ERYSENG PARVO

Procedural steps taken and scientific information after the authorisation

Application number	Scope	Opinion / Notification [1] issued on	Commission Decision Issued [2] / amended on	Product Information affected [3]	Summary
R/0006	Renewal of the marketing authorisation.	21/02/2019	26/04/2019	SPC, Labelling and PL	The European Commission renewed the marketing authorisation for ERYSENG PARVO.
IG/1023/G	This was an application for a group of variations. C.I.9.a - Changes to an existing pharmacovigilance system as described in the DDPS - Change in the QPPV and/or QPPV contact details and/or back-up procedure 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	13/02/2019	n/a		The Agency accepted the group of variations to change the QPPV and update the existing pharmacovigilance system (DDPS).
IG/0793	A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient	22/06/2017	02/07/2018	Annex II	The Agency accepted the variation to change the address of the manufacturer of the biological active substance.
IG/0623	C.II.6.a - Changes to the labelling or the PL which are not connected with the SPC - Administrative	11/02/2016	17/02/2017	PL	The Agency accepted the variation to update the list of local

[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] A CD is issued for procedures that affect the terms of the marketing authorisation (e.g. SPC, Annex II, Labelling, PL). The CD is issued within 2 months of the opinion for variations falling under the scope of Article 23.1a(a) of Regulation (EU) No. 712/2012, or within 1 year for other procedures.
[3] SPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).

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	information concerning the holder's representative				representatives in the package leaflet.
IB/0002	B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)	28/07/2015	n/a		The Agency accepted the variation for a change in test procedure for the finished product.
IG/0565	C.II.6.a - Changes to the labelling or the PL which are not connected with the SPC - Administrative information concerning the holder's representative	24/07/2015	22/01/2016	PL	The Agency accepted the variation for a change in the list of local representatives.
WS/0618	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	15/01/2015	22/01/2016	SPC, Labelling and PL	The Agency accepted the worksharing procedure for a new claim of association between the two vaccines ERYSENG PARVO and UNISTRAIN PRRS, by mixing them prior to use for administration at one site.