EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

14 February 2014
EMA/CVMP/60159/2014
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (initial authorisation)

Parvoduk

International non-proprietary name (INN): Live attenuated Muscovy duck parvovirus

On 13 February 2014, 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 Parvoduk, suspension and diluent for suspension for injection. The product is intended for the active immunisation of Muscovy ducks to reduce weight loss and lesions of Muscovy duck parvovirosis and Derzsy's disease and, in the absence of maternally derived antibodies, also to prevent mortality. The applicant for this veterinary medicinal product is MERIAL.

The active substance of Parvoduk is live attenuated Muscovy duck parvovirus strain GM 199. The product is a live attenuated viral vaccine, ATCvet code: QI01BD03, which is administered via the subcutaneous route.

The benefits of Parvoduk are the induction of active immunity in the target species against Muscovy duck parvovirosis and Derzsy's disease. Onset of immunity was demonstrated to be 11 days after the primary vaccination course and duration of immunity 26 days after the primary vaccination course. In ducklings free of maternally derived antibodies a single vaccination at day 1 will lead to an onset of immunity after 14 days. No adverse reactions have been reported during the studies performed as part of the application for a marketing authorisation.

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 Parvoduk and therefore recommends the granting of the marketing authorisation.

[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.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8447
E-mail info@ema.europa.eu **Website** www.ema.europa.eu