EUROPEAN COMMISSION



Health and Food Safety Directorate General

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Standing Committee on *Veterinary Medicinal Products*30 January 2025

CIRCABC Link: https://circabc.europa.eu/ui/group/a2ba6dd7-f812-406a-8b1c-2aaf25ec4277/library/b798707e-369f-4367-8c26-867583dd319e?p=1&n=10&sort=modified_DESC

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** Development of the implementing act on GMP for autogenous vaccines under Article 93(2) of Regulation (EU) 2019/6: state of play and next steps.

Section B Draft(s) presented for an opinion

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) .../... amending Regulation (EU) 2018/782 concerning the assessment by the European Medicines Agency of maximum residue limits in chemical-unlike biological substances

(PLAN/2024/1244)

Legal Basis: Regulation (EC) No 470/2009

Procedure: Regulatory procedure with scrutiny

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 chemical-unlike biological substances

(PLAN/2024/1245)

Legal Basis: Regulation (EC) No 470/2009

Procedure: Examination procedure

B.03 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) .../... amending Implementing Regulation (EU) 2017/12 as regards the requirements for applications and requests for the establishment of a 'no MRL required' classification for chemical-unlike biological substances

(PLAN/2024/2136)

Legal Basis: Regulation (EC) No 470/2009

Procedure: Examination procedure

B.04 Exchange of views and possible technical agreement of the Committee on a draft Commission Implementing Regulation (EU) .../... amending Regulation (EU) No 37/2010 as regards the classification of the substance ketoprofen with respect to its maximum residue limit in foodstuffs of animal origin

(PLAN/2024/2759)

Legal Basis: Regulation (EU) No 37/2010

Procedure: Examination procedure

Section C <u>Draft(s) presented for discussion</u>

C.01 Exchange of views of the Committee on a draft Commission Implementing Regulation establishing a list of substances which are essential for the treatment of equine species, or which bring added clinical benefit compared to other treatment options available for equine species and for which the withdrawal period for equine species shall be six months

(PLAN/2023/2342)

Legal Basis: Regulation (EU) 2019/6 **Procedure:** Examination procedure

C.02 Exchange of views of the Committee on a draft Commission Implementing Regulation laying down good manufacturing practice for veterinary medicinal products in accordance with Regulation (EU) 2019/6 of the European Parliament and of the Council

(PLAN/2023/2343)

Legal Basis: Regulation (EU) 2019/6 **Procedure:** Examination procedure

C.03 Exchange of views of the Committee on a draft Commission Implementing Regulation on laying down good manufacturing practice for active substances used as starting materials in veterinary medicinal products in accordance with Regulation (EU) 2019/6 of the European Parliament and of the Council

(PLAN/2024/1994)

Legal Basis: Regulation (EU) 2019/6 **Procedure:** Examination procedure