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Veterinary Medicines Division

Questions and answers on Girolan and its associated name Apralan

Outcome of a procedure under Article 34 of Directive 2001/82/EC
(EMA/V/A/122)

On 15 February 2018, the European Medicines Agency (the Agency) completed a review of Girolan and its associated name, Apralan. 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 the aforementioned product in the European Union (EU).

What is Girolan and its associated name Apralan?

Girolan is a veterinary medicinal product available as a powder for use in drinking water/milk containing apramycin sulfate as the active substance. Apramycin is a broad-spectrum aminocyclitol antibiotic produced by a strain of *Streptomyces tenebrarius*. Girolan is indicated for the treatment of bacterial enteritis caused by *Escherichia coli* in pigs; treatment of bacterial enteritis caused by *Escherichia coli* and clinical outbreaks due to *Salmonella enterica* subsp. *enterica* serovar Dublin (*Salmonella* Dublin) in pre-ruminant calves; treatment of colibacillosis caused by *Escherichia coli* in chickens and treatment and metaphylaxis of bacterial enteritis caused by *Escherichia coli* in rabbits.

Girolan (and its associated name Apralan) is marketed in Denmark, France, Germany, Ireland, Italy, The Netherlands, Portugal, Spain and the United Kingdom.

Why was Girolan and its associated name Apralan reviewed?

Girolan is authorised in the EU via national procedures. Spain 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 Girolan (and its associated name Apralan) is marketed.

On 24 June 2016, Spain referred the matter to the CVMP in order to harmonise the product information for Girolan (and its associated name Apralan) in the EU.

What are the conclusions of the CVMP?

Based on the evaluation of the currently-available data, the CVMP concluded by majority that the product information for Girolan and its associated name Apralan should be harmonised across the EU.

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

The European Commission issued a decision on 8 May 2018.