EUROPEAN COMMISSION

Health and Food Safety Directorate General

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Standing Committee on *Veterinary Medicinal Products*
20 June 2024

CIRCABC Link: *https://circabc.europa.eu/ui/group/a2ba6dd7-f812-406a-8b1c-2aaf25ec4277/library/32fe345a-a4f5-45e2-b599-92d31c002814?p=1&n=10&sort=modified_DESC*

SUMMARY REPORT

The Chair opened the meeting by reminding participants about the confidentiality of the documents for the meeting and of the discussions in the meeting. At the request of a Member State, an AOB point was added in advance of the meeting. The agenda of the meeting was adopted.

A.01 State of play of implementation of Regulation (EU) 2019/6 on Veterinary Medicinal Products

The Commission informed the Member States of the state of play of the implementation of Regulation (EU) 2019/6 on Veterinary Medicinal Products.

A.02 Information on a draft Commission Implementing Regulation (EU) laying down the list of third countries or regions thereof authorised for the entry into the Union of certain animals and products of animal origin intended for human consumption in accordance with Regulation (EU) 2017/625 as regards the application of the prohibition of use of certain antimicrobial medicinal products

The Committee was informed of the state of play of the listing of third countries that will be authorised to export animals and products derived therefrom intended for human consumption to the EU.

A.03 Collection of data on antimicrobial medicinal products used in animals (Article 57 of Regulation (EU) 2019/6) – Update from Member States

The Commission recalled the upcoming deadlines for the submission of data on the sales and use of antimicrobials in animals and asked the Member States to update the Committee on the progress in their countries. A small number of Member States reported that they will be ready to submit their sales data on time. One Member Sate warned of discrepancies between the sales data reported in the Union product database and in their national database. A Member State signalled that the use data for the first couple of years may not be comprehensive.

A.04 Recording of annual volume of sales in the Union product database (Article 58(12) Regulation (EU) 2019/6) – State of play

The Commission services briefed the Committee on the current rates of recording of the annual volume of sales (VoS) data in the Union product database (UPD). The Commission acknowledged the considerable progress made by the Member States (MSs) in improving the quality of product data in the UPD, especially as regards antimicrobial veterinary medicinal products. The Commission invited the MSs: to contact their marketing authorisation holders (MAHs) to request those who have not recorded VoS yet to do so; to contact their MAHs to confirm which packages and products are not marketed and therefore have no VoS attached; as well as to continue their efforts to correct the product data in the UPD to enable MAHs to record their VoS data.

A.05 Information on the legal framework under Regulation (EC) No 470/2009 and chemical-unlike biological substances

The Commission informed the Member States of an inconsistency in the EU legislation between Implementing Regulation (EU) 2018/782 and Delegated Regulation (EU) 2019/2090 as regards the status of chemical-unlike biological substances. Currently, these substances are considered low-risk (e.g. normal constituents of food as amino acids, lipids, carbohydrates, etc.), and they do not require a full evaluation, unlike other substances used in VMPs. These substances are listed separately by the European Medicines Agency (EMA).

To ensure legal certainty, several legal Acts should be amended to add these substances to the table 1 (“allowed substances”) of the Annex to Regulation (EU) No 37/2010, and to amend Annex I to Regulation (EU) 2018/782 to require EMA to directly determine if a "no MRL required" classification is suitable or if a full risk assessment is necessary for these substances. Member States welcomed the explanations and the preparation of the draft proposals which are expected to be discussed at an upcoming meeting.

A.06 Discussion on measures on GMP for veterinary medicinal products under Article 93(2) of Regulation (EU) 2019/6

The Commission explained the legal requirements in connection with the development of the implementing acts referred to in Article 93(2) of Regulation (EU) 2019/6.

Concerns about possible negative effects derived from the conversion of the current GMP guidelines into a legal act were expressed by several Member States.

The following was agreed:

1. Separate acts will be developed covering respectively (i) GMP requirements for active substances, (ii) GMP requirements for veterinary medicinal products, and (iii) GMP requirements for inactivated immunological veterinary medicinal products.
2. Alignment of the GMP requirements for veterinary medicinal products with the GMP requirements for human medicinal products and international standards should be kept. To this end, the implementing acts will be amended as necessary to reflect updates in the GMP requirements for human medicinal products/international standards.

3. With a view to assist the Commission in the drafting of the implementing acts, a sub-group of the Expert Group on Veterinary Medicinal Products will be established.

C.01 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) establishing a list of antimicrobials which shall not be used in accordance with Articles 112 and 113 of Regulation (EU) 2019/6 of the European Parliament and of the Council or which shall only be used in accordance with those Articles subject to certain conditions

(PLAN/2020/9134)

The Commission informed the Committee that the public consultation of the draft Implementing Regulation would close on 20 June 2024, midnight, and presented the feedback received until the morning of 20 June. The Commission also updated the Committee about the next steps in the process towards the adoption of the draft Implementing Regulation.

M.01 Availability of vaccines against vector-borne animal diseases, namely Bluetongue and Epizootic Haemorrhagic Disease, and the local situations at a national level

Some Member States shared information concerning the use of Bluetongue serotype 3 vaccines according to Article 110(2) of Regulation (EU) 2019/6. One Member State informed of the authorisation to use a vaccine for Epizootic Haemorrhagic Disease according to Article 110(2) of Regulation (EU) 2019/6.