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Veterinary Medicines and Product Data Management

Committee for Medicinal Products for Veterinary Use

Post authorisation summary of opinion*

Porcilis AR-T DF (EMEA/V/C/055/X/009)

On 14 July 2010, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion,** recommending approval of an extension of the marketing authorisation for the veterinary medicinal product Porcilis AR-T DF. The marketing authorisation holder for this veterinary medicinal product is Intervet International BV.

Porcilis AR-T DF was authorised initially on 16 November 2000. It has an indication for the reduction of clinical signs of progressive atrophic rhinitis in piglets by passive oral immunisation with colostrum from dams actively immunised with the vaccine.

This new extension is primarily to replace the original host with a new host, which results in a new expression system for the active substance Protein dO (a non-toxic deletion derivative of *Pasteurella multocida* dermonecrotic toxin); the plasmid encoding Protein dO remains unaltered. A slightly different declared strength of Protein dO has also been a result of this extension application. Additionally, several other minor changes have been included, such as the addition of two new larger pack sizes (100 ml and 250 ml PET vials), changes to the preparation of the finished product and changes to control tests. The main proposed change has been supported by additional stability-, safety- and efficacy studies.

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.

The CVMP, on the basis of quality, safety and efficacy data submitted, considers that there is a favourable benefit to risk balance for Porcilis AR-T DF and therefore recommends the granting of the extension of the marketing authorisation.

* Summaries of opinion are published without prejudice to the Commission Decision, which will normally be issued within 90 days from adoption of the Opinion.
** 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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