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Veterinary Medicines Division

Questions and answers on the environmental impact of moxidectin-containing veterinary medicines used in cattle, sheep and horses

Outcome of a referral procedure under Article 35 of Directive 2001/82/EC (EMEA/V/A/116)

On 11 May 2017, the European Medicines Agency completed a review of oral, topical and injectable moxidectin-containing veterinary medicines used in cattle, sheep and horses. The Agency's Committee for Medicinal Products for Veterinary Use (CVMP) concluded that these medicines might have a long-term impact on the environment due to their persistent, bioaccumulative and toxic (PBT) properties. Consequently, the CVMP recommended measures to mitigate against the environmental risks, as well as warnings, to be included within the product information. In addition, a condition was placed on the marketing authorisations with the purpose of obtaining field data to determine whether, under actual conditions of use and relevant environmental conditions, the hazards due to the PBT properties of these products can be prevented.

What is moxidectin?

Moxidectin is a broad-spectrum antiparasitic medicine widely used to treat and prevent parasitic infections (such as roundworms, fluke and lice) in both food-producing and companion animals.

Why were veterinary medicines containing moxidectin reviewed?

On 22 October 2015, the German competent authority triggered a review of veterinary medicines containing moxidectin because of concerns that moxidectin may have PBT properties and could therefore pose a serious risk to the environment.

The CVMP was requested to consider whether moxidectin meets the criteria to be classified as a PBT substance and, if necessary, to provide recommendations on appropriate measures to prevent environmental exposure.

Which data has the CVMP reviewed?

The CVMP reviewed available data on PBT properties of moxidectin. These included data from companies and from the published literature.

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What are the conclusions of the CVMP?

Based on the evaluation of the currently-available data from laboratory studies, the CVMP concluded that moxidectin fulfils the criteria to be considered a PBT substance, and that its use poses a risk to the environment.

The CVMP also noted that veterinary medicines containing moxidectin are an effective and important therapeutic option for treating internal and external parasites in cattle, sheep and horses.

In order to minimise the identified environmental risks, the CVMP recommended risk mitigation measures and warnings, to be included in the product information, including a precaution that treatment should only be given when necessary and should be based on faecal counts or an evaluation risk of infestation at the animal or herd level. The CVMP also concluded that the marketing authorisation holders should investigate whether, under relevant environmental conditions of use, moxidectin is detected in the local environment. The CVMP recommended obtaining samples from relevant environmental compartments after use of the 5 mg/ml pour-on solution or 100 mg/ml injectable solution in beef cattle on pasture. The sampling will help generate further data to assess the environmental exposure of moxidectin and will be a condition for maintaining the marketing authorisations of these veterinary medicines in the EU.

The European Commission issued a decision on 25 September 2017.