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Health and Food Safety Directorate General

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Standing Committee on Veterinary Medicinal Products

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AGENDA

Section A Information and/or discussion

- A.01** State of play of implementation of Regulation (EU) 2019/6 on Veterinary Medicinal Products.
- A.02** Discussion on the establishment under Article 107(6) of Regulation (EU) 2019/6 of a list of antimicrobials which shall not be used in accordance with Articles 112 and 113 of the same Regulation or which shall only be used in accordance with these articles subject to certain conditions.
- A.03** Scientific Advice under Article 93(2) of Regulation (EU) 2019/6 on measures on GMP for veterinary medicinal products and active substances used as starting materials – Presentation by EMA and feedback on the outcome of the targeted stakeholder consultation.
- A.04** Discussion on the state of play on the implementation of Regulation (EU) 2022/839 of the European Parliament and of the Council (QRDv9 updates).
- A.05** Collection of data on antimicrobial medicinal products used in animals (Article 57 of Regulation (EU) 2019/6) and recording of annual volume of sales in the Union product database (Article 58(12) Regulation (EU) 2019/6) – follow-up to the discussion at the last meeting.
- A.06** Information on the state of play on the implementation of Commission Delegated Regulation (EU) 2023/905 supplementing Regulation (EU) 2019/6 of the European Parliament and of the Council as regards the application of the prohibition of use of certain antimicrobial medicinal products in animals or products of animal origin exported from third countries into the Union.
- A.07** Information by the Commission on cases of falsified vaccines against rabies.

Section B **Draft(s) presented for an opinion**

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) amending Regulation (EU) No 37/2010 as regards the classification of the substance sodium salicylate with respect to its maximum residue limit in foodstuffs of animal origin

(PLAN/2023/2348)

Legal Basis: Regulation (EU) No 37/2010

Procedure: Examination procedure

B.02 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) amending Regulation (EU) No 37/2010 as regards the substance 17 β -oestradiol

(PLAN/2023/2920)

Legal Basis: Regulation (EU) No 37/2010

Procedure: Examination procedure

B.03 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) adopting a list of the abbreviations and pictograms common throughout the Union to be used for the purposes of Articles 10(2) and 11(3) of Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC

(PLAN/2023/921)

Legal Basis: Regulation (EU) 2019/6

Procedure: Examination procedure

B.04 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) adopting uniform rules on the size of small immediate packaging units referred to in Article 12 of Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC

(PLAN/2023/922)

Legal Basis: Regulation (EU) 2019/6

Procedure: Examination procedure

B.05 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) amending Implementing Regulation (EU) 2021/17 establishing a list of variations not requiring assessment in accordance with Regulation (EU) 2019/6 of the European Parliament and of the Council

(PLAN/2023/2278)

Legal Basis: Regulation (EU) 2019/6

Procedure: Examination procedure

B.06 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Decision (EU) concerning, in the framework of Article 54 of Regulation (EU) 2019/6 of the European Parliament and of the Council, the marketing authorisations for the veterinary medicinal products "Procactive 300 mg/ml suspension for injection for cattle, sheep and pigs and associated names"

Legal Basis: Regulation (EU) 2019/6

Procedure: Examination procedure