29 July 2016
EMA/462829/2016
Veterinary Medicines Division

Questions and answers on veterinary medicinal products containing altrenogest to be administered orally to pigs and horses

Outcome of a referral procedure under Article 35 of Directive 2001/82/EC (EMEA/V/A/095)

On 19 May 2016, the European Medicines Agency (the Agency) completed a review of the potential serious risk to the environment from the use of veterinary medicinal products containing altrenogest and administered orally to pigs and horses. The Agency's Committee for Medicinal Products for Veterinary Use (CVMP) concluded that overall benefit-risk balance for the veterinary medicinal products containing altrenogest for pigs is positive, but recommended amendments to the product information to make the user aware that altrenogest may be hazardous for fish and other aquatic organisms.

The CVMP also concluded that the use of concerned products in mares is not considered to pose a risk to the environment, given the minimal environmental exposure associated with the use in individual animals when used as specified in the product information.

What is altrenogest?

Altrenogest is a synthetic steroidal hormone, an orally active progestogen. It is included in veterinary medicinal products currently authorised in the European Union (EU) for gilts and mares for zootechnical purposes (oestrus synchronisation). Veterinary medicinal products containing altrenogest are essential in modern pig production, as the synchronisation of oestrus in gilts is a tool facilitating strict batch farrowing, with obvious benefits for the management and hygiene in these farms and, consequently, the health of the animals.

Why were veterinary medicinal products containing altrenogest reviewed?

On 21 March 2013, Germany initiated a procedure under Article 35 of Directive 2001/82/EC for the aforementioned veterinary medicinal products. Germany expressed concerns that veterinary medicinal products containing altrenogest may present a potential serious risk to the environment as the active substance is a steroid hormone and data from publicly available literature show a high risk to aquatic organisms arising from other steroids with a similar molecular structure. The CVMP was requested to review the available data and to evaluate whether the products, when used as specified in the product

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information, can be expected to have adverse effects on the reproduction of aquatic organisms, when present in very low and environmentally relevant concentrations, as it is the case for other progestins.

Which data has the CVMP reviewed?

Proprietary data and scientific references on environmental fate studies, metabolism, ecotoxicity and exposure were provided by the marketing authorisation holders in this Article 35 referral procedure.

What are the conclusions of the CVMP?

Based on the evaluation of the currently available data and conservative calculations, the CVMP concluded that a risk for fish and other aquatic organisms associated with the zootechnical use of veterinary medicinal products containing altrenogest in gilts cannot be excluded for certain geographical areas. The CVMP further concluded that these products are essential in modern pig production and there is no alternative available at present in the EU for oestrus synchronisation of gilts and, therefore, in order to address the risk to the environment, risk mitigation measures should be included in the product information to lower the risk and to make the user aware that altrenogest may be hazardous for fish and other aquatic organisms. Consequently, the CVMP concluded that the overall benefit-risk balance for the concerned products for pigs is positive, but recommended variations to the terms of the marketing authorisations in order to amend the product information accordingly.

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

With regard to the use of veterinary medicinal products containing altrenogest in mares, the CVMP concluded that the use in these target species is not considered to pose a risk to the environment given the minimal environmental exposure associated with the use in individual animals, when used as specified in the product information.

The European Commission issued a decision on 29 July 2016.