28 September 2017
EMA/586006/2017
Veterinary Medicines Division

Questions and answers on Zanil and associated names, and generic products thereof

Outcome of a referral procedure under Article 35 of Directive 2001/82/EC (EMEA/V/A/124)

On 13 July 2017, the European Medicines Agency (the Agency) completed a review of the consumer safety of the withdrawal periods (meat, milk and offal) for cattle, sheep and goats for Zanil and associated names, and generic products thereof. 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 withdrawal periods for cattle, sheep and goats to provide assurance for consumer safety.

What are Zanil and associated names, and generic products thereof?

The veterinary medicinal products Zanil and associated names, and generic products thereof, are oral suspensions containing 34 mg oxyclozanide per ml. Oxyclozanide is a salicylanilide anthelmintic, used for the treatment of fasciolosis in cattle, sheep and goats and also for elimination of gravid tapeworm segments (*Moniezia* spp).

Why were Zanil and associated names, and generic products thereof reviewed?

France noted that across the European Union for Zanil and associated names, and generic products thereof, there are different approved withdrawal periods for cattle, sheep and goats, e.g. cattle meat and offal from 10 days to 28 days; cattle milk from zero hours to 108 hours; sheep meat and offal from 14 days to 28 days; sheep milk from 'do not use in sheep producing milk for human consumption' to 7 days; goat meat and offal 14 days; goat milk zero days.

Consequently, on 1 September 2016, France 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 milk, meat and offal derived from treated cattle, sheep and goats.

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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 Zanil and associated names, and generic products thereof, is positive and agreed that the withdrawal periods (meat, milk and offal) for cattle, sheep and goats should be 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 28 September 2017.