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Veterinary Medicines Division

# Questions and answers on Ronaxan and its associated names

Outcome of a referral procedure under Article 34 of Directive 2001/82/EC (EMEA/V/A/135)

On 17 June 2021, the European Medicines Agency (the Agency) completed a review of Ronaxan and its associated names. 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 medicines in the European Union (EU).

## What is Ronaxan and its associated names?

Ronaxan is a veterinary medicine available as 20 mg, 100 mg and 250 mg tablets containing doxycycline hyclate as active substance. Doxycycline is an antibiotic used to treat infections caused by bacteria in dogs and cats.

Ronaxan and its associated names is marketed in Belgium, Croatia, Czech Republic, Denmark, France, Germany, Greece, Ireland, Italy, Lithuania, Luxembourg, Malta, Norway, Portugal, Romania, Slovak Republic, Spain, Sweden, the Netherlands, United Kingdom (Northern Ireland)[1].

## Why was Ronaxan reviewed?

Ronaxan is authorised in the EU via national procedures. This has led to divergences across Member States in the way the veterinary medicine can be used, as seen in the differences in the product information in the countries where Ronaxan is marketed.

On 12 August 2019, the German veterinary medicines authority referred the matter to the CVMP in order to harmonise the product information for Ronaxan in the EU.

## What are the conclusions of the CVMP?

Based on the evaluation of the currently available data, the CVMP concluded by consensus that the product information for Ronaxan and its associated names should be harmonised across the EU.

1 For the United Kingdom, as from 1 January 2021, EU Law applies only to the territory of Northern Ireland (NI) to the extent foreseen in the Protocol on Ireland/NI.

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Consequently, the CVMP recommended that variations to the terms of the marketing authorisations for the aforementioned medicines are required in order to amend the product information accordingly.

The amended product information is available on the Agency’s website, under the 'All documents' tab.

The European Commission issued a decision on 30 August 2021.