17 May 2013
EMA/CVMP/257822/2013
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (initial authorisation)

AFTOVAXPUR DOE

Common name: inactivated vaccine against foot-and-mouth disease

On 16 May 2013, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion[2], recommending the granting of a marketing authorisation for the veterinary medicinal product AFTOVAXPUR DOE, emulsion for injection. The product is intended for active immunisation of cattle and sheep from 2 months of age and pigs from 10 weeks of age against foot-and-mouth disease (FMD) to reduce clinical signs. The applicant for this veterinary medicinal product is MERIAL.

The active substance of AFTOVAXPUR DOE consists of a maximum of three inactivated, purified FMD virus strains (multi-strain) of the following seven strains: O1 Manisa, O1 BFS, O Taiwan 3/97, A22 Iraq, A24 Cruzeiro, A Turkey 14/98 and Asia 1 Shamir. This is an immunological veterinary medicinal product that is administered via the intramuscular or subcutaneous route to induce active immunity against FMD in the target species.

The benefits of AFTOVAXPUR DOE are the stimulation of active immunity of cattle, sheep and pigs against FMD virus strains related to those contained in the vaccine. Onset of immunity has been demonstrated 4 weeks after vaccination. Vaccination of cattle, sheep, and pigs induced the production of neutralising antibodies that persisted for at least 6 months. In cattle, the antibody levels measured were above those shown to be protective. The most common side effects are a local reaction at the injection site and a slight increase of the rectal temperature.

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

[1] Summaries of opinion are published without prejudice to the Commission Decision, which will normally be issued within 90 days from adoption of the opinion.
[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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The CVMP, on the basis of quality, safety and efficacy data submitted, considers that there is a favourable benefit to risk balance for AFTOVAXPUR DOE and therefore recommends the granting of the marketing authorisation.