23 April 2019
EMA/CVMP/199498/2019
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (post-authorisation)

Suvaxyn PRRS MLV

Common name: porcine respiratory and reproductive syndrome virus, live

On 16 April 2019, 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 Suvaxyn PRRS MLV. The marketing authorisation holder (MAH) for this veterinary medicinal product is Zoetis Belgium SA.

Suvaxyn PRRS MLV is currently authorised as lyophilisate and solvent for suspension for injection. The variation concerns the reduction of the onset of immunity for fattening pigs and gilts and sows from 28 days to 21 days and the extension of the duration of immunity for gilts and sows from 16 weeks to 26 weeks.

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.

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