EUROPEAN COMMISSION

Health and Food Safety Directorate General

sante.g.3(2024)7985526

Standing Committee on *Veterinary Medicinal Products*
1 October 2024

CIRCABC Link: *https://circabc.europa.eu/ui/group/a2ba6dd7-f812-406a-8b1c-2aaf25ec4277/library/89c12281-c505-40c1-a2d6-8312ee4e42e2?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. 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 Collection of data on antimicrobial medicinal products used in animals (Article 57 of Regulation (EU) 2019/6) – Update from Member States

The Commission informed the Committee that all Member States have submitted their antimicrobial sales data. As some submissions came after the legal deadline of 30 June 2024, the Commission cautioned that delays in data submission in the future may affect the timely data processing and reporting by the European Medicines Agency.

The Commission also briefed the Committee on the state of play of submission of the antimicrobial use data for which the legal deadline expired on 30 September 2024. The Commission urged those Member State which were in the process of submitting their data to complete the process as soon as possible.

A.03 Recording of annual volume of sales in the Union product database (Article 58(12) Regulation (EU) 2019/6) – Update from Member States

Some Member States reported having been in contact with their marketing authorisation holders (MAHs) to ensure that they record the required data in the Union Product Database (UPD). The Commission highlighted that recording the volume of sales data will enable pharmacovigilance activities and could also help identify UPD data quality issues. The Commission reminded the Member States of their responsibility to make sure that MAHs fulfil their legal obligation under Article 58(12).

A.04 Information on the legal framework under Regulation (EC) No 470/2009 and chemical-unlike biological substances

The Commission informed the Committee on the necessary amendments of legal Acts to add chemical-unlike biological substances to the table 1 ("allowed substances") of the Annex to Regulation (EU) No 37/2010.

The Committee was also informed that the mandate to provide scientific advice to confirm that the concerned chemical-unlike biological substances do not pose any risk to public health had already been submitted to the Agency, with foreseen feedback early 2025. Considering this, the Commission informed the Committee that the draft amendments of the legal Acts would be presented at the Standing Committee in March 2025.

A.05 Discussion on a working document on the amendment of Regulation (EU) 2021/17 establishing a list of variations not requiring assessment in accordance with Regulation (EU) 2019/6

The Implementing Regulation (EU) 2021/17 setting up the list of variations not requiring assessment needs regular updates based upon new scientific and technical developments. The Commission presented a working document combining changes proposed by industry, EMA, CMDv and the Commission.

A.06 Discussion on a working document on the establishment under Article 115(5) of Regulation (EU) 2019/6 of a list of substances which are essential for the treatment of equine species, or which bring added clinical benefit compared to other treatment options available for equine species and for which the withdrawal period for equine species shall be six months

The Commission presented the working document which was received well by the Member States. The Committee discussed some elements like the most appropriate transitional period to allow stakeholders to adapt to the new provisions and the recommendations provided in the EMA scientific advice for certain substances.

A.07 Information on the discussions held at the first meeting of Expert Group on GMP for veterinary medicinal products under Article 93(2) of Regulation (EU) 2019/6

The Commission informed the Committee on the state of play of the discussions held at the Commission's Expert sub-Group on GMP for veterinary medicinal products under Article 93(2) of Regulation (EU) 2019/6.