18 January 2021
EMA/42905/2021
Veterinary Medicines Division

Questions and answers on the review of withdrawal periods for Valbazen 100 mg/ml Total Spectrum Wormer oral suspension and associated names, including its generic/hybrid products

Outcome of a procedure under Article 35 of Directive 2001/82/EC (EMEA/V/A/140)

On 5 November 2020, the European Medicines Agency (the Agency) completed a review of the withdrawal periods (milk, meat and offal) for cattle for Valbazen 100 mg/ml Total Spectrum Wormer oral suspension and associated names, including its generic/hybrid products. 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 should be changed to provide assurance for consumer safety.

What are Valbazen and its generic/hybrid products?

The veterinary medicines Valbazen and its generic/hybrid products are oral suspensions containing 100 mg or 200 mg albendazole per ml. Albendazole is a broad-spectrum multi-purpose antiparasitic used for the treatment of gastrointestinal infestations with roundworms, lungworms and tapeworms and adult flukes of *Fasciola hepatica*. Veterinary medicines containing albendazole are used in cattle most often as single oral use.

Why were Valbazen and its generic/hybrid products reviewed?

On 3 February 2020, the German veterinary medicines authority requested that the CVMP review all available data and recommend withdrawal periods for milk, meat and offal from cattle treated with Valbazen and its generic/hybrid products.

The German authority considered that the withdrawal periods for cattle in the European Union (EU) might not be adequate to ensure consumer safety, noting that they differed across the EU, ranging from 5 to 28 days for edible tissues and from 72 to 120 hours for milk.

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

The Committee was requested to issue an opinion on whether the marketing authorisations for the above-mentioned products should be maintained, varied, suspended or withdrawn across the European Union.

Which data has the CVMP reviewed?

The CVMP reviewed available data on residue depletion in cattle for the veterinary medicines Valbazen and its generic/hybrid products, 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 Valbazen and its generic/hybrid products continue to outweigh the risks. The CVMP recommended that for the protection of consumer safety, the withdrawal periods for milk, meat and offal from cattle treated with these veterinary medicines should be 84 hours for milk and 7 days for meat and offal.

The Committee recommended the variation to the terms of the marketing authorisation 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 18 January 2021.