



Brussels, 26.6.2017  
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**COMMISSION IMPLEMENTING DECISION**

**of 26.6.2017**

**concerning, in the framework of Article 35 of Directive 2001/82/EC of the European Parliament and of the Council, the marketing authorisations for veterinary medicinal products containing “zinc oxide” to be administered orally to food producing species**

(Text with EEA relevance)

## COMMISSION IMPLEMENTING DECISION

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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<sup>1</sup>, and in particular Article 38(1) thereof,

Having regard to the opinions of the European Medicines Agency, formulated on 8 December 2016 by the Committee for Medicinal Products for Veterinary Use in accordance with Article 36 (1) of Directive 2001/82/EC and on 16 March 2017 after re-examination in accordance with Article 36 (4) of Directive 2001/82/EC,

Whereas:

- (1) Veterinary medicinal products authorised by the Member States must meet the requirements of Directive 2001/82/EC.
- (2) On 1 February 2016, the Kingdom of the Netherlands and the French Republic 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 or refusing the application for the marketing authorisations for the veterinary medicinal products concerned.
- (4) The Commission consulted the Member States and stakeholders which presented their views on the potential adverse impact stemming from the immediate withdrawal of the marketing authorisations in certain Member States. While recognising the environmental impact depended on the soil type, it is necessary to allow time to develop alternatives that are available and affordable and change pig farming practices without increasing the use of antimicrobials.
- (5) The Commission considers, therefore, that Member States should be provided with appropriate time to withdraw the marketing authorisations for the veterinary medicinal products concerned.

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<sup>1</sup> OJ L 311, 28.11.2001, p. 1

(6) 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 existing national marketing authorisations for the veterinary medicinal products referred to in Annex I.

A Member State may defer the withdrawal of the marketing authorisations for the veterinary medicinal products referred to in Annex I, if it considers that the immediate withdrawal of the marketing authorisations may have adverse impact in its territory given the lack of availability of alternatives and the change required in pig farming practices.

The period of the deferral shall not exceed five years from the date of the adoption of this Decision.

*Article 2*

The Member States shall refuse the application for the marketing authorisations for the medicinal products referred to in Annex I on the basis of the scientific conclusions set out in Annex II.

*Article 3*

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 “zinc oxide” to be administered orally to food producing species that are not included in Annex I.

*Article 4*

This Decision is addressed to the Member States.

Done at Brussels, 26.6.2017

*For the Commission*

*Xavier PRATS MONNÉ*

*Director-General*

