14 September 2018
EMA/CVMP/562184/2018
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (post-authorisation)

RESPIPORC FLUpan H1N1

Common name: porcine influenza vaccine (inactivated)

On 13 September 2018, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion[2], recommending the granting of a variation to the terms of the marketing authorisation for the veterinary medicinal product RESPIPORC FLUpan H1N1. The marketing authorisation holder for this veterinary medicinal product is IDT Biologika GmbH

RESPIPORC FLUpan H1N1 is currently authorised as suspension for injection for pigs. The variation concerns widening of the limits for a finished product specification parameter (potency upper limit) and demonstration of safety in target animals. The variation introduces changes to the Summary of Product Characteristic (SPC) and other product information.

Detailed conditions for the use of this product are described in the updated summary of product characteristics (SPC), for which an updated version reflecting the changes will be published in the revised European public assessment report (EPAR) and will be available in all official European Union languages after the variation to the marketing authorisation has been granted by the European Commission.

[1] Summaries of opinion are published without prejudice to the Commission Decision.
[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.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5545
Send a question via our website www.ema.europa.eu/contact