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CONTRIBUTION

From:	General Secretariat of the Council
To:	Working Party on Pharmaceuticals and Medical Devices (Attachés) Working Party on Pharmaceuticals and Medical Devices (EMA fees)
Subject:	EMA fees proposal - comments from the Latvian delegation

Delegations will find attached comments from the Latvian delegation on EMA fees proposal.

Comments on Proposal for a Regulation of the European Parliament and of the Council on fees and charges payable to the European Medicines Agency, amending Regulation (EU) 2017/745 of the European Parliament and of the Council and repealing Council Regulation (EC) No 297/95 and Regulation (EU) 658/2014 of the European Parliament and of the Council
(16070/22)

Latvia is grateful for the prepared document and believes that it makes a significant contribution to the harmonization of the area.

In the paragraph 3 of Annex III and preamble 12 of the proposal 16070/22 is proposed to set the annual pharmacovigilance fee for veterinary medicines authorised not only in centralised procedure, but also authorised by the national competent authorities in accordance with Chapter III, Sections 2 to 5 of Regulation (EU) 2019/6.

Latvia calls for clarification of proposal 16070/22 regarding the determination of the annual pharmacovigilance fee for nationally authorised veterinary medicines

– to remove subparagraph 3.2 of Annex III of the proposal and to clarify accordingly paragraph 3 and subparagraph 3.3. and 3.4. of Annex III and preamble 12 of proposal:

LV proposal:

"III Annex

3. Annual pharmacovigilance fee for medicinal products for human use authorised in accordance with Directive 2001/83/EC ~~and for veterinary medicinal products authorised by competent authorities of the Member States in accordance with Regulation (EU) 2019/6~~:

3.1. For medicinal products for human use authorised in accordance with Directive 2001/83/EC, a fee of EUR 190 per chargeable unit-human, shall apply once per year for the Agency's pharmacovigilance activities including analysis of Union-wide health data to support better decision-making with real world evidence. The Agency shall retain the fee revenue from the annual pharmacovigilance fee.

~~3.2. For veterinary medicinal products authorised by competent authorities of the Member States in accordance with Chapter III, Sections 2 to 5 of Regulation (EU) 2019/6, a fee of EUR 80 per chargeable unit-veterinary shall apply once per year for the Agency's pharmacovigilance activities. The Agency shall retain the fee revenue from the annual pharmacovigilance fee.~~

3.3. The total payable amount of the annual fees referred to in points 3.1 ~~and 3.2~~ for each marketing authorisation holder shall be calculated by the Agency on the basis of the number of chargeable units-human ~~and chargeable units-veterinary, respectively,~~ which correspond to the information recorded on 1 July of each year.

3.4. The annual fees referred to in points 3.1 ~~and 3.2~~ shall be due on 1 July of every year and shall cover the period from 1 January to 31 December of that calendar year.

Preamble 12:

(12) A specific annual fee should be charged for medicinal products authorised in accordance with Directive 2001/83/EC ~~and for veterinary medicinal products authorised by the Member States in accordance with Regulation (EU) 2019/6~~ specifically for the pharmacovigilance activities carried out by the Agency that benefit marketing authorisation holders overall. Those activities relate to information technology, in particular maintenance of the EudraVigilance database referred to in Article 24(1) of Regulation (EC) No 726/2004, ~~the Union product database referred to in Article 55(1) of Regulation (EU) 2019/6 and the Union pharmacovigilance database~~

~~referred to in Article 74(1) of that Regulation~~, the monitoring of selected medical literature and the timely access to and analysis of Union-wide health data to support decision-making throughout the product lifecycle on medicines with valid and reliable real-world evidence."

Rationale:

Paragraph 8 of Article 2 of Regulation 2019/6 stipulates that "This regulation shall, except as regards the centralized marketing authorisation procedure be without prejudice to national provisions of fees." Latvia doubts whether the proposal to set the centralized annual pharmacovigilance fee for nationally authorised veterinary medicines comply with Paragraph 8 of Article 2 of Regulation 2019/6.

There are concerns, that determination of the additional annual fee for each nationally authorised veterinary medicinal product will affect the availability of veterinary medicines in countries with small market of the VMPs