Suvaxyn PRRS MLV

Procedural steps taken and scientific information after the authorisation

Application number	Scope	Opinion/ Notification[1] issued on	Commission Decision Issued / amended on	Product Information affected[2]	Summary[3]
A45/0005		20/05/2020	18/08/2020	SPC and PL	Pursuant to Article 45 of Regulation (EC) No. 726/2004, the European Commission requested on 7 November 2019 the opinion of the European Medicines Agency further to the suspension of use of Suvaxyn PRRS MLV in Denmark based on the precautionary principle following findings of recombinant virus involving the product. The CVMP was requested to consider the concerns related to animal health and to give its recommendation whether the marketing authorisation of this product should be maintained, varied, suspended or withdrawn.
II/0004/G	This was an application for a group of variations. C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification	16/04/2019	18/06/2019	SPC and PL	The European Commission amended the decision granting the marketing authorisation to reduce the onset of immunity for fattening pigs and gilts and sows from 28 days to 21 days and to extend the duration of immunity for gilts and sows from 16 weeks to 26 weeks. Additionally, the variation concerns the following changes to the product information: change of the wording 'seronegative sows' to 'PRRS virus-naïve gilts and sows', change of the wording 'seropositive sows' to 'non-PRRS virus-naïve gilts and sows (i.e. either previously immunised against PRRS virus via

[1] Notifications are issued for type I variations (unless part of a group including a type II variation or higher procedure or a worksharing application). Opinions are issued for all other procedures.
[2] SPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).
[3] Since October 2019 summary information is no longer published for variations that do not impact upon the product information

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	of an approved one C.I.6.z - Change(s) to therapeutic indication(s) - Other variation				vaccination or exposed to PRRS virus via field infection)' and deletion of the wording 'The use is not recommended during lactation'.
IB/0003	B.II.f.1.b.5 - Stability of FP - Extension of the shelf life of the finished product - Biological/immunological medicinal product in accordance with an approved stability protocol	10/08/2018	11/04/2019	SPC	The Agency accepted the variation to extend the shelf-life of the finished product from 18 months to 2 years.
IG/0951	C.I.9.b - Changes to an existing pharmacovigilance system as described in the DDPS - Change(s) in the safety database and/or major contractual arrangements for the fulfilment of PhV obligations, and/or change of the site undergoing PhV activities	05/07/2018	n/a		The Agency accepted the variation to update the current detailed description of the pharmacovigilance system (DDPS).
IB/0001/G	This was an application for a group of variations. B.I.d.1.a.4 - Stability of AS - Change in the re-test period/storage period - Extension or introduction of a re-test period/storage period supported by real time data B.II.f.1.b.5 - Stability of FP - Extension of the shelf life of the finished product - Biological/immunological medicinal product in accordance with an approved stability protocol	26/04/2018	11/04/2019	SPC, Labelling and PL	The Agency accepted the group of variations to extend the shelf-life of an active substance and to extend the shelf-life of the finished product from 12 to 18 months. In addition, local representatives were deleted from the package leaflet.