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Veterinary Medicines Division

Questions and answers on Ketabel 100 mg/ml solution for injection and associated names (ketamine)

Outcome of a procedure under Article 33(4) of Directive 2001/82/EC (EMEA/V/A/133)

On 5 December 2019, the European Medicines Agency (the Agency) completed an arbitration procedure following a disagreement among Member States of the European Union (EU) regarding the authorisation of the medicine Ketabel 100 mg/ml solution for injection and associated names (thereafter called Ketabel). The Agency's Committee for Medicinal Products for Veterinary Use (CVMP) concluded that the benefits of Ketabel outweigh its risks, and recommended that the marketing authorisation be granted in France and in all concerned Member States: Austria, Bulgaria, Czech Republic, Germany, Estonia, Greece, Finland, Hungary, Ireland, Iceland, Lithuania, Latvia, the Netherlands, Norway, Portugal, Romania, Sweden, Slovenia, Slovakia and the United Kingdom[1].

What is Ketabel?

Ketabel is a veterinary medicine available as solution for injection and contains 100 mg ketamine as active substance per ml product. Ketabel is used in combination with a sedative for immobilisation, sedation and general anaesthesia for cattle, pigs, sheep, goats, dogs, cats, horses, guinea pigs, hamsters, rabbits, rats and mice.

Ketabel is a generic medicine which means that it was developed to contain the same active substance and work in the same way as a 'reference medicine' already authorised in the EU called Imalgene 1000.

Why was Ketabel reviewed?

Bela-Pharm GmbH & Co. KG submitted Ketabel to the French veterinary medicines authority for a decentralised procedure. This is a procedure where one Member State (the 'reference Member State', in this instance France) assesses a medicine with a view to granting a marketing authorisation that will be valid in this country as well as in other Member States (the 'concerned Member States', see list above) where the company has applied for a marketing authorisation.

[1] As of 1 February 2020, the UK is no longer an EU Member State. However, EU law still applies to the UK during the transition period.

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However, the Member States were not able to reach an agreement and the French authority referred the matter to the CVMP for arbitration on 5 July 2019.

The grounds for the referral were concerns raised by the German veterinary medicines authority that considered the proposed meat and offal withdrawal period of 1 day (limited to 20 ml of injection volume) for cattle, pigs, sheep and goats, when the product is administered by intramuscular route is not acceptable. 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 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 differences between Ketabel and Imalgene 1000 do not affect the absorption of ketamine at the injection site when the medicine is given by injection into a muscle. The Committee considered that a withdrawal period of 1 day with a limitation of the injection volume to 20 ml is sufficient to guarantee the consumer safety when Ketabel is given to cattle, pigs, sheep and goats by injection into a muscle.

The European Commission issued a decision on 4 March 2020.