7 January 2016
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Veterinary Medicines Division

Questions and answers on Solamocta 697 mg/g Powder for Use in Drinking Water for Chickens, Ducks and Turkeys (amoxicillin trihydrate)

Outcome of a procedure under Article 33(4) of Directive 2001/82/EC, as amended

On 4 November 2015, 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 veterinary medicinal product Solamocta 697 mg/g Powder for Use in Drinking Water for Chickens, Ducks and Turkeys. The Agency's Committee for Medicinal Products for Veterinary Use (CVMP) concluded that the marketing authorisation for Solamocta can be granted provided that the recommended revised instructions on product administration and prudent use warnings are added to the product information.

What is Solamocta 697 mg/g Powder for Use in Drinking Water for Chickens, Ducks and Turkeys?

Solamocta contains 800 mg amoxicillin trihydrate (equivalent to 697 mg amoxicillin) as an active substance per gram product. Amoxicillin is a bactericidal antibiotic belonging to the semisynthetic penicillin group. The product is indicated for treatment of infections in chickens, turkeys and ducks caused by bacteria susceptible to amoxicillin.

Why was Solamocta 697 mg/g Powder for Use in Drinking Water for Chickens, Ducks and Turkeys reviewed?

Eurovet Animal Health B.V. submitted a marketing authorisation application, under Article 13(3) of Directive 2001/82/EC (i.e. hybrid or mixed application), for Solamocta to the United Kingdom via the decentralised procedure referring to the reference product Amoxinsol 100% w/w Powder for Oral Solution authorised in the United Kingdom. This is a procedure where one Member State (the 'reference Member State', in this instance the United Kingdom) assesses a veterinary 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', in this instance Austria, Belgium, Czech Republic, Denmark, France, Germany, Greece, Hungary, Ireland, Italy, Luxembourg, Poland, Portugal, Slovakia, Spain and The Netherlands).

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However, the Member States were not able to reach an agreement and the Veterinary Medicines Directorate of the United Kingdom referred the matter to the CVMP for arbitration on 28 May 2015.

The grounds for the referral were concerns raised by Denmark that the marketing authorisation of Solamocta may present a potential serious risk to human and animal health. Denmark considered that Solamocta is essentially different from the reference product Amoxinsol 100% w/w Powder for Oral Solution and that these differences could be sufficient to require a formal bioequivalence study. In addition, Denmark raised a concern that the advice for prudent use in the product information is insufficient.

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 a satisfactory justification has been provided that the product, Solamocta, is eligible for a waiver from the requirement to demonstrate *in vivo* bioequivalence with the reference product in accordance with section 7.1.c) of the CVMP guideline on the conduct of bioequivalence studies for veterinary medicinal products (EMA/CVMP/016/00-Rev.2) and that the excipients will not impact the bioavailability or safety of this product compared to the reference product. The Committee recommended revised instructions on product administration and advice on prudent use to address responsible use in relation to development of antimicrobial resistance.

Thus the CVMP concluded that the concerns expressed by Denmark should not prevent the granting of marketing authorisations and recommended marketing authorisation be granted in the concerned Member States. The CVMP also recommended that the product information for Solamocta be amended.

The European Commission issued a decision on 7 January 2016.