EUROPEAN COMMISSION

Health and Food Safety Directorate General

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Standing Committee on *Veterinary Medicinal Products*
27 November 2024

CIRCABC Link: *https://circabc.europa.eu/ui/group/a2ba6dd7-f812-406a-8b1c-2aaf25ec4277/library/3326c8c3-132b-4532-ab2a-ee313aac54c6?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.

Section A Information and/or discussion

A.01 Discussion on a draft Implementing act on the establishment under Article 115(5) of Regulation (EU) 2019/6 of 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

The Commission presented a working document which was generally supported by the Member States.

The Commission reassured the Committee that future amendments to the list of substances to be established by the draft legal act will be considered, as appropriate in light of new scientific evidence.

A.02 Development of implementing acts on GMP for veterinary medicinal products under Article 93(2) of Regulation (EU) 2019/6: status quo and next steps

The Commission provided an overview of the work on the implementing act on GMP for veterinary medicinal products and on the implementing act on GMP 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 was acknowledged.

Further, it was agreed that, if the documents are amended following the internal consultations within the Commission, the revised documents would be swiftly sent to the Standing Committee and any concern that may be identified would be addressed at a dedicated meeting of the expert sub-group. Additionally, the Commission reassured Member States that the implementing acts will be revised as necessary on the basis of experience with the implementation thereof. To this end, the expert sub-group will be kept active.

Finally, Member States were invited to submit their considerations regarding the date of application of the implementing acts.

A.03 Discussion on the state of play on the implementation of Regulation (EU) 2022/839 of the European Parliament and of the Council (QRDv9 updates)

The Commission took stock of the situation noting that the processing of the required variations at the national level was still very low. In light of the huge amount of variations to be processed, it is advisable to focus variation applications on G.1.18 aspects only, in particular regarding authorisations under MRP/DP. It was also noted that, pursuant to Regulation (EU) 2022/839, batches compliant with the packaging and labelling requirements set forth in the Regulation (EC) No 726/2004 and Directive 2001/82/EC can continue to be released until 29 January 2027. Batches released thereafter would have to be compliant with the labelling and packaging requirements under Regulation (EU) 2019/6.

Section B Draft 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) 2021/17 establishing a list of variations not requiring assessment in accordance with Regulation (EU) 2019/6

(PLAN/2023/2278)

The Commission presented the draft Implementing Regulation, which aims to amend Regulation (EU) 2021/17 establishing a list of variations not requiring assessment in accordance with Regulation (EU) 2019/6.

Vote taken: Favourable opinion.

Section C Draft(s) presented for discussion

C.01 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) amending Commission Regulation (EU) 2018/782 of 29 May 2018 establishing the methodological principles for the risk assessment and risk management recommendations referred to in Regulation (EC) No 470/2009

(PLAN/2024/1244)

The Commission presented a draft Implementing Regulation for discussion, tasking EMA to assess whether a "no MRL required" classification is appropriate for a given chemical-unlike biological substance.

C.02 Exchange of views 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 presented a draft Implementing Regulation for discussion, aiming to include chemical-unlike biological substances into Table 1 ("allowed substances") in the Annex to Regulation (EU) No 37/2010 following advice from EMA.

Member States provided comments on the format of the table in the Annex.

C.03 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) amending Implementing Regulation (EU) 2017/12 regarding the form and content of the applications and requests for the establishment of maximum residue limits in accordance with Regulation (EC) No 470/2009 of the European Parliament and of the Council

(PLAN/2024/2136)

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