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Veterinary Medicines Division

Questions and answers on Vey Tosal 100 mg/ml+0.05 mg/ml solution for injection for horses, cattle, dogs and cats and associated names (butafosfan, cyanocobalamin)

Outcome of a procedure under Article 33(4) of Directive 2001/82/EC (EMEA/V/A/148)

On 15 February 2023, the European Medicines Agency (the Agency) completed an arbitration procedure following a disagreement amongst Member States of the European Union (EU) regarding the authorisation of the medicine Vey Tosal 100 mg/ml+0.05 mg/ml solution for injection for horses, cattle, dogs and cats and associated names (thereafter called Vey Tosal). The Agency's Committee for Veterinary Medicinal Products (CVMP) concluded that the benefits of Vey Tosal outweigh its risks, and that the marketing authorisation can be granted in Czechia and in the following Member States of the EU: Austria, Belgium, Bulgaria, Croatia, Cyprus, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden and the United Kingdom (Northern Ireland).

What is Vey Tosal?

Vey Tosal is a veterinary medicine available as solution for injection and contains 100 mg of butafosfan per ml and 0.05 mg of cyanocobalamin (vitamin B12) per ml as active substances. Vey Tosal is used in horses, cattle, dogs and cats as supportive treatment for metabolic or reproductive disorders when supplementation of phosphorus and vitamin B12 is needed. In case of metabolic disorders occurring around the time of giving birth, or in case of tetany (muscle spasm and twitching caused by deficiency of salts) or paresis (milk fever), this medicine should be administered in addition to magnesium and calcium, respectively. It may be used also to support muscle function in the presence of deficiencies of phosphorus and/or vitamin B12.

This veterinary medicine can be administered intravenously in cattle and horses and intravenously, intramuscularly and subcutaneously in dogs and cats.

Vey Tosal was developed as a 'hybrid medicine' which means that it is similar to a 'reference medicine' that is already authorised in the EU, containing the same active substances. However, the therapeutic indication and routes of administration for Vey Tosal are different compared to the reference medicine

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called Catosal. In addition, Vey Tosal contains a different excipient (ingredient of a medicine other than the active substance).

Why was Vey Tosal reviewed?

Veyx-Pharma GmbH submitted the marketing authorisation application for Vey Tosal to the Czech veterinary medicines authority via a decentralised procedure. This is a procedure where one Member State (the 'reference Member State', in this instance Czechia) assesses a medicine with a view to granting a marketing authorisation that will be valid in this country, as well as in the other Member States (the 'concerned Member States', see list above) where the company has applied for a marketing authorisation.

However, the Member States were not able to reach an agreement on the outcome of the assessment and consequently the Czech veterinary medicines agency referred the matter to the CVMP for arbitration on 25 August 2022.

The grounds for the referral were concerns raised by the German veterinary medicines authority that, in their view, the data submitted in support of the intramuscular and subcutaneous routes of administration in dogs and cats did not confirm that Vey Tosal is bioequivalent to the reference medicine Catosal. Germany therefore considered that the authorisation of Vey Tosal may present a potential serious risk to animal health.

What are the conclusions of the CVMP?

Based on evaluation of the currently available data and the scientific discussion within the Committee, the CVMP concluded that bioequivalence to the reference medicine has been shown. The Committee concluded that the difference in excipient between Vey Tosal and the reference medicine Catosal would not result in a clinically relevant effect on the amount of active substance that is released into the bloodstream after intramuscular and subcutaneous administration in dogs and cats.

The CVMP concluded that the benefits of Vey Tosal outweigh its risks and recommended that the marketing authorisation be granted in all Member States concerned.

The European Commission issued a decision on 3 April 2023.