EUROPEAN COMMISSION

Health and Food Safety Directorate General

sante.ddg2.g.5(2020)2031105

Standing Committee on *Veterinary Medicinal Products*
10 March 2020

CIRCABC Link: *https://circabc.europa.eu/w/browse/9772d63b-f137-4402-8326-ddd448e944a7*

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.

Representatives from 12 Member States were physically present during the meeting, and representatives of 6 Member States participated remotely at the meeting (by audioconference or videoconference).

A.02 Items for information and exchange of views:

1. **Brexit session - implications of the withdrawal agreement and transition period (UKTF).**

   The Commission services (from the UKTF) presented the latest developments as regards the implications of the UK withdrawal agreement and the transition period. Some of the main changes brought about by the UK withdrawal were reminded (*e.g.* as regards batch release, co-labelling, possible new requirements from the UK in view of a modified marketing authorisation system; the UK can no longer be 'Reference Member State', nor trigger referrals). The hard deadline of 1 January 2021 was also recalled and the importance to ensure 'readiness' towards upcoming changes, in particular for industry, was reiterated. Special arrangements for Northern Ireland as part of the Protocol were also presented. Committee members were informed that a Note summarising all the different points mentioned would soon be made available.

2. **Update from the Commission on the state of play and next steps of the implementation of the 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.

3. **Update from EMA on the ongoing work on scientific advice for IAs – expert working groups' activities and progress (IC).**

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 system master file;

(iii) good distribution practice for active substances used as starting materials in veterinary medicinal products;

(iv) good distribution practice for veterinary medicinal products;

(v) format of the data to be collected on antimicrobial medicinal products used in animals;

(vi) rules on oral administration

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

(viii) list of antimicrobials which shall not be used or used in accordance to Articles 112, 113 and 114 or may be used subject certain conditions.

4. **Presentation by the Commission of the draft implementing acts (IAs):**

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

The Commission services presented a revised COM working document on the future IA on the list of variations not requiring assessment. A first draft had already been presented to the Committee on 2 December 2019.

A discussion followed. Main comments from MS were: 1) on the advantages and disadvantages of having the requirements laid in an implementing act vs. in a guidance document; 2) on the new structure of the Annex and related numbering according to type of changes vs. the old classification system according to the part of the product in the guidance; 3) on the possible need for more detailed requirements on conditions and documents that should be provided. MS expressed the need for greater clarity about the procedures to be followed (incl. for updates of the Annex).

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

The Commission services presented a revised COM working document on the future IA on the Union Product Database. A first draft had already been presented to the Committee on 2 December 2019.

A discussion followed. MS acknowledged great progress had been made on the draft but still had a few comments, for example: 1) need to clarify further what some specific terms refer to (e.g. 'super user', 'international standards'); 2) need to explain the reasoning behind the proposed timelines (e.g. for certain updates to be made the UPD); 3) a few questions on the unique identification number and the fact that it should be detailed to pack size level.

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

The Commission services presented an update of the work since its initial presentation to the Committee on 2 December 2019.

MS overall seemed to welcome the approach for the design of the future logo (blue with the letters 'Vet').

The Commission services asked for written comments from the Member States on the three above COM working documents on the future IAs by **24 March 2020.**

A.03 AOB.

There were no items under AOB.