EUROPEAN COMMISSION

Health and Food Safety Directorate General

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Standing Committee on *Veterinary Medicinal Products*
30 September 2020

CIRCABC Link: *https://circabc.europa.eu/w/browse/88c9e536-3bab-4b47-ad13-030b07b4b356*

SUMMARY REPORT

Section A Information and/or discussion

The agenda of the meeting was adopted.
No items were added by Member States under AOB.

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 the new VMP Regulation and explained the prioritisation of the work on the Implementing Acts (IA) and Delegated Acts (DA) foreseen in the new Regulation.

A.02 Information point on EU-UK readiness and preparedness as from 1 January 2021:

The Commission services presented the ongoing work on EU-UK readiness and preparedness for the end of the transition period. As of 1 January 2021, the Withdrawal Agreement together with the Ireland and Northern Ireland (IE/NI) Protocol starts applying.

The Commission services reiterated that the guidance explaining the implications of the Withdrawal Agreement including IE/NI protocol in the area of medicinal products was included in the European Commission and EMA Notice published on 13 March 2020, Parts B and C in particular.

MS asked some questions as regards the practical implications of the IE/NI protocol, in particular relating to batch release and marketing authorizations for NI territory.

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 adopting the design of a common logo for the retail of veterinary medicinal products at a distance.

The Commission services presented a draft Commission Implementing Regulation for the design of a common logo for the retail of veterinary medicinal products at a distance. The Commission services informed the MS of the outcome of the Feedback Mechanism.

A discussion followed during which Member States expressed their support for the draft act and for the proposed logo.

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 establishing the list of variations not requiring assessment.

The Commission services presented the draft Commission Implementing Regulation establishing a list of variations not requiring assessment. The Commission services informed the MSs of the outcome of the Feedback Mechanism.

A discussion followed on the Annex to the implementing act, especially on the detailed requirements on conditions and documents that should be provided. Member States expressed the need for additional discussions.

Vote postponed.

B.03 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation laying down the necessary measures and practical arrangements for the Union database on veterinary medicinal products (Union product database)

The Commission services presented the draft Commission Implementing Regulation laying down the necessary measures and practical arrangements for the Union database on veterinary medicinal products (Union product database). The Commission services informed the MSs of the outcome of the Feedback Mechanism.

A discussion followed during which Member States asked additional questions relating to the draft, mostly to clarify aspects relating to the format for electronic submission to the Union product database (UPD), the notifications the UPD should send to users, as well as to the level of detail of the data fields of the UPD.

Overall, Member States expressed their support for the draft, with one stating its reservations.

The Committee delivered its opinion through a written procedure.

Outcome of the vote by written procedure: Favourable opinion.