EUROPEAN COMMISSION

Health and Food Safety Directorate General

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Standing Committee on *Veterinary Medicinal Products*

2 July 2021

CIRCABC Link: *https://circabc.europa.eu/w/browse/8577efff-5c51-491a-a9c6-3d7b4c0fe538*

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 and also outlined the necessary technical arrangements to ensure that confidentiality.

The agenda of the meeting was adopted.

Section A Information and/or discussion

A.01 Update from the Commission on the state of play of the implementation of Regulation (EU) 2019/6 on veterinary medicinal products.

The Commission services presented the ongoing work on the implementation of Regulation (EU) 2019/6 and explained the prioritisation of the work on the Implementing and Delegated Acts foreseen therein.

The Commission services reminded Member States that Regulation (EU) 2019/6 will start to apply from January 2022 and invited Member States to take the necessary steps to prepare themselves for a timely implementation of the new EU rules.

A.02 Update from the Commission on EU-UK issues related to Brexit, including the implementation of IE/NI Protocol.

The Commission provided an update on the latest developments and responded to questions raised by the Member States in advance of the meeting.

A.03 Update on existing authorisations/renewals.

The Commission informed Member States on the content of the Notice on existing authorisations, adopted on 8 July and published on 9 July.

Section B Draft(s) presented for an opinion

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation on measures on good distribution practice for active substances used as starting materials in veterinary medicinal products.

The Commission services presented the draft Commission Implementing Regulation.

The Commission services informed the Member States of the outcome of the Feedback Mechanism. The Commission services presented some proposals for changes based on the feedback received. Those were discussed and agreed by the Member States.

One Member State, supported by another, raised questions relating to the possibility to cover good distribution practice certificates and statements of non-compliance with the good distribution practice. The Commission services explained that adopting the implementing acts on the good distribution practice of active substances used as starting materials in veterinary medicinal products and for veterinary medicinal products should be considered a priority to allow the industry time for implementation of the draft measures. The issue of certificates and non-compliance statements is to be referred to the Commission's Legal Service and could be revisited at a later stage in light of the legal feasibility of such documents.

Member States expressed their support for the draft.

The Committee delivered its opinion through a written procedure.

Outcome of the vote by written procedure: Favourable opinion.

B.02 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation on good distribution practice for veterinary medicinal products.

The Commission services presented the draft Commission Implementing Regulation.

The Commission services informed the Member States of the outcome of the Feedback Mechanism. The Commission services presented some proposals for changes based on the feedback received. Those were discussed and agreed by the Member States.

Member States expressed their support for the draft.

The Committee delivered its opinion through a written procedure.

Outcome of the vote by written procedure: Favourable opinion.

B.03 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation on Good Pharmacovigilance Practice for VMPs and the format, content and summary of the Pharmacovigilance System Master File.

The Commission services presented the draft Commission Implementing Regulation.

The Commission services presented some proposals for changes based on the feedback received. Most of these were discussed and agreed by the Member States. The Commission informed Member States about the proposal to remove some of the elements of the summary of the pharmacovigilance system master file from the draft act; Member States were of the view that the text should not be modified in this regard.

Member States expressed their support for the draft.

The Committee delivered its opinion through a written procedure.

Outcome of the vote by written procedure: Favourable opinion.