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Veterinary Medicines Division

Questions and answers on the review of withdrawal periods for Stresnil 40 mg/ml solution for injection for pigs and associated names, and generic products thereof

Outcome of a procedure under Article 35 of Directive 2001/82/EC (EMEA/V/A/138)

On 16 July 2020, the European Medicines Agency (the Agency) completed a review of the withdrawal periods (meat and offal) for pigs for Stresnil 40 mg/ml solution 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 pigs should be changed to provide assurance for consumer safety.

What are Stresnil and its generics?

The veterinary medicines Stresnil and its generics are injectable solutions containing 40 mg azaperone per ml. Azaperone is a sedative used in pigs for the treatment of aggressive behaviour, control of aggression in sows, prevention of stress, obstetric conditions, as pre-medication in local or general anaesthesia and for palliative treatment of enzootic muscular dystrophy. Veterinary medicines containing azaperone can be used in pigs by injection into the muscle.

Why were Stresnil and its generics reviewed?

On 17 September 2019, the German veterinary medicines authority requested that the CVMP review all available data and recommend withdrawal periods for meat and offal from pigs treated with Stresnil and its generics.

The German authority considered that the withdrawal periods for pigs in the European Union (EU) might not be adequate to ensure consumer safety, noting that they differed across the EU, ranging from 7 to 18 days.

Consequently, the German authority asked the CVMP to carry out a full assessment of the benefit-risk balance of Stresnil and its generics, and to issue an opinion on whether the marketing authorisations

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for the above-mentioned products should be maintained, varied, suspended or withdrawn across the EU.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 pigs for the veterinary medicines Stresnil 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 Stresnil and its generics continue to outweigh the risks. The CVMP recommended that the withdrawal period for meat and offal from pigs treated with these veterinary medicines should be 18 days, with a limit to the injection volume of 5 ml 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 12 October 2020.