EUROPEAN
COMMISSION

Brussels, 16.3.2015
C(2015) 1916 final

COMMISSION IMPLEMENTING DECISION

of 16.3.2015

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" 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 11 December 2014 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 12 May 2014, 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 amending 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 amend 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 national marketing authorisations referred to in Article 1 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 3

This Decision is addressed to the Member States.

Done at Brussels, 16.3.2015

For the Commission

Ladislav MIKO
Acting Director-General

CERTIFIED COPY
For the Secretary-General,

Jordi AYET PUIGARNAU
Director of the Registry
EUROPEAN COMMISSION