EUROPEAN COMMISSION

Health and Food Safety Directorate General

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Standing Committee on *Veterinary Medicinal Products*
31 January 2023

CIRCABC Link: *https://circabc.europa.eu/ui/group/a2ba6dd7-f812-406a-8b1c-2aaf25ec4277/library/15afb1f9-712a-4d42-ae16-b75ffc56c256*

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. No items were added under AOB.

Section A Information and/or discussion

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

The Commission services informed the Member States on the state of play of the implementation of Regulation (EU) 2019/6 on Veterinary Medicinal Products.

A.02 Draft mandate to the European Medicines Agency for a scientific advice on the implementing measure under Article 115(5) of Regulation (EU) 2019/6 as regards the 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 services presented the draft mandate. Overall, the Member States received well the mandate.

One Member State noted that the consideration of substances listed in table 2 of the Annex to Commission Regulation (EU) No 37/2010 has to be done very carefully and that these should only be included in the list in case consumer safety is not compromised. Another Member State mentioned that the current list contains substances intended for diagnosis only, while Article 115(5) of the VMP Regulation is more specific on treatments. The Commission services indicated that the mandate provides for a revision of the current entries and that the new list will reflect the legal basis in the VMP Regulation.

The chair closed this agenda item with no change to the draft mandate.

A.03 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:

The Commission services received a joint request from the EMA and the CMDv to amend the Regulation (EU) 2021/17 establishing variations not requiring assessment with 3 variations not yet listed in the Implementing Regulation. The Commission services informed the Member States on the nature of these proposals.

A.04 Information on the Commission Notice - Application of the Union's veterinary medicines acquis in markets historically dependent on medicines supply from or through parts of the United Kingdom other than Northern Ireland:

The Commission services informed the Member States of the Commission Notice on the "Application of the Union's veterinary medicines acquis in markets historically dependent on medicines supply from or through parts of the United Kingdom other than Northern Ireland" adopted in December 2022.

A.05 Update on the discussion as regards Diclofenac - Member State's update including any new information on reported vulture deaths in the Member States that have diclofenac authorised and potential new authorisations given at national level:

The Commission services invited the Members States to provide any new information on reported vulture deaths linked to the use of diclofenac and new marketing authorisations for veterinary medicinal products containing diclofenac. No new cases of vulture deaths linked to the use of diclofenac have been reported. One Member State informed that flunixin meglumine has been included in their national monitoring system on vulture deaths.

Section B <u>Draft(s) presented for an opinion</u>

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) amending Regulation (EU) No 37/2010 to classify the substance ketoprofen as regards its maximum residue limit:

The Commission services presented the draft Implementing Regulation regarding the possible new entry for the substance ketoprofen in poultry as regards its maximum residue limit.

In view of the concerns expressed by some Member States, the Commission will send additional questions to the Committee for Veterinary Medicinal Products.

Vote postponed.