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Health and Food Safety Directorate General

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Standing Committee on *Veterinary Medicinal Products*
15 November 2023

CIRCABC Link: *https://circabc.europa.eu/ui/group/a2ba6dd7-f812-406a-8b1c-2aaf25ec4277/library/8f708794-8389-4c43-9f23-f650744e7b01?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. Two items were added under AOB upon request from Member States.

Section A Information and/or discussion

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 Discussion on the establishment under Article 107(6) of Regulation (EU) 2019/6 of a list of antimicrobials which shall not be used in accordance with Articles 112 and 113 of the same Regulation or which shall only be used in accordance with these articles subject to certain conditions

The Commission presented, in a working document, its proposed approach on the establishment of the list on the basis of the Scientific Advice of the European Medicines Agency.

The working document was received well. The Member States raised questions of technical nature. The Commission provided clarifications.

The Commission asked the Member States for their comments in writing by 30 November 2023.

Following the reception of the Member States' comments, the Commission will present a revised document at the next meeting of the Committee.

A.03 Information on the state of play on 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

The Commission informed the Member States that the Commission Implementing Regulation, which amends the existing export certificates, received a positive opinion of the Standing Committee on Plant and Animal Health, Food and Feed on 19 October. The act has been sent for adoption and is expected to be published in the OJ in February 2024. The publication will mark the beginning of a 30-month period preceding the full implementation of Article 118 of the VMP Regulation.

Member States were informed of the state of play of the listing of third countries authorised to export animals and products derived therefrom intended for human consumption to the EU.

A.04 Collection of data on antimicrobial medicinal products used in animals – State of play on the implementation of Article 57 of Regulation (EU) 2019/6 at Member State level

The Commission recalled the legal obligations of the Member States regarding the collection and reporting of data on the sales and use of antimicrobials in animals.

Several Member States confirmed that all necessary arrangements are in place in their territories and explicitly thanked the Commission for the financial support provided.

Others expressed concerns on the progress made and explained that they are facing problems, such as lack of resources or issues with competences split between different national authorities.

A.05 Recording of annual volume of sales in the Union product database – State of play on the implementation of Article 58(12)

The Commission informed the Committee that, as per data provided by the European Medicines Agency, a very low number of Marketing Authorisation Holders have recorded in the Union Product Database the sales for their products for the year 2022.

Timely recording of sales is particularly important as it may have an impact on the collection and provision of data on sales of antimicrobials by some Member States, as well as on the publication of the incidences of suspected adverse events by the European Medicines Agency.

The Commission urged the Member States to resolve outstanding quality issues with their data in the Union Product Database, so that Marketing Authorisation Holders can record their sales data, as well as to remind their Marketing Authorisation Holders of their obligations to record sales data for their products.

A.06 Information on ongoing files linked to MRLs

– **Information on a proposal for an amendment of Commission Regulation (EU) No 37/2010 as regards the application of MRL to dried, diluted, processed or compound foods**

The Commission informed the Member States about a possible initiative to explicitly extend the application of Maximum Residue Limits to dried, diluted, processed, and

compound foods for which specific maximum limits are not established. Such extension aims at considering variations in the concentrations of pharmacologically active substances and their residues resulting from processes like drying, dilution, and other forms of processing. This approach would also consider the relative proportions of ingredients in the case of compound foods. The possible amendment would align with the existing approach applied to contaminants (according to Article 3 of Commission Regulation (EU) 2023/915) and pesticide residues (according to Article 20 of Regulation (EC) No 396/2005).

- **Information on a proposal for an amendment of Commission Delegated Regulation (EU) 2019/2090 as regards a change in the definition of "unauthorised substance"**

The Commission informed the Member States about a potential initiative to modify the definition of 'unauthorised substances' established in Article 2 of Commission Delegated Regulation (EU) 2019/2090. This amendment would introduce an exception for chemical-unlike biological substances, for which the European Medicines Agency has concluded that an evaluation of Maximum Residue Limits is not required and therefore will not be listed in Table 1 (allowed substances) in the Annex to Commission Regulation (EU) No 37/2010. Since these biological substances are not explicitly excluded from the current definition, they could potentially be considered as unauthorised. Therefore, a revision of the definition would be needed to explicitly grant an exemption to these substances.

Section B Draft presented for an opinion

B.01 Exchange of views and technical agreement of the Committee on a draft Commission Implementing Regulation (EU) amending Regulation (EU) No 37/2010 as regards the classification of the substance sodium salicylate with respect to its maximum residue limit in foodstuffs of animal origin

The Commission services presented the draft Implementing Regulation concerning the potential establishment of a numerical MRL for sodium salicylate in chicken and its extrapolation to other poultry other than turkey.

Technical agreement: qualified majority in favour.

Section C Draft(s) presented for discussion

C.01 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) adopting a list of the 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 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC

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 a draft Commission Implementing Regulation (EU) adopting a list of the abbreviations and pictograms common throughout the Union. Member States supported the draft proposal as tabled.

C.02 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) adopting uniform rules on the size of small immediate packaging units referred to in Article 12 of Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC

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.

The Commission presented draft Commission Implementing Regulation (EU) adopting uniform rules on the size of small immediate packaging units. Member States supported the draft proposal as tabled.

Miscellaneous

M.01 Increase of withdrawals of national marketing authorisations

A Member State noted an increase in the number of national marketing authorisations being withdrawn from the market and asked if other Member States were facing a similar situation. No other Member State was aware on a significant increase in the number of marketing authorisations being withdrawn on their market. However, Member States were invited to report in case they monitor important changes in the availability of VMPs on their market.

M.02 Bluetongue serotype 3

A Member State reported on the impact of the emergence of Bluetongue serotype 3 on its territory. The emergence in September 2023 of this serotype 3 had a serious impact on animal health, namely for sheep. Due to the decline in temperature, the number of infections is slowing down. However, in spring the spreading of the disease is likely to accelerate again. Therefore, support of the other Member States was requested in urging pharmaceutical companies to work on vaccines for serotype 3.