17 March 2017
EMA/CVMP/154135/2017
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (initial authorisation)

RESPIPORC FLUpan H1N1

Common name: Porcine influenza vaccine (inactivated)

On 16 March 2017, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive final opinion[2], recommending the granting of a marketing authorisation for the veterinary medicinal product RESPIPORC FLUpan H1N1 suspension for injection for pigs, intended for active immunisation of pigs against swine influenza caused by pandemic subtype H1N1v further to a re-examination of the initial opinion adopted by CVMP on 8 December 2016. The applicant for this veterinary medicinal product is IDT Biologika GmbH.

RESPIPORC FLUpan H1N1 is an inactivated vaccine containing influenza virus A/Jena/VI5258/2009(H1N1)pdm09 (ATCvet code QI09AA03) as active substance. It stimulates an active immunity against pandemic porcine influenza A/Jena/VI5258/2009 (H1N1)pandemic09-like virus. It induces neutralising and haemagglutination-inhibiting antibodies against this subtype.

The benefits of RESPIPORC FLUpan H1N1 are its active immunisation of pigs from the age of 8 weeks onwards against pandemic H1N1 porcine influenza virus to reduce viral lung load and viral excretion. The most common side effects are transient increase in rectal temperature and transient swelling up at the site of injection.

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-risk balance for RESPIPORC FLUpan H1N1 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 67 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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