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Standing Committee on
Veterinary Medicinal Products
22 January 2018

CIRCABC Link: *https://circabc.europa.eu/w/browse/5794fcf3-2732-4424-8666-7ce2f92f1142*

SUMMARY REPORT

A.01 Opening and adoption of the agenda.

A.02 Strategic approach to pharmaceuticals in the environment – state of play and update by the Commission on the latest developments.

The Commission's representative from DG ENV gave a presentation on the development of the strategic approach to pharmaceuticals. She explained the issue, outlined the background to the development of the approach, and summarised the activities undertaken to support the development of the approach, in particular the ongoing consultation process. She briefly ran through the possible options presented in the consultation documents. She stressed that developing the approach is the first of a two-stage process and that full impact assessment will be necessary for any legislative changes. In response to questions from Member States she acknowledged that some of the questions in the targeted consultation questionnaire might not have been easy to answer objectively but stressed that the Commission would avoid interpreting the results in a superficial manner. There would be no workshop before adoption of the Commission Communication but dialogue would continue afterwards and workshops on following up specific options might be held.

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Regulation establishing the methodological principles for the risk assessment and risk management recommendations referred to in Regulation (EC) No 470/2009.

The Commission's representative explained that this draft Commission Regulation establishes the methodological principles for the risk assessment and risk management. Article 13 of the MRL Regulation (EC) No 470/2009 foresees that the Commission shall adopt, in consultation with the Agency, Member States and interested parties measures regarding the methodological principles for the risk assessment and risk management.

This draft Regulation is based on the CVMP document on the methodological principles for the risk assessment and risk management which provides an overview of the data to be submitted and describes how the submitted data are used in the

evaluation of MRL applications of pharmacologically active substances. This document was presented by a representative of the European Medicines Agency during the Standing Committee of June 2017.

The Commission's representative explained that in accordance to the procedures of the Commission, a four week Public consultation took place between the 15/11/2017 and 13/12/2017.

Vote taken: Favourable opinion.

B.02 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Decision granting marketing authorisation under Regulation (EC) No 726/2004 of the European Parliament and of the Council for "MiPet Easecto - sarolaner", a veterinary medicinal product.

The Commission's representative explained that the Commission services submitted the draft Commission Implementing Decision on 17 November 2017, for an opinion to be given by written procedure.

During the written procedure in December, the Commission had been made aware of potential issues related to the product packaging. Therefore, in accordance with Article 8(3) of the Rules of Procedure of the Standing Committee on veterinary medicinal products, it was decided to terminate the written procedure and to refer the vote to the Standing Committee of 22 January 2018.

The representative of the European Medicines Agency made a presentation on the issues related to the product packaging. It was concluded that the draft Decision submitted initially to the written procedure remained valid.

Vote taken: Favourable opinion.

M.01 Biocides

A Member State raised concern about the delay in adopting the decision clarifying that permethrin based products for pour on application in cattle are considered veterinary medicinal products and not biocides.

The Commission's representative explained that following some procedural discussions with Member States, it is expected that the matter will be discussed again in the Standing Committee on biocides in March 2018 or May 2018. The Commission's representative encouraged the Member States to have bilateral discussions with the competent authority responsible for biocides in their Member State.

M.02 Specific veterinary medicinal products

The Chair gave an update on the state of play of the centralised authorisation of the veterinary medicinal product "Oxybee".