Porcilis PCV M Hyo

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]
IA/0014	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	15/06/2020		Annex II	The Agency accepted the variation to change the name of the manufacturing site for the active substance.
WS/1717	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	20/02/2020		SPC and PL	The Agency accepted the variation to modify the product information to include associated use combinations for Porcilis PCV M Hyo, Porcilis Lawsonia and Porcilis PRRS.
R/0012	Renewal of the marketing authorisation.	18/07/2019	13/09/2019	SPC, Labelling and PL	The European Commission renewed the marketing authorisation for Porcilis PCV M Hyo.
II/0011/G	This was an application for a group of variations. B.I.a.1.e - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The change relates to a biological AS or a starting material [-] used in the manufacture of a biological/immunological product	22/05/2019	13/09/2019	Annex II	The Agency accepted the group of variations to add a manufacturing site for the M. hyopneumoniae antigen and other changes in the manufacturing process.

[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

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

	B.I.a.2.c - Changes in the manufacturing process of the AS - The change refers to a [-] substance in the manufacture of a biological/immunological substance which may have a significant impact on the medicinal product and is not related to a protocol				
WS/1467	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	16/04/2019	13/09/2019	SPC and PL	The Agency accepted the variation to change the product information to include an associated non-mixed use of Porcilis PCV M Hyo and Porcilis PRRS to allow concurrent administration of both vaccines.
II/0008/G	This was an application for a group of variations. B.I.a.1.e - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The change relates to a biological AS or a starting material [-] used in the manufacture of a biological/immunological product B.I.a.3.e - Change in batch size (including batch size ranges) of AS or intermediate - The scale for a biological/immunological AS is increased/decreased without process change (e.g. duplication of line) B.II.b.1.c - Replacement or addition of a manufacturing site for the FP - Site where any manufacturing operation(s) take place, except batch release/control, and secondary packaging, for biol/immunol medicinal products or pharmaceutical forms manufactured by complex manufacturing processes	13/09/2018	n/a		The Agency accepted the group of variations to add a site responsible for the production of the M. hyopneumoniae antigen and for filling and blending of the finished product, and to increase the M. hyopneumoniae batch size from 2000L to 3000L.
IG/0967/G	This was an application for a group of variations. 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 C.I.9.c - Changes to an existing pharmacovigilance system as described in the DDPS - Other change(s) to the DDPS that does not impact on the operation of the PhV system	26/07/2018	n/a		n/a
II/0007	C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one	25/05/2018	27/06/2018	SPC, Labelling and PL	The European Commission amended the decision granting the marketing authorisation to modify the approved therapeutic indication to include an additional posology. Additionally, the applicant took the opportunity to make some editorial changes in the dossier Part 3 and 4 and align the product information with the latest QRD template.
II/0006/G	This was an application for a group of variations. B.I.a.1.e - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The	05/10/2017	20/02/2018	Annex II	The Agency accepted the variation to introduce two additional manufacturing sites and additional changes to the manufacturing and quality control of Porcilis PCV M Hyo. Furthermore, some editorial changes in Part 2 of the dossier

	change relates to a biological AS or a starting material [-] used in the manufacture of a biological/immunological product B.I.a.1.e - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The change relates to a biological AS or a starting material [-] used in the manufacture of a biological/immunological product B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation B.I.b.2.d - Change in test procedure for AS or starting material/reagent/intermediate - Substantial change to or replacement of a biological/immunological/immunochemical test method or a method using a biological reagent for a biological AS B.I.b.2.e - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure (including replacement or addition) for the AS or a starting material/intermediate				were accepted.
IB/0005	C.I.4.z - Change(s) in the SPC, Labelling or package leaflet further to a veterinary PSUR	17/02/2017	20/02/2018	SPC and PL	The Agency accepted the variation to amend the product information to implement the outcome of a PSUR assessment.
IG/0718/G	This was an application for a group of variations. 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 C.I.9.c - Changes to an existing pharmacovigilance system as described in the DDPS - Other change(s) to the DDPS that does not impact on the operation of the PhV system	22/09/2016	n/a		n/a
II/0003	B.I.a.1.e - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The change relates to a biological AS or a starting material [-] used in the manufacture of a biological/immunological product	10/12/2015	14/12/2016	Annex II	The Agency accepted the variation to introduce an additional manufacturer of the M. hyopneumoniae antigen.
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)	17/04/2015	n/a		The Agency accepted the variation to replace the reference vaccine for the M. hyopneumoniae potency testing.
IB/0001	B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)	17/04/2015	n/a		The Agency accepted the variation to replace the current reference vaccine for the M. hyopneumoniae potency testing.