18 August 2021
EMA/279146/2021
Veterinary Medicines Division

Questions and answers on the review of injectable veterinary medicines containing vitamin A for use in food producing species

Outcome of a referral procedure under Article 35 of Directive 2001/82/EC (EMEA/V/A/141)

On 12 May 2021, the European Medicines Agency (the Agency) completed a review of the safety of injectable veterinary medicines containing vitamin A for use in food producing species. The Agency's Committee for Medicinal Products for Veterinary Use (CVMP) concluded that regulatory measures and risk mitigation measures should be taken to assure consumer and user safety, including the amendment of withdrawal periods for milk, meat and offal for food producing species. 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.

What is vitamin A?

Vitamin A is a fat-soluble vitamin which is essential for most mammalian species.

Injectable veterinary medicines containing vitamin A (retinol and its esters) as sole active substance or in combination with other active substances are used, for example, for the treatment and prevention of vitamin A deficiencies, decreased fertility, growth-related abnormalities such as rickets, maintenance therapy for stressful situations, diarrhoea and infectious diseases, during pregnancy and lactation as well as for stimulation of growth and productivity.

Why were injectable veterinary medicines containing vitamin A reviewed?

On 25 June 2020, the German veterinary medicines authority requested that the CVMP review all available data and recommend withdrawal periods for milk, meat and offal for food producing animals treated with injectable veterinary medicines containing vitamin A. The Committee was also requested to consider whether other risk management measures are feasible for these veterinary medicines as well as to assess the extent of user exposure due to accidental self-injection and the resulting risk, with a view to recommending appropriate user safety warnings.

The German authority considered that the withdrawal periods in the European Union (EU) might not be adequate to ensure consumer safety, noting that withdrawal periods differed across the EU: from 0 to

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60 days for meat and offal and from 0 to 5 days for milk. There were also significant inconsistencies in user safety warnings, ranging from none applied to very detailed user warnings.

Consequently, the German authority asked the CVMP to carry out an assessment of the benefit-risk balance of injectable veterinary medicines containing vitamin A for use in food producing species and to issue an opinion on whether the marketing authorisations for these medicines should be maintained, varied, suspended or withdrawn across the EU.

Which data has the CVMP reviewed?

No proprietary residue depletion data or kinetic parameters were provided by the concerned companies. The CVMP reviewed residue depletion data from published literature, data from National Competent Authorities as well as proposals for risk mitigation measures provided by the concerned marketing authorisation holders.

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 withdrawal periods for milk, meat and offal for food producing animals should be amended and certain warnings should be included in the product information [summary of product characteristics (SPC), labelling and package leaflet]. The Committee recommended regulatory and risk mitigation measures in order to provide assurance for consumer and user safety.

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 August 2021.