22 October 2015
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Veterinary Medicines Division

Questions and answers on Gutal 1000 g/kg premix for medicated feeding stuff for piglets (zinc oxide)

Outcome of a procedure under Article 33(4) of Directive 2001/82/EC, as amended

On 6 May 2015, the European Medicines Agency (the Agency) completed an arbitration procedure following a disagreement among Member States of the European Union (EU) regarding the authorisation of the veterinary medicinal product Gutal 1000 g/kg premix for medicated feeding stuff for piglets. The Agency's Committee for Medicinal Products for Veterinary Use (CVMP) concluded that the marketing authorisation for Gutal can be granted provided that the recommended risk mitigation measures, which are anticipated to reduce the accumulation of zinc in the environment, are added to the product information.

What is Gutal 1000 g/kg premix for medicated feeding stuff for piglets?

The active substance of Gutal is zinc oxide. The product is indicated for the prevention of post-weaning diarrhoea in piglets. Gutal is a generic veterinary medicinal product based on a reference product, ZincoTec Zinc Oxide 100% Premix for Medicated Feeding Stuff, which is authorised in the United Kingdom.

Why was Gutal 1000 g/kg premix for medicated feeding stuff for piglets reviewed?

Huvepharma NV submitted a marketing authorisation application for Gutal to the United Kingdom via the decentralised procedure. This is a procedure where one Member State (the 'reference Member State', in this instance the United Kingdom) assesses a veterinary medicine with a view to granting a marketing authorisation that will be valid in this country as well as in other Member States (the 'concerned Member States', in this instance Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, The Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia and Spain).

However, the Member States were not able to reach an agreement and the Veterinary Medicines Directorate of the United Kingdom referred the matter to the CVMP for arbitration on 30 September 2014.

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The grounds for the referral were concerns raised by France and The Netherlands that the marketing authorisation of Gutal may present a potential serious risk to the environment and that the risk mitigation measures proposed to control the risk are inadequate to control or prevent continuous zinc accumulation and, in addition, they are not feasible to implement in all pig farms.

What are the conclusions of the CVMP?

Based on evaluation of the currently available data and the scientific discussion within the Committee, the CVMP concluded that a risk to the environment has been identified due to accumulation of zinc, but that there is some uncertainty associated with the scale of this risk. Therefore, the Committee recommended several risk mitigation measures to be included in the product information, which are anticipated to reduce the accumulation of zinc in the environment.

Thus the CVMP concluded that the concerns expressed by France and the Netherlands should not prevent the granting of marketing authorisations and recommended marketing authorisation be granted in the concerned Member States. The CVMP also recommended that the product information for Gutal be amended.

The European Commission issued a decision on 22 October 2015.