



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

9 December 2016
EMA/CVMP/748641/2016
Committee for Medicinal Products for Veterinary Use

Summary of opinion¹ (initial authorisation)

RESPIPORC FLUpa H1N1

Common name: Swine influenza vaccine (inactivated)

On 8 December 2016, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a negative opinion², recommending the refusal of the granting of a marketing authorisation for the veterinary medicinal product RESPIPORC FLUpa H1N1 suspension for injection for pigs.

The applicant for this veterinary medicinal product is IDT Biologika GmbH.

The active substance of RESPIPORC FLUpa H1N1 is an inactivated influenza A virus/Jena/VI5258/2009 (H1N1)pdm09, and it is an immunological medicinal product (QI09AA03) developed for active immunisation of pigs against swine influenza caused by pandemic subtype H1N1.

The grounds for the negative opinion relate to efficacy and quality.

The CVMP, on the basis of quality, safety and efficacy data submitted, considers that the benefit-risk balance for RESPIPORC FLUpa H1N1 was not demonstrated to be favourable and therefore cannot recommend the granting of a marketing authorisation.

¹ Summaries of opinion are published without prejudice to the Commission Decision, which will normally be issued within 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.

