EUROPEAN COMMISSION

Health and Food Safety Directorate General

sante.g.3(2023)6941733

Standing Committee on *Veterinary Medicinal Products*
26 June 2023

CIRCABC Link: *https://circabc.europa.eu/ui/group/a2ba6dd7-f812-406a-8b1c-2aaf25ec4277/library/d00b8734-0f9a-4f13-90b3-95266d7f0ba1?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. One item was added under AoB upon request from the Commission.

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 Implementation of Regulation (EU) 2022/839 of the European Parliament and of the Council laying down transitional rules for the packaging and labelling of veterinary medicinal products authorised or registered in accordance with Directive 2001/82/EC and Regulation (EC) No 726/2004

The Commission reminded the Member States of the relevance of ensuring a well-planned submission of the relevant variations (to implement the new QRD template) in order to avoid an unintended situation at the end of the transition period.

The Commission informed of its intention to monitor progress and to request regular feedback from Member States.

Some Member States indicated that the number of applications received so far was rather low and could make it difficult achieving the proposed goal in time.

A.03 EMA Scientific advice under Article 107(6) of Regulation (EU) 2019/6 for the establishment of a list of antimicrobials which shall not be used in accordance with Articles 112, 113 and 114 of the same Regulation or which shall only be used in accordance with these articles subject to certain conditions - Presentation by EMA

The Chair of the Expert Group which worked on the EMA scientific advice presented it on behalf of the Agency. Questions by Member States were mostly related to clarifications on the scope of recommendations.

The Commission proposed a step-wise approach to the scope of the implementing acts under Article 107(6) as regards animal species.

A.04 Information on next steps concerning the implementation of Commission Delegated Regulation (EU) 2023/905 supplementing Regulation (EU) 2019/6 of the European Parliament and of the Council as regards the application of the prohibition of use of certain antimicrobial medicinal products in animals or products of animal origin exported from third countries into the Union

Member States were informed of the state of play of the preparatory work for the two implementing acts necessary for the implementation of Commission Delegated Regulation (EU) 2023/905 (list of approved third countries and amendment of official certificates).

The opinion of the Standing Committee on Animals, Plants, Food and Feed, section controls and import conditions, would be sought for.

A.05 Exchange of views on the list of the abbreviations and pictograms common throughout the Union, in accordance with Article 17(2)

Article 17(2) of the Regulation (EU) 2019/6 requires the Commission to adopt implementing acts establishing a list of abbreviations and pictograms common throughout the Union to be used for the purposes of Articles 10(2) and 11(3) of Regulation (EU) 2019/6.

The Commission presented the outcome of the exchanges of the discussions at the level of the Expert Working Group on veterinary medicinal products with regards to the acceptable pictograms.

A discussion and exchange of views on the policy options for the development of the implementing acts under Article 17(2) of Regulation (EU) 2019/6 took place.

The Commission will launch a targeted stakeholder consultation on the pictograms for which the Expert Working Group agreed to be included in this targeted stakeholder consultation. Member States were invited to forward this targeted stakeholder consultation to the representation of national associations of VMP retailers or animal keepers.

A.06 Exchange of views on on uniform rules on the size of small immediate packaging units, in accordance with Article 17(3)

Article 17(3) of the Regulation (EU) 2019/6 requires the Commission to adopt implementing acts establishing uniform rules on the size of small immediate packaging units referred to in Article 12 of Regulation (EU) 2019/6.

A discussion and exchange of views on the policy options for the development of the implementing acts under Article 17(3) of Regulation (EU) 2019/6 took place, including on the rules for a possible derogation to the general rule on the size of small immediate packaging units.

AoB Provision of data for the ongoing ESVAC reporting and collection of data for the volume of sales and use reporting in accordance with Article 57 of Regulation (EU) 2019/6

The Commission services recalled that the progress towards the target set in the Farm to Fork Strategy to reduce overall EU sales of antimicrobials for farmed animals and in aquaculture by 50% by 2030 is being measured on the basis of data provided on a voluntary basis by the Member States under the European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) project. The Commission services called on the Member States to provide their 2022 sales data for the ESVAC project. This is particularly important because it allows to continue measuring reliably the progress towards the achievement of the Farm to Fork Strategy target.

The Commission services reminded Member States about their obligation under Article 57 of Regulation (EU) 2019/6 to collect and send to the European Medicines Agency (EMA) data on the volume of sales and use of antimicrobials. The Commission services highlighted that Member States should be collecting those data in 2023 and be prepared to send them to EMA for the first time in 2024.

Section B <u>Draft(s) presented for an opinion</u>

B.01 Exchange of views and technical agreement of the Committee on a draft Commission Implementing Regulation (EU) amending Regulation (EU) No 37/2010 to classify the substance rafoxanide as regards its maximum residue limit.

The Commission services presented the draft Implementing Regulation concerning the potential establishment of a numerical MRL for ketoprofen in poultry species.

Technical agreement: unanimity

B.02 Exchange of views and technical agreement of the Committee on a draft Commission Implementing Regulation (EU) amending Regulation (EU) No 37/2010 to classify the substance ketoprofen as regards its maximum residue limit.

The Commission services presented the draft Implementing Regulation concerning the potential establishment of a numerical MRL for rafoxanide in bovine and ovine species, specifically in relation to milk, and its potential extrapolation to all ruminants.

Technical agreement: unanimity