EUROPEAN COMMISSION

Health and Food Safety Directorate General

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Standing Committee on *Veterinary Medicinal Products*
30 September 2019

CIRCABC Link: *https://circabc.europa.eu/w/browse/69ea7490-8cab-41a1-9aa3-b7bfb74bac91*

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 Update on the state of play of the implementation of the new Regulation on veterinary medicinal products.

Member States agreed that the Commission's update on the state of play of the implementation of the new Regulation will not be repeated as the participants remain the same as in Expert Group Veterinary Pharmaceutical Committee's meeting that took place in the morning of the same day.

A.03 EMA advice on the implementing acts (IAs) to be adopted 12 months before entry into application of the new Regulation on veterinary medicinal products:

a) Advice on implementing measures under Article 60(1) of Regulation (EU) 2019/6 on veterinary medicinal products - Scientific recommendation on the list of variations not requiring assessment:
The representative of the European Medicinal Agency (EMA) gave a presentation on the content of the EMA advice. A short discussion followed.

b) Advice to the European Commission on the Union Product Database:
The representative of EMA gave a presentation on the content of the EMA advice. A short discussion followed.

The Commission services asked for written comments from the Member States on the two above-mentioned EMA advices by 31/10/2019.

A.04 Ongoing work on scientific advice for IAs – update from EMA on the Expert Working Groups' activities and progress:

EMA updated on the progress of the work of EMA working groups for the advices on:

(i) good pharmacovigilance practice;
(ii) pharmacovigilance master file;
(iii) format for the collection of data on antimicrobial medicinal products used in animals;
(iv) list of antimicrobials or groups of antimicrobials reserved for treatment of certain infections in humans;
(v) good distribution practice for VMPs;
(vi) good distribution practice for active substances used as starting material in VMPs.

EMA informed the Member States that work on the scientific advice for the above items is in progress and the advice to the Commission is expected to be on time.