EUROPEAN COMMISSION

Health and Food Safety Directorate General

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# SUMMARY REPORT OF THE STANDING COMMITTEE ON PLANTS, ANIMALS, FOOD AND FEED HELD IN BRUSSELS ON 14 DECEMBER 2018

**(Section *Veterinary Medicinal Products*)**

***CIRCABC Link:*** *https://circabc.europa.eu/w/browse/15d1ee97-3ef4-48ef-a36c-58adc23451ce*

## A.01 Opening and adoption of the agenda.

The agenda of the meeting was adopted.

## A.02 Draft Regulation on Veterinary Medicinal Products – overview and roadmap for implementation (role of the Standing Committee).

The Commission services gave a presentation updating the Members on:

- the finalised adoption of the new Veterinary Medicinal Products Regulation;
- the implementation work ahead as regards the implementing acts (IA) to be drafted and adopted;
- the detailed timelines and the institutional settings under which the process is to take place;
- the role the Standing Committee has to play in the process.

The Commission presented the draft mandates to be addressed to EMA, requesting its scientific advice for the first batch of IAs that need to be prepared.

The Member States were invited to comment on the draft mandates during the meeting.

In addition, the Commission requested feedback from the Member States in writing on all four mandate texts by 11 January 2019, including the comments made orally during the meeting of 14 December 2018.

## A.03 Draft mandates to EMA on scientific advice for implementing acts.

### A.03.1. IAs to be adopted 12 months before entry into application of the new Regulation

- establishing a list of variations not requiring assessment

  No comment.

- measures and practical arrangements for veterinary medicinal product database

- involvement of National Competent Authorities, but also industry and relevant actors, in the integration of data to ensure efficacy and inter-operability of the IT systems

- appropriate timing for Member States to provide relevant expert support while designing the architecture of the database

- role in the governance of the project

- both short-term and long-term goals should be defined as regards which information the database should provide

- financial model to ensure the maintenance of the database

- overall objectives and timing to be kept focused and realistic, to ensure timely delivery.

**A.03.2. IAs to be adopted 12 months before entry into application of the new Regulation**

- good pharmacovigilance practice

1. data necessary to establish good pharmacovigilance practice should be taken into account while preparing the database; coordination is essential as the timelines to deliver on the database and on this mandate are different
2. questioning if elements will be transposable from the human medicines system to the veterinary medicines system, as different rules apply (e.g. see signal detection under the human medicine system, which has kept the periodic safety update report (PSUR)).

- pharmacovigilance system master file (PSMF)

1. take into account feedback from pharmacovigilance inspectors
2. reflect on how to ensure an independent management for the PSMF, so that every time there is a change it does not escalate to trigger a multitude of following changes.

The Commission took note of the preliminary remarks of the delegates on the draft mandates and concluded that at this stage there seemed to be a general agreement with the approach as proposed by the Commission, subject to any further comments by the Members States.

The Commission reminded the Members States that they were invited to comment in writing on the mandates by 11 January 2019.

**A.04 A.O.B.**

No items raised under Any Other Business.