EUROPEAN COMMISSION

Health and Food Safety Directorate General

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Standing Committee on *Veterinary Medicinal Products*

4 June 2019

CIRCABC Link: *https://circabc.europa.eu/w/browse/3613efa3-5946-4de9-9ff4-3523034ea71b*

SUMMARY REPORT

A.01 Opening and adoption of the agenda.

The agenda of the meeting was adopted. No items were added by Member States under AOB.

A.02 Draft mandates to EMA on scientific advice for implementing acts to be adopted by the date of entry into application of the new Regulation (28 January 2022):

a) format for the collection of data on antimicrobial medicinal products used in animals;

b) list of antimicrobials or groups of antimicrobials reserved for treatment of certain infections in humans;

c) good distribution practice (GDP) for veterinary medicinal products;

d) GDP for active substances used as starting material in veterinary medicinal products.

On all of the above listed items, the Commission services presented draft mandate texts and asked for written comments from the Member States by 18/06/2019.

A.03 Update from the Commission on the work on the implementing act on the design of the common logo to be displayed on websites offering veterinary medicinal products for sale at a distance (to be adopted by the date of entry into application of the new Regulation - 28 January 2022).

The Commission services explained to the Member States that due to the fact that there is no need for any specific scientific input in this regard, granting a mandate to EMA for a scientific advice is not necessary.

A.04 Ongoing work on scientific advice for implementing acts from the "first implementation package" – update from EMA on the expert working groups' activities and progress:

a) list of variations not requiring assessment;

b) measures and practical arrangements for VMP database;

c) good pharmacovigilance practice;

d) pharmacovigilance system master file.

The EMA informed the Member States that work on the scientific advice for the above items is almost completed with fine-tuning in progress. On pharmacovigilance items, the work is ongoing with the interim report planned to be submitted by the end of September 2019.

A.05 Any Other Business.

The Commission services reminded the Member States that in case there are mistakes in the translations into national languages of Regulation (EU) 2019/6, all errors spotted should be communicated to the Council secretariat (email: dql.rectificatifs@consilium.europa.eu). A template document should be used, which will be shared via CIRCABC after the meeting.

The Commission services reminded the Member States valid email addresses to be used in case of reasoned requests for a meeting of the Standing Committee.

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Decision granting marketing authorisation under Regulation (EC) No 726/2004 of the European Parliament and of the Council for "HorStem - equine umbilical cord mesenchymal stem cells", a veterinary medicinal product.

The representative of the European Medicinal Agency (EMA) gave a short summary of the authorisation procedure for HorStem. In its first vote on HorStem, the Committee for Medicinal Products for Veterinary Use (CVMP) did not reach the absolute majority thus recommending by default the refusal of the granting of the marketing authorisation for the above-mentioned veterinary medicinal product[1]. On 21 February 2019 the CVMP, having considered the grounds for the re-examination request[2] in accordance with Article 34(2) of Regulation (EC) No 726/2004, concluded, by a majority of 27 out of 30 votes, that its negative opinion of 11 October 2018 should be revised, and recommended the granting of a marketing authorisation[3]. In accordance with Article 31(1) of Regulation (EC) 726/2004, part of the European Public Assessment report[4] on the above mentioned VMP is a risk management plan (on quality) and a comprehensive post-marketing surveillance study in 800 horses. Finally, the measures taken to ensure sufficient quality of different batches (potency assay) and the additional benefits of the risk management plan were explained.

A presentation was given by one Member State on its concerns regarding the product. A short discussion took place where the majority of the Member States expressed the view that they supported the conclusions of the CVMP/EMA.

Vote taken: Favourable opinion.

1 EMA/CVMP/197477/2018 Opinion of the Committee for Medicinal Products for Veterinary Use on the granting of a marketing authorisation 11/10/2018

2 EMA/CVMP/870401/2018 Applicant's detailed grounds for requesting a re-examination - Rapp's assessment report

3 EMA/CVMP/120703/2019 Opinion of the Committee for Medicinal Products for Veterinary Use on the granting of a marketing authorisation

4 EMA/CVMP/114463/2019 CVMP final assessment report of an application for the granting of a community marketing authorisation for HorStem