20 May 2019
EMA/246018/2019
Veterinary Medicines Division

Questions and answers on veterinary medicinal products containing 50 mg closantel per ml (as a single active substance) presented as solutions for injection for subcutaneous use in sheep

Outcome of a referral procedure under Article 35 of Directive 2001/82/EC (EMEA/V/A/126)

On 21 February 2019, the European Medicines Agency (the Agency) completed a review of the consumer safety of the withdrawal periods (meat and offal) for sheep for veterinary medicinal products containing 50 mg closantel per ml (as a single active substance) presented as solutions for injection. The Agency's Committee for Medicinal Products for Veterinary Use (CVMP) concluded that the overall benefit-risk balance for the concerned products is positive and recommended amendments to the withdrawal periods for sheep to provide assurance for consumer safety. Withdrawal period refers to the minimum period of time from administering the last dose of veterinary medicinal product and the production of meat or other animal-derived products for food.

What is closantel?

Closantel is intended for use in cattle and sheep for the treatment and control of adult and immature flukes, nematodes and larval stages of some arthropods and is administered subcutaneously by injection or as an oral solution. In addition, cattle may also be treated topically on their skin.

Why were solutions for injection containing 50 mg closantel per ml (as a single active substance) reviewed?

The United Kingdom noted that, for veterinary medicinal products containing closantel presented as solutions for injection, there are different approved withdrawal periods for sheep across the European Union e.g. sheep meat and offal, from 28 days to 107 days.

Consequently, on 5 February 2018, the United Kingdom initiated a procedure under Article 35 of Directive 2001/82/EC for the aforementioned veterinary medicinal products. The CVMP was requested to review all available residue depletion data and recommend withdrawal periods for meat and offal derived from treated sheep.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

Which data has the CVMP reviewed?

Proprietary data and scientific references on residue depletion were provided by the marketing authorisation holders.

What are the conclusions of the CVMP?

Based on the evaluation of the currently-available data, the CVMP concluded that the overall benefit-risk balance for veterinary medicinal products containing 50 mg closantel per ml (as a single active substance) presented as solutions for injection for subcutaneous use in sheep, is positive and agreed that the withdrawal periods (meat and offal) for sheep should be harmonised and amended to provide assurance for consumer safety. The CVMP recommended that variations to the terms of the marketing authorisations for the aforementioned veterinary medicinal products are required in order to amend the product information accordingly.

The European Commission issued a decision on 20 May 2019.