EUROPEAN COMMISSION

Health and Food Safety Directorate General

**sante.ddg2.g.5(2020)581021**

**Standing Committee on *Veterinary Medicinal Products***
**2 December 2019**

***CIRCABC Link:*** *https://circabc.europa.eu/w/browse/1710c56c-ea18-4f86-b173-60b94908944a*

# 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 from the Commission on the state of play of the implementation of the new Regulation on veterinary medicinal products.

The Commission services presented the ongoing work on the implementation of the new VMP Regulation and explained the prioritisation of the work on the Implementing Acts (IA) and Delegated Acts (DA) foreseen in the new Regulation.

## A.03 Draft mandate to EMA on the establishment of a list of antimicrobials, which shall not be used in accordance with Articles 112-114 or which shall be used in accordance with these articles.

The Commission services presented the draft mandate from the Commission to EMA for the scientific advice regarding the establishment, under the new Regulation on veterinary medicinal products, of a list of antimicrobials which shall not be used in accordance with Articles 112-114 or which shall be used in accordance with these articles. The Commission services asked Member States for written comments by 17 January 2020. Afterwards, the mandate will be sent to EMA.

## A.04 Update from EMA on the ongoing work on scientific advice for IAs – expert working groups' activities and progress.

The representative of EMA gave a presentation 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.

**A.05 Draft implementing acts (IAs) to be adopted 12 months before entry into application of the new Regulation on veterinary medicinal products:**

a) **IA on the list of variations not requiring assessment**

The Commission services presented Commission working document on the future IA on the list of variations not requiring assessment.

A discussion followed. Member States mainly commented on the practicalities of the future new system for variations, e.g. concept of "rejection" versus "invalidation"; clear differentiation between conditions and requirements for specific variations listed in the annex; proposed order in the list of variations in the annex and its numbering.

b) **IA on the Union Product Database**

The Commission services presented Commission working document on the future IA on the Union Product Database.

A discussion followed. Member States gave a number of detailed comments, *inter alia* on the need for some additional clarifications of terms used in the draft or introduction of additional definitions and on the need to better explain and define responsibilities and obligations of all actors included in the development and functioning of the database.

c) **IA on the common logo to identify retailers offering veterinary medicinal products for sale at a distance**

The Commission services presented Commission working document on the future IA on the common logo to identify retailers offering veterinary medicinal products for sale at a distance.

A discussion followed. Member States' comments referred mainly to the choice of an online logo for websites offering veterinary medicines between a separate vet logo or an identical logo already existing on the human medicines side.

**A.06 AOB.**

There were no items under AOB.