20 June 2017
EMA/398380/2017
Veterinary Medicines Division

Questions and answers on veterinary medicinal products containing methylprednisolone hydrogen succinate presented as solutions for injection for use in the target species cattle

Outcome of a referral procedure under Article 35 of Directive 2001/82/EC (EMEA/V/A/119)

On 16 March 2017, the European Medicines Agency (the Agency) completed a review of the consumer safety of the withdrawal periods for cattle (meat and offal) for veterinary medicinal products containing methylprednisolone hydrogen succinate presented as solutions for injection. The Agency's Committee for Medicinal Products for Veterinary Use (CVMP) concluded that, in the absence of appropriate residue depletion data, a withdrawal period for meat and offal derived from treated cattle cannot be set. The CVMP recommended the refusal of the granting of a marketing authorisation for the target species cattle and variation of the existing marketing authorisations in order to remove any reference to the target species cattle for veterinary medicinal products containing methylprednisolone hydrogen succinate.

What is methylprednisolone hydrogen succinate?

Methylprednisolone hydrogen succinate is an ester of the synthetic glucocorticoid methylprednisolone. Veterinary medicinal products containing methylprednisolone hydrogen succinate are used for treatment of inflammatory or allergic conditions and also for treatment and prevention of shock conditions.

Why were veterinary medicinal products containing methylprednisolone hydrogen succinate reviewed?

Germany considered that the withdrawal period of 6 days for cattle (meat and offal) treated with methylprednisolone hydrogen succinate-containing products might not be sufficient to ensure consumer safety.

On 2 May 2016, Germany initiated a referral procedure under Article 35 of Directive 2001/82/EC for the aforementioned products. The CVMP was requested to review all available residue depletion data and to recommend withdrawal periods for meat and offal derived from treated cattle.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5545
Send a question via our website www.ema.europa.eu/contact

Which data has the CVMP reviewed?

In the absence of product-specific residue depletion data or any other information concerning residues of veterinary medicinal products containing methylprednisolone hydrogen succinate, the CVMP considered the available residue depletion data used for the establishment of maximum residue limits for methylprednisolone (EMEA/MRL/798/01)[1].

What are the conclusions of the CVMP?

Based on the evaluation of the currently-available data, the CVMP concluded that the benefit-risk balance for veterinary medicinal products containing methylprednisolone hydrogen succinate presented as solutions for injection is not favourable in the absence of adequate residue depletion data to justify a withdrawal period of 6 days for cattle (meat and offal). The CVMP recommended the refusal of the granting of a marketing authorisation for the target species cattle and variation of the existing marketing authorisations in order to remove any reference to the target species cattle for veterinary medicinal products containing methylprednisolone hydrogen succinate presented as solutions for injection.

The European Commission issued a decision on 20 June 2017.

[1] CVMP EPMAR for methylprednisolone (EMEA/MRL/798/01) - link