EUROPEAN
COMMISSION

Brussels, 14.7.2016
C(2016) 4708 final

COMMISSION IMPLEMENTING DECISION

of 14.7.2016

concerning, in the framework of Article 35 of Directive 2001/82/EC of the European Parliament and of the Council, the marketing authorisations for all veterinary medicinal products containing "colistin" in combination with other antimicrobial substances to be administered orally

(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 Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for veterinary use[1], and in particular Article 38(1) thereof,

Having regard to the opinion of the European Medicines Agency, formulated on 21 April 2016 by the Committee for Medicinal Products for Veterinary Use,

Whereas:

(1) Veterinary medicinal products authorised by the Member States must meet the requirements of Directive 2001/82/EC.

(2) On 4 May 2015, the European Commission referred a question to the Committee for Medicinal Products for Veterinary use under Article 35(1) of Directive 2001/82/EC, pursuant to which, in specific cases where the interests of the Union are involved, a matter may be referred to that Committee before a decision is reached on a request for a marketing authorisation or on the suspension or withdrawal of an authorisation, or on any other variation to the terms of a marketing authorisation which appears necessary.

(3) The scientific assessment by the Committee, 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 withdrawing the marketing authorisations for the veterinary medicinal products concerned.

(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 withdraw the national marketing authorisations for the veterinary medicinal products referred to in Annex I on the basis of the scientific conclusions set out in Annex II.

[1] OJ L 311, 28.11.2001, p. 1

Article 2

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 “colistin” in combination with other antimicrobial substances to be administered orally that are not included in Annex I.

Article 3

This Decision is addressed to the Member States.

Done at Brussels, 14.7.2016

For the Commission

Xavier PRATS MONNÉ
Director-General

CERTIFIED COPY
For the Secretary-General,

Jordi AYET PUIGARNAU
Director of the Registry
EUROPEAN COMMISSION