EUROPEAN COMMISSION

Health and Food Safety Directorate General

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Standing Committee on *Veterinary Medicinal Products*
26 January 2022

CIRCABC Link: *https://circabc.europa.eu/w/browse/c34aaa12-dd3a-4628-8650-67f453ea1707*

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 and also outlined the necessary technical arrangements to ensure that confidentiality.

The agenda of the meeting was adopted.

Two items were added under AOB. The Commission added an update on Article 94(5) and a Member State requested an update on the implementation of the common logo for on-line sales of veterinary medicines.

Section A Information and/or discussion

A.01 Update from the Commission on the state of play of the implementation of Regulation (EU) 2019/6 on veterinary medicinal products:

The Commission services presented the state of play on the ongoing work on the implementation of Regulation (EU) 2019/6.

A.02 New Commission Notice on the application of the Union's pharmaceutical acquis in markets historically dependent on medicines supply from or through parts of the UK other than Northern Ireland for veterinary medicinal products:

The Commission gave a presentation on the new Commission Notice on UK and small markets that will apply until the end of 2022.

A.03 Titanium dioxide:

Presentation of Commission Regulation (banning use of titanium dioxide as an additive in food but allowing its use as an additive in veterinary medicinal products provisionally, with a 3-year review clause).

A.04 Follow up to the discussion on 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:

Spain gave an update on the measures taken following the first diclofenac intoxication of a vulture in Europe. The Commission invited Member States to keep it informed on the situation.

A.05 Article 152 of Regulation (EU) 2019/6 on veterinary medicinal products:

Commission informed Member States that it was working intensively to find an urgent solution to address the problems of interpretation in relation Article 152(2) in order to provide legal certainty to all interested parties and avoid shortages of veterinary medicines/disruption in supply chains.

A.06 Follow up to the Commission Implementing Decision, in the framework of Article 35 of Directive 2001/82/EC of the European Parliament and of the Council, concerning the marketing authorisations for veterinary medicinal products containing "zinc oxide" to be administered orally to food producing species:

The Commission presented the latest state of play and Member States provided input on the status of relevant marketing authorisations at national level. A vast majority of Member States confirmed that the marketing authorisations concerned had or were in the process of being withdrawn and that they would be in compliance by the requested deadline, which is June 2022.

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 establishing the format of the data to be collected and reported in order to determine the volume of sales and the use of antimicrobial medicinal products in animals in accordance with Regulation (EU) 2019/6 of the European Parliament and of the Council.

The Commission services presented the draft Commission Implementing Regulation.

Member States expressed their support for the draft including a modification requested by two Member States, which was supported by the other Member States.

The Committee delivered its opinion through a written procedure.

Outcome of the vote by written procedure: Favourable opinion.

Miscellaneous:

M.01 New Rules of Procedure for the Standing Committee under Regulation (EU) 2019/6:

The Commission services presented the draft Rules of Procedure for the Standing Committee under Regulation (EU) 2019/6.

Member States expressed their support for the draft.

The Member States confirmed their agreement in writing following the meeting.

M.02 Exchange of views on the application of Article 94(5):

Member States confirmed that, during the legislative process, there was no intention to change the rules in connection with certificates for APIs manufacturing sites. It was also stressed the current risk-based approach to inspections should be maintained, as provided for also under the Regulation. With a view to resolve doubts among

manufacturers of veterinary medicinal products, it was agreed to develop a common interpretation.

M.03 Common logo for on-line sales:

The Commission services gave updates on the implementation of Commission Regulation (EU) 2021/1904 on the common logo for on-line sales.