17 February 2023
EMA/CVMP/40684/2023
Committee for Veterinary Medicinal Products (CVMP)

Summary of opinion[1] (post-authorisation)

Suvaxyn PRRS MLV

Common name: Porcine respiratory and reproductive syndrome virus vaccine (live)

On 15 February, the Committee for Veterinary Medicinal Products (CVMP) adopted a positive opinion[2], recommending the granting of a group of variations to the terms of the marketing authorisation for the veterinary medicinal product Suvaxyn PRRS MLV. The marketing authorisation holder for this veterinary medicinal product is Zoetis Belgium.

Suvaxyn PRRS MLV is currently authorised as lyophilisate and solvent for suspension for injection. The variation concerns the addition of nasal use as an additional route of administration and modification of the approved therapeutic indication to include protection against heterologous subtype-1 AUT15-33, subtype-2 BOR57 and subtype-3 Lena strains of the PRRS virus.

Detailed conditions for the use of this product are described in the summary of product characteristics (SPC), the updated version of which, 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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