package-information-leaflets-e-pil;
LT: https://www.vvkt.lt/index.php?2881636729;
EE: https://www.ravimiamet.ee/ravimid-ja-ohutus/muugiload/haiglaravimite-epil-projekt

[2] LV https://www.zva.gov.lv/en/news-and-publications/news/survey-results-show-most-often-hospitals-use-electronic-package-leaflets;
EE https://www.ravimiamet.ee/media/1407/download

[3] Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, amending Regulation (EC) No 1394/2007 and Regulation (EU)

information (as opposed to paper leaflets) should also lead to administrative cost reductions," heads of the Estonian, Latvian and Lithuanian medicines agencies request for extension of the Project period for three years, starting on the 1st of January, 2024 and also applying an opportunity to expand the project not only to medicinal products used in hospital, but also other medicinal products administered by healthcare professionals to assess further whether the use of electronic package information leaflets is ensuring safe use of medicines and whether their use could improve availability of medicines used in the healthcare institutions.

The signatories of this letter reserve the possibility to implement extension of the Project to other medicinal products administered by healthcare professionals depending on the national regulatory features.

Yours sincerely,

Katrin Kiisk	Indra Dreika	Gytis Andrulionis
Director General State Agency of Medicines Estonia	Director State Agency of Medicines Latvia	Director State Medicines Control Agency Lithuania

No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006 (https://health.ec.europa.eu/system/files/2023-04/com_2023_193_1_act_en.pdf)