European Medicines Agency
Press office

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PRESS RELEASE
European Medicines Agency recommends suspension of classical swine fever vaccine Porcilis Pesti

The European Medicines Agency's Committee for Medicinal Products for Veterinary Use (CVMP) has recommended to the European Commission the temporary suspension of the marketing authorisation for Porcilis Pesti, a centrally authorised marker vaccine intended for use as part of vaccination campaigns to eradicate classical swine fever.

The recommendation to suspend the marketing authorisation for Porcilis Pesti follows the recall of the vaccine in April 2008. The marketing authorisation holder, Intervet International BV, had removed all batches of Porcilis Pesti from the market, when they detected during ongoing stability studies that some batches showed a reduced shelf-life.

As the root cause of the instability has not yet been identified and the extent of the stability problem, including its impact on the potency of the vaccine, is still unknown, the CVMP is now recommending suspension of the marketing authorisation. The committee considers that this suspension should be lifted once the marketing authorisation holder is able to provide sufficient data to substantiate an appropriate shelf life for the product and adequate information in relation to the underlying cause.

The CVMP's recommendation was forwarded to the European Commission who will now issue a formal decision.

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Notes:

1. A press release was issued at the time of the recall of Porcilis Pesti: http://www.emea.europa.eu/vetdocs/PDFs/EPAR/Porcilispesti/23772808en.pdf
2. More information about Porcilis Pesti is available in the European Public Assessment Report (EPAR): http://www.emea.europa.eu/vetdocs/vets/Epar/porcilispesti/porcilispesti.htm
3. The suspension of a marketing authorisation is a precautionary measure, during which time a medicinal product is unavailable. The lifting of the suspension is conditional on the marketing authorisation holder resolving the issues identified by the Agency and the subsequent decision of the European Commission. The CVMP can only issue a formal opinion on a suspension following a formal request from the Commission.
4. This press release, together with other information on the work of the EMEA, can be found on the EMEA website: www.emea.europa.eu

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