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*

SUMMARY REPORT

The Chair opened the meeting by reminding participants about the confidentiality of the documents for the meeting and of the discussions in the meeting. The agenda of the meeting was adopted.

A.01 State of play of implementation of Regulation (EU) 2019/6 on Veterinary Medicinal Products

The Commission informed the Committee of the state of play of the implementation of the Regulation and requested the views of the Member States concerning the empowerments in Regulation (EU) 2019/6 for delegated or implementing acts with no legal deadline for adoption.

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

The Commission informed the Committee about the first meeting of the expert sub-group and noted that discussions on a working document were ongoing.

Section B <u>Draft presented for an opinion</u>

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 for chemical-unlike biological substances

(PLAN/2024/1244)

The Commission services presented a draft Regulation establishing that EMA should determine whether a classification of 'no MRL required' is appropriate for a given chemical-unlike biological substance.

Vote taken: Favourable opinion.

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)

The Commission services presented a draft Implementing Regulation adding the 5 chemical-unlike biological substances currently included in the EMA's list into Table 1 ("allowed substances") in the Annex to Regulation (EU) No 37/2010.

Vote taken: Favourable opinion.

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)

The Commission services presented a draft Implementing Regulation aiming to define the specific content requirements for applications concerning chemical-unlike biological substances, aligning with the amendments to Commission Regulation (EU) 2018/782.

Vote taken: Favourable opinion.

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)

The Commission services presented a draft Implementing Regulation which establishes a numerical MRL for ketoprofen in all ruminants, porcine and equine species. The Committee expressed its support for the proposal.

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)

The Commission presented an overview of the draft Implementing Regulation. Minor editorial changes were agreed.

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)

Please see point C.03.

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)

The Commission provided an overview of the draft Implementing Regulations on GMP for veterinary medicinal products and for active substances used in veterinary medicinal products foreseen in Article 93(2) of Regulation (EU) 2019/6. The work done by the expert sub-group and the Commission services was acknowledged by the Committee noting that the draft Implementing Regulations are the best possible approach to meet the requirements of Regulation (EU) 2019/6. Nevertheless, it was stressed that the alignment with the GMP requirements for human medicinal products should be maintained also in the future. The Commission addressed questions raised by some Member States and reassured the Committee that the Implementing Regulations will be revised as necessary to maintain the alignment with the GMP guidelines for human medicines. Finally, the Standing Committee expressed support for deferring the date of application.