EUROPEAN COMMISSION

Health and Food Safety Directorate General

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**Standing Committee on *Veterinary Medicinal Products***
**5 May 2021**

***CIRCABC Link:*** *https://circabc.europa.eu/w/browse/6776d861-28dd-4877-bb9b-91cdb31230ba*

# SUMMARY REPORT

## Opening and adoption of the agenda:

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.

One item was added under AOB by a Member State requesting an update on the revision of fees payable to the EMA.

## 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 ongoing work on the implementation of Regulation (EU) 2019/6 and explained the prioritisation of the work on the Implementing and Delegated Acts foreseen therein.

The Commission services reminded Member States that Regulation (EU) 2019/6 will start to apply from January 2022 and invited Member States to take the necessary steps to prepare themselves for a timely implementation of the new EU rules, in particular the need to prepare and submit in time their national information for the initial input to the Union product database.

The Commission Services underlined that Reference Member States need to be ready with and submit the common information for veterinary medicinal products authorised under the decentralised or mutual recognition procedures once the Union Product Database functionality for doing so becomes available. This will allow the Member States Concerned to upload their corresponding national information for those veterinary medicinal products.

### A.02 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 authorisation given at national level.

The Commission services requested Member States to update the Commission with regard to veterinary medicinal products containing diclofenac on their markets.

No Member State reported having authorised any new diclofenac-containing veterinary medicinal product recently. Member States have not received reports of any suspicious vulture deaths since the last follow-up at the Standing Committee meeting in September 2018.

As regards the confirmed case of a cinereous vulture poisoning (reported in a peer-reviewed publication), the Member State concerned provided more detailed information on the case, arguing that this first report remains an isolated case since diclofenac was first authorised in the country in 2013 and the relevant measures were put in place. That Member State assured the Commission that they will continue to monitor the situation. The Commission asked also for a written account from that Member State.

**A.03 Follow up to the Commission Implementing Decision concerning, in the framework of Article 35 of Directive 2001/82/EC of the European Parliament and of the Council, the marketing authorisations for veterinary medicinal products containing "zinc oxide" to be administered orally to food producing species.**

Most Member States informed that they have already complied or are on the way to fully comply with the Decision by June 2022, that in most cases no major challenges have been encountered and where zinc oxide has been taken off the market no increase of antimicrobial use was observed, thanks to good cooperation with stakeholders (including farmers).

One Member State asked if there would be possibility to extend the transition period by three additional years, due to the difficulties they encounter to phase out the use of zinc oxide. The Commission services indicated that the Member States had already been given a five-year transitional period and that the initial deadline which is June 2022 is to be respected. The Member States have one year from now to take the necessary steps.

**A.04 Update from the Commission on EU-UK issues related to Brexit, including the implementation of IE/NI Protocol.**

The Commission services gave an update on the state of play. No questions were raised by the Member States during the meeting. Two Member States sent questions in writing prior to the meeting, regarding the implications of using a UK-authorised reference product for EU generic applications. The Commission services explained that they will answer those questions in writing, as further internal reflection is needed.

**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 laying down rules for the application of Regulations (EU) 2016/429, (EU) 2016/1012 and (EU) 2019/6 of the European Parliament and of the Council with regard to the identification and registration of equine animals and establishing model identification documents for those animals.**

The Commission services presented the draft Commission Implementing Regulation.

Two Member States pointed to an error in the draft in regard to reference to "veterinary medicinal products" in certain places where the reference should only be to "medicinal products", covering both human and veterinary products. The Commission proposed changes in the draft to eliminate that error. This issue also affects the delegated act that

preceded the implementing act under discussion and is now adopted (COM Delegated Regulation (EU) 2021/577 - Medication record in the Horse Passport - published on 9 April 2021). Therefore, the delegated act will also require correction. The Commission services explained that they will proceed with the adoption procedure of the Implementing Regulation, and in parallel will launch a procedure to rectify the error in the Delegated Act as soon as possible.

In addition, one Member State raised two points as regards the draft Implementing Regulation, i.e. the lack of signature of the operator upon the declaration of the horse off the food-chain, and the seven-day period, for which that Member State proposed to be specified if it relates to working days or calendar days. The Commission services explained that these issues are outside the empowerment of Article 109(2) of Regulation 2019/6 and that they were discussed and agreed by experts in other Committees that are involved (in particular on Animal Health Law).

Overall, Member States expressed their support for the draft, upon the correction of the error. In view of the favourable outlook, the Commission services informed the Member States that their opinion would be sought by means of a written procedure to be launched after the meeting.

The Committee delivered its opinion through a written procedure.

**Outcome of the vote by written procedure:** Favourable opinion.

**Miscellaneous:**

**M.01 Revision of EMA fees:**

The Commission services gave an update on the ongoing revision of EMA fees, currently at the impact assessment stage, and the possible provisional arrangements between the date of application of Regulation (EU) 2019/6 and the adoption of a new framework on EMA fees.