5 October 2017
EMA/585749/2017
Veterinary Medicines Division

Questions and answers on Lincocin and its associated names

Outcome of a procedure under Article 34 of Directive 2001/82/EC (EMEA/V/A/123)

On 13 July 2017, the European Medicines Agency (the Agency) completed a review of Lincocin. 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 Lincocin in the European Union (EU).

What is Lincocin?

Lincocin is a veterinary medicinal product available as powder for oral solution and contains 400 mg lincomycin per gram of product. Lincomycin is a lincosamide antibiotic which is produced by *Streptomyces lincolnensis*. Lincocin is indicated for the treatment and metaphylaxis of enzootic pneumonia caused by *Mycoplasma hyopneumoniae* in pigs and treatment and metaphylaxis of necrotic enteritis caused by *Clostridium perfringens* in chickens.

Lincocin (and associated names, such as Lincocine poudre soluble and Albiotic Pulver 400 mg/g) is marketed in Belgium, Denmark, France, Germany, Hungary, Ireland, Poland and United Kingdom.

Why was Lincocin reviewed?

Lincocin is authorised in the EU via national procedures. The European Commission 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 Lincocin is marketed.

On 5 July 2016, the European Commission referred the matter to the CVMP in order to harmonise the product information for Lincocin (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 Lincocin and its associated names should be harmonised across the EU. Consequently, the CVMP recommended that variations to the terms of the marketing authorisations for the aforementioned product are required in order to amend the product information accordingly.

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

The European Commission issued a decision on 5 October 2017.