14 July 2017
EMA/275123/2017
Veterinary Medicines Division

Questions and answers on Denagard 45% and its associated names

Outcome of a procedure under Article 34 of Directive 2001/82/EC (EMEA/V/A/114)

On 12 April 2017, the European Medicines Agency (the Agency) completed a review of Denagard 45%. The Agency's Committee for Medicinal Products for Veterinary Use (CVMP) concluded that there is a need to harmonise the product information (summary of product characteristics (SPC), labelling and package leaflet) for Denagard 45% in the European Union (EU).

What is Denagard 45%?

Denagard 45% is a veterinary medicinal product available as granules for use in drinking water and contains 450 mg tiamulin hydrogen fumarate per gram product. Tiamulin is a semi-synthetic antibiotic belonging to the pleuromutilin group of antibiotics and works by inhibiting bacterial protein synthesis. Denagard 45% is indicated for the treatment of swine dysentery, colitis, ileitis, enzootic pneumonia and pleuropneumonia in pigs; chronic respiratory disease in chickens and infectious sinusitis and airsacculitis in turkeys.

Denagard 45% (and associated names such as Tiamutin 45%, Denagard 450 mg/g and Denagard vet 450 mg/g) is marketed in Austria, Belgium, Czech Republic, Finland, Germany, Greece, Hungary, Italy, Latvia, Lithuania, the Netherlands, Poland, Portugal, Romania, Slovak Republic and Spain.

Why was Denagard 45% reviewed?

Denagard 45% is authorised in the EU via national procedures. Germany noted that there are divergences across Member States in the way the veterinary medicinal product can be used, as seen in the differences in the product information in the countries where Denagard 45% is marketed.

On 24 August 2016, Germany referred the matter to the CVMP in order to harmonise the product information for Denagard 45% (and associated names) in the EU.

What are the conclusions of the CVMP?

Based on the evaluation of the currently-available data, the CVMP concluded that the product information for Denagard 45% and its associated names should be harmonised across the EU.

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The amended product information is available on the 'All documents' tab.

The European Commission issued a decision on 14 July 2017.