9 November 2012
EMA/CVMP/283906/2012
Committee for Medicinal Products for Veterinary Use

Post-authorisation summary of opinion*

Naxcel

Ceftiofur

On 8 November 2012, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a negative opinion**, recommending the refusal of a variation to the terms of the marketing authorisation for the veterinary medicinal product Naxcel. The marketing authorisation holder for this veterinary medicinal product is Pfizer Limited.

The scope of the variation was a new indication for the cattle presentation: Treatment of bovine respiratory disease in cases where treatment with another antimicrobial has failed.

The grounds for the refusal of the variation relate to the following points:

- Efficacy of Naxcel for the new proposed indication has not been satisfactorily confirmed by clinical trials as only one out of three clinical studies showed significant efficacy. However, concerns were raised in regard to the inclusion criteria of the animals included in this study, and the clinical relevance of the data for the proposed new indication.
- Insufficient data have been presented on the use of Naxcel in the proposed (restricted) target population of animals to be treated ("cases where treatment with another antimicrobial has failed");
- The use of Naxcel in cattle and, subsequently, exposure of ceftiofur is anticipated to increase due to the nature of the disease to be treated, resulting in increased risk of development of resistance;
- There is a trend of increase in resistance in bovine commensals against ceftiofur, recently confirmed in some countries.

The CVMP, on the basis of the safety and efficacy data submitted, considered that the benefit-risk balance for the proposed new indication for Naxcel was not demonstrated to be favourable, and therefore could not recommend the variation of the marketing authorisation.

* Summaries of opinion are published without prejudice to the Commission Decision.
** Applicants may appeal any CVMP opinion, provided they notify the European Medicines Agency in writing of their intention to appeal within 15 days of receipt of the opinion.

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