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Health and Food Safety Directorate General

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Standing Committee on *Veterinary Medicinal Products*
22 February 2024

CIRCABC Link: *https://circabc.europa.eu/ui/group/a2ba6dd7-f812-406a-8b1c-2aaf25ec4277/library/78724352-a71c-4d3e-b594-640f028dcd01?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.

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 a revised working document, based on Member States' comments received after the previous meeting of the Standing Committee.

The revised working document was received well. The Member States raised questions of technical nature. The Commission and the European Medicines Agency provided clarifications.

The Commission asked the Member States for their comments on the document discussed.

A.03 Scientific Advice under Article 93(2) of Regulation (EU) 2019/6 on measures on GMP for veterinary medicinal products and active substances used as starting materials – Presentation by EMA and feedback on the outcome of the targeted stakeholder consultation

The European Medicines Agency presented its Scientific advice on GMP for veterinary medicinal products and active substances used as starting materials. The Commission also presented the outcome of the targeted stakeholder consultation on this advice.

The Commission informed the Committee that the Commission will draft two implementing acts: an implementing act on GMP measures for veterinary medicinal products and an implementing act on GMP measures for starting materials.

A.04 Discussion on the state of play on the implementation of Regulation (EU) 2022/839 of the European Parliament and of the Council (QRDv9 updates)

The Commission took stock of the situation noting that the processing of the required variations at the national level was still very low. In light of the huge amount of variations to be processed, it is advisable to focus variation applications on G.1.18 aspects only, in particular regarding authorisations under MRP/DP. It was also noted that, pursuant to Regulation (EU) 2022/839, batches compliant with the packaging and labelling requirements set forth in the Regulation (EC) No 726/2004 and Directive 2001/82/EC can continue to be released until 29 January 2027. Batches released thereafter would have to be compliant with the labelling and packaging requirements under Regulation (EU) 2019/6.

A.05 Collection of data on antimicrobial medicinal products used in animals (Article 57 of Regulation (EU) 2019/6) and recording of annual volume of sales in the Union product database (Article 58(12) Regulation (EU) 2019/6) – follow-up to the discussion at the last meeting

The Commission informed the Committee that letters were sent to national competent authorities to help them progress with the data collection.

The European Medicines Agency reported that issues with the quality of data in the Union Product Database need to be urgently resolved by the national competent authorities - namely reference Member States - to enable the Agency to meet its legal obligation to report on the antimicrobial sales data.

Some Member States referred to technical difficulties which create delays and additional workload. The Agency and the national competent authorities will remain in contact in view of resolving the pending issues.

This topic will remain a rolling agenda point for the upcoming meetings of the Standing Committee, where Member States will be asked to update the Committee about their progress in data collection and reporting.

A.06 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 Committee of the publication on 12 February 2024 of Commission Implementing Regulation (EU) 2024/399, which amends the existing export certificates. This Regulation will apply as from 3 September 2024 and marks the beginning of a 24-month period preceding the full implementation of Article 118 of the VMP Regulation.

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

A.07 Information by the Commission on cases of falsified vaccines against rabies

The Commission informed the Committee of increasing cases of illegal pet trade with forged health certificates and falsified rabies antibody titration test reports. Member States were requested to spread the information and support trainings on controls.

Section B Draft presented for an opinion

B.01 Exchange of views and possible opinion 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

(PLAN/2023/2438)

The Commission presented the draft Implementing Regulation, which aims to broaden the existing MRL for sodium salicylate to chicken and its extrapolation to all poultry species other than turkeys. This aligns with the scientific opinion of the EMA's Committee on Veterinary Medicinal Products.

Vote taken: Favourable opinion.

B.02 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) amending Regulation (EU) No 37/2010 as regards the substance 17β-oestradiol

(PLAN/2023/2920)

The Commission presented the draft Implementing Regulation, which aims to remove the entry of 17β-oestradiol from Table 1 of Regulation (EU) No 37/2010 since Council Directive 96/22/EC prohibits the administering of this substance to farm animals.

Vote taken: Favourable opinion.

B.03 Exchange of views and possible opinion 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

(PLAN/2023/921)

The Commission presented the draft Implementing Regulation (EU) adopting a list of the abbreviations and pictograms common throughout the Union, as well as the outcome of the public consultation on this draft act.

Vote taken: Favourable opinion.

B.04 Exchange of views and possible opinion 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

(PLAN/2023/922)

The Commission presented the draft Implementing Regulation (EU) adopting uniform rules on the size of small immediate packaging units, as well as the outcome of the public consultation on this draft act.

Vote taken: Favourable opinion.

B.05 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) amending Implementing Regulation (EU) 2021/17 establishing a list of variations not requiring assessment in accordance with Regulation (EU) 2019/6 of the European Parliament and of the Council

(PLAN/2023/2278)

The Commission presented a draft Implementing Regulation, which aims at updating the list variations that do not require assessment (VNRA) in order to include the variations derived from the two legal acts above (rules on pictograms and abbreviations, and on the size of small immediate packaging units) as VNRA.

Vote taken: Favourable opinion.

B.06 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Decision (EU) concerning, in the framework of Article 54 of Regulation (EU) 2019/6 of the European Parliament and of the Council, the marketing authorisations for the veterinary medicinal products "Procactive 300 mg/ml suspension for injection for cattle, sheep and pigs and associated names"

The Commission services presented the information received from the EMA coordination group (CMDv) and Committee on Veterinary Medicinal Products (CVMP) in the context of this procedure and explained the applicable legal framework.

One Member State was of the opinion that the proposal can mean that this product does not meet the necessary requirements, regarding the risk to the environment. Furthermore, this Member State was of the opinion that a more thorough Phase II environmental risk assessment would clarify whether there is a concrete risk or not. If this proposal is adopted this could mean that in the future there will be no requirement for environmental risk assessment for similar cases, for the same or other types of active substances. This could mean that there will still be products placed on the EU market, which are not covered by an environmental risk assessment, and no data will be generated for old molecules.

The Commission services noted that environmental concerns should be duly considered in the context of the assessment of marketing authorisation and variation applications, as foreseen in Regulation (EU) 2019/6. In this regard, the Commission services noted that the draft Commission Decision on Procactive is only relevant to the application of the Article 18(7) of the Regulation (EU) 2019/6 to this procedure having due regard to the specificities of the case as discussed during the meeting. Article 18(7) of the Regulation (EU) 2019/6 should be applied having regard to the specific circumstances of each application. Accordingly, in application of Article 18(7) of the Regulation (EU) 2019/6, the submission of ERA data may be required in the context of future generic applications.

Vote taken: Favourable opinion.