13 July 2021
EMA/324090/2021
Veterinary Medicines Division

Questions and answers on the review of modified live porcine respiratory and reproductive syndrome (PRRS) virus vaccines

Outcome of a referral procedure under Article 35 of Directive 2001/82/EC (EMEA/V/A/142)

On 15 April 2021, the European Medicines Agency (the Agency) completed a review of the safety and effectiveness of modified live porcine respiratory and reproductive syndrome (PRRS) virus vaccines. The Agency's Committee for Medicinal Products for Veterinary Use (CVMP) concluded that the benefits of modified live PRRS virus vaccines continue to outweigh the risks and that additional warnings should be included in the product information in order to continue ensuring the safe use of these vaccines.

What are modified live PRRS virus vaccines?

Modified live porcine respiratory and reproductive syndrome virus vaccines, or PRRS MLV vaccines, are widely used to reduce the clinical impact of the disease, reduce the presence of the virus in the blood of infected pigs as well as the virus transmission in vaccinated populations. The disease in gilts/sows may result in lowered farrowing (birth) rates, increase in abortions, stillborn, mummified as well as weak live born piglets and deaths, whilst the respiratory disease in suckling and weaned pigs can lead to high mortality rates. Live vaccines contain strains of live PRRS virus, which have been weakened so that they do not cause disease but shedding of the vaccine strain may occur for a variable period of time after vaccination, depending on the vaccine strain.

Modified live PRRS virus vaccines are available in all EU Member States.

Why were modified live PRRS virus vaccines reviewed?

Following a case of a genetic recombination between two PRRS MLV vaccines, the CVMP reviewed the available data on the centrally authorised veterinary medicinal product Suvaxyn PRRS MLV. On 18 June 2020, the CVMP adopted an opinion[1] which stated that the benefit-risk balance of the product remained positive and that there was no product-specific concern identified for Suvaxyn PRRS MLV that would make the product different from other authorised modified live PRRS virus vaccines in terms of potential for recombination. In addition, the Committee recommended several warnings to be included

[1] CVMP Scientific conclusions and grounds for amendment of the summary of product characteristics and package leaflet of Suvaxyn PRRS MLV – link

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in the product information of Suvaxyn PRRS MLV, but it was recognised that such warnings would also be applicable to other PRRS MLV vaccines authorised in the European Union (EU).

Consequently, on 6 July 2020, the European Commission asked the CVMP to carry out an assessment of the benefit-risk balance of modified live PRRS virus vaccines and to issue an opinion on whether the marketing authorisations for these vaccines should be maintained, varied, suspended or withdrawn across the EU.

Which data has the CVMP reviewed?

The CVMP reviewed pharmacovigilance data, studies on vaccine virus shedding and spreading, scientific literature as well as proposals for risk mitigation measures provided by the concerned marketing authorisation holders.

What are the conclusions of the CVMP?

Based on the evaluation of the currently available data and the scientific discussion within the Committee, the CVMP concluded that the benefits of modified live PRRS virus vaccines continue to outweigh the risks, and that the products continue to be considered an appropriate tool for the management of PRRSV infection/disease in Europe. The Committee recommended that certain warnings should be included in the product information in order to limit the opportunity for modified live PRRS viruses to circulate and to reduce the risk and the frequency of recombination between PRRS viruses including PRRS vaccine strains.

The full changes made to the product information are detailed in Annex III of the CVMP opinion under 'All documents'.

The European Commission issued a decision on 13 July 2021.