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Veterinary Medicines Division

Questions and answers on the review of withdrawal periods for Betamox LA 150 mg/ml suspension for injection and associated names, and generic products thereof

Outcome of a procedure under Article 35 of Directive 2001/82/EC (EMEA/V/A/132)

On 16 July 2020, the European Medicines Agency (the Agency) completed a review of the withdrawal periods for cattle, sheep and pigs for Betamox LA 150 mg/ml suspension for injection and associated names, and generic products thereof. The withdrawal period is the minimum time that has to elapse before an animal treated with a medicine can be slaughtered so that its meat or other animal derived products may be used for human consumption.

The Agency's Committee for Medicinal Products for Veterinary Use (CVMP) concluded that the benefits of these medicines continue to outweigh the risks but that the maximum injection volume per site and the withdrawal periods for cattle, sheep and pigs should be changed to provide assurance for consumer safety.

What are Betamox LA and its generics?

The veterinary medicines Betamox LA and associated names, and generic products thereof are suspensions for injection which contain 150 mg amoxicillin (as amoxicillin trihydrate) per ml. Amoxicillin is a broad-spectrum antibiotic of the β-lactam family belonging to the aminopenicillin group. This active substance has time-dependent bactericidal activity and acts against Gram-positive and some Gram-negative microorganisms. Betamox LA and its generics can be used in cattle, sheep and pigs by injection into the muscle.

Why were Betamox LA and its generics reviewed?

On 11 February 2019, the German veterinary medicines authority requested that the CVMP review all available data and recommend withdrawal periods for milk, meat and offal from cattle and sheep, and for meat and offal from pigs treated with Betamox LA and its generics.

The German authority considered that the withdrawal periods for these target species in the European Union (EU) might not be adequate to ensure consumer safety, noting that they differed across the EU.

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Consequently, the German authority asked the CVMP to carry out a full assessment of the benefit-risk balance of Betamox LA and its generics, and to issue an opinion on whether the marketing authorisations for the above-mentioned products should be maintained, varied, suspended or withdrawn across the EU.

Which data has the CVMP reviewed?

The CVMP reviewed available data on residue depletion in cattle, sheep and pigs for the veterinary medicines Betamox LA and its generics, which indicate how long a medicine takes to fall below maximum residue limits (MRLs) in the animal's body. These contained data from companies, including studies and published literature.

What are the conclusions of the CVMP?

Based on the evaluation of the currently available data and the scientific discussion within the Committee, the CVMP concluded that the benefits of Betamox LA and its generics, continue to outweigh the risks. The CVMP recommended that for the protection of consumer safety the following withdrawal periods are justified for intramuscular administration and in combination with a restriction of the injection volume to 15 ml per injection site for cattle and to 4 ml for sheep and pigs:

Cattle:

Meat and offal: 39 days

Milk: 108 hours (4.5 days)

Pigs:

Meat and offal: 42 days

Sheep:

Meat and offal: 29 days

Milk: Not authorised for use in sheep producing milk for human consumption

The Committee recommended the variation to the terms of the marketing authorisations for these veterinary medicines.

The full changes made to the product information are detailed in Annex III of the CVMP opinion under 'All documents'.

The European Commission issued a decision on 12 October 2020.