5 December 2019
EMA/CVMP/633397/2019
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (post-authorisation)

Velactis

International non-proprietary name (INN): cabergoline

On 5 December 2019, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a final negative opinion recommending the refusal of a variation to the terms of the marketing authorisation for the veterinary medicinal product Velactis. This opinion was adopted following a request by the marketing authorisation holder for re-examination of the CVMP's initial negative opinion of 12 September 2019. The marketing authorisation holder for this veterinary medicinal product is CEVA Santé Animale.

The scope of the variation applied for was to provide information on the underlying cause(s) for the serious adverse events associated with the use of Velactis, to change the current conditions of use and provide further risk management measures to allow the safe use in the target species, and, consequently, to allow the lifting of the suspension of the marketing authorisation.

The grounds for the negative opinion relate to the following points*:*

- Insufficient evidence was provided on the underlying cause(s) of the adverse events after use of Velactis in cows at drying-off;
- The proposed new conditions of use did not reduce the incidence of serious adverse events, i.e. recumbency and associated deaths;
- Proposed new risk management measures are extensive, and acceptance and implementation of, and compliance with the measures to be taken by farmers and veterinarians cannot be ensured. Without clear knowledge of the underlying causes and risk factors, it is not possible to conclude on effective risk mitigation measures;
- The overall benefit-risk balance is considered to remain negative.

Therefore, the CVMP has recommended the refusal of the variation to the terms of the marketing authorisation for Velactis.

[1] Summaries of opinion are published without prejudice to the Commission Decision.

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