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Veterinary Medicines Division

Questions and answers on the review of withdrawal periods for Dinolytic 12.5 mg/ml and 5 mg/ml solutions for injection and associated names, and generic products thereof

Outcome of a procedure under Article 35 of Directive 2001/82/EC (EMEA/V/A/136)

On 18 June 2020, the European Medicines Agency (the Agency) completed a review of the withdrawal periods (meat and offal) for cattle for Dinolytic 12.5 mg/ml and 5 mg/ml solutions 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 withdrawal periods for cattle meat and offal should be changed.

What are Dinolytic and its generics?

The veterinary medicines Dinolytic 12.5 mg/ml and 5 mg/ml and associated names, and generic products thereof, are injectable solutions containing dinoprost which is a synthetic analogue of prostaglandin $F_{2\alpha}$ ($PGF_{2\alpha}$). This active substance is used in cattle for reproductive management. Veterinary medicines containing dinoprost can be used in cattle by injection into the muscle.

Why were Dinolytic and its generics reviewed?

On 3 September 2019, the French veterinary medicines authority requested that the CVMP review all available data and recommend withdrawal periods for meat and offal from cattle treated with Dinolytic and its generics.

The French authority considered that the withdrawal periods for cattle in the European Union (EU) might not be adequate to ensure consumer safety, noting that withdrawal periods differed across the EU: from 0 to 3 days for cattle meat and offal.

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Consequently, the French authority asked the CVMP to carry out a full assessment of the benefit-risk balance of Dinolytic 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on whether the marketing authorisations for the above-mentioned products should be maintained, varied, suspended or withdrawn across the EU.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 for the veterinary medicines Dinolytic and its generics, which indicate how long a medicine takes to fall below maximum residue limits (MRLs) in the animal's body. These included data from companies, from national competent authorities 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 Dinolytic and its generics, continue to outweigh the risks. The CVMP agreed that the withdrawal period for meat and offal from cattle treated with these veterinary medicines should be 2 days for the protection of consumer safety.

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 16 September 2020.