8 February 2013
EMA/CVMP/35976/2013
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (post-authorisation)

Equilis Prequenza Te

International non-proprietary name (INN): Vaccine against equine influenza and tetanus in horses

On 7 February 2013, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion[2], recommending the granting of an extension and variations to the terms of the marketing authorisation for the veterinary medicinal product Equilis Prequenza Te. The marketing authorisation holder for this veterinary medicinal product is Intervet International B.V.

The changes agreed by the CVMP concern 10 variations (Type IA, IB and II) which range from the replacement of the A/equine-2/Newmarket/1/93- H3N8 (= American lineage) strain with the A/equine-2/South Africa/4/03 strain, the replacement of the Newmarket/2/93 master seed virus to the omission of the 2nd inactivation control test.

Additionally an extension to change the source material used to produce the antigens from commercial eggs to MDCK-ISC cells was approved as part of this procedure.

Detailed conditions for the use of this product will be described in the updated summary of product characteristics (SPC) which will be published in the revised European public assessment report (EPAR) and will be available in all official European Union languages after the extension to the marketing authorisation has been granted by the European Commission.

[1] Summaries of opinion are published without prejudice to the Commission Decision.
[2] 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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