EUROPEAN COMMISSION

Health and Food Safety Directorate General

sante.ddg2.g.5(2019)3456439

Standing Committee on Plants, Animals, Food and Feed

Section *Veterinary Medicinal Products*

04 June 2019

CIRCABC Link: *https://circabc.europa.eu/w/browse/993c1828-ee4e-4417-bffc-e8a5725ffdc7*

AGENDA

Section A Information and/or discussion

A.01 Opening and adoption of the agenda. (CS)

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): (JS + LG)

- format for the collection of data on antimicrobial medicinal products used in animals;
- list of antimicrobials or groups of antimicrobials reserved for treatment of certain infections in humans;
- good distribution practice (GDP) for veterinary medicinal products;
- good distribution practice (GDP) for active substances used as starting material in veterinary medicinal products.

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). (AL)

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: (JP + LG)

- list of variations not requiring assessment;
- measures and practical arrangements for veterinary medicinal product database;
- good pharmacovigilance practice;
- pharmacovigilance system master file (PSMF).

A.05 Any Other Business. (CS)

Section B Draft(s) presented for an opinion

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. (B5)

(SANTE/1753117/2019)

Legal Basis: Regulation (EC) No 726/2004 - Art. 35(2)

Procedure: Examination procedure