EUROPEAN
COMMISSION

Brussels, 28.3.2023
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COMMISSION IMPLEMENTING DECISION

of 28.3.2023

concerning, in the framework under Article 83 of Regulation (EU) 2019/6 of the European Parliament and of the Council, the marketing authorisations for veterinary medicinal products containing N-methyl pyrrolidone as an excipient

(Text with EEA relevance)

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(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to 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, and in particular Article 84(3) thereof,

Having regard to the opinion of the European Medicines Agency, formulated on 8 December 2022 by the Committee for Veterinary Medicinal Products,

Whereas:

(1) On 3 May 2022, the Federal Republic of Germany requested the European Medicines Agency to give an opinion under Article 83 of Regulation (EU) 2019/6 concerning the marketing authorisations for veterinary medicinal products containing N-methyl pyrrolidone as an excipient.

(2) The scientific assessment performed by the Committee for Veterinary Medicinal Products, the conclusions of which are set out in Annex II to this Decision, shows that, in the interests of the Union, the marketing authorisations for the veterinary medicinal products referred to in Annex IA should be maintained unchanged.

(3) The scientific assessment performed by the Committee for Veterinary Medicinal Products, the conclusions of which are set out in Annex II to this Decision, shows that, in the interests of the Union, a decision should be taken amending the marketing authorisations for the veterinary medicinal products referred to in Annexes IB, IC and ID.

(4) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Veterinary Medicinal Products,

HAS ADOPTED THIS DECISION:

Article 1

The Member States concerned shall maintain national marketing authorisations for the veterinary medicinal products referred to in Annex IA on the basis of the scientific conclusions set out in Annex II.

Article 2

The Member States concerned shall amend the national marketing authorisations for the veterinary medicinal products referred to in Annexes IB, IC and ID on the basis of the scientific conclusions set out in Annex II.

Article 3

The national marketing authorisations referred to in Article 2 shall be based on the amendments to the summary of the product characteristics, the labelling and the package leaflet set out in Annex III.

Article 4

The Member States shall take account of the scientific conclusions set out in Annex II for the assessment of the efficacy and safety of veterinary medicinal products containing N-methyl pyrrolidone as an excipient that are not included in Annex I.

Article 5

This Decision is addressed to the Member States.

Done at Brussels, 28.3.2023

For the Commission
Sandra GALLINA
Director-General

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For the Secretary-General

Martine DEPREZ
Director
Decision-making & Collegiality
EUROPEAN COMMISSION