EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

The Director-General

Brussels, 31 August 2026
SANTE.D.1/BM/en/(2026)7243497

By E-Mail Only:
permrep.eu@mfa.ee
For the attention of Ambassador
Katrin JUHANDI, Deputy
Permanent Representative of
Estonia

Subject: Implementation of the new Pharmaceuticals Legislation - Delegated and Implementing Acts by the Commission

Dear Ambassador Juhandi,

I am writing to you regarding the forthcoming implementation of the new Pharmaceuticals Legislation by the Commission with the preparation of the delegated and implementing acts provided for in the revised Directive and Regulation.

In December 2025, the European Parliament and the Council reached a political agreement on this reform. After the on-going legal linguistic review and the translation, the Council is expected to vote on these texts in September, and the European Parliament's vote is scheduled in October. Subject to their formal adoption and subsequent publication in the *Official Journal of the European Union* in November, the legislation is expected to enter into force in December this year.

While this finalisation process is on-going, the Commission has already started preparations for the implementation of this legislation, notably by preparing the draft acts for which it has been empowered under the new pharmaceutical legislation.

The Commission will prepare these acts in cooperation with the Member States representatives, either within the Standing Committee on medicinal products for human use for the draft implementing acts or within the Pharmaceutical Committee for the draft delegated acts.

By means of this letter, we would like to draw your attention to the significant joint implementation work that will be required over the next two years. In particular, a greater number of meetings will be organised, covering a range of technical subjects. In this context, I would like to underline that the meetings of the Standing Committee will not be confined to discussions and votes on specific draft Commission decisions concerning marketing authorisations for individual medicinal products. They will also concern discussions and votes on the different implementing acts to be adopted under the revised framework. Similarly, the Commission will consult experts of the Pharmaceutical Committee on the draft delegated acts.

As it is the case nowadays, invitations and draft agendas of the upcoming meetings of the Standing and Pharmaceutical Committees will be addressed to the Permanent Representations of the Member States via the "Advanced Gateway to your Meetings" (AGM). By this letter we would like to draw your attention to the importance of forwarding the invitations to the relevant national expert(s) in light of the draft agendas.

Yours sincerely,

Sandra GALLINA