Porcilis PCV

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]
II/0014/G	This was an application for a group of variations. B.II.d.2.c - Change in test procedure for the finished product - Substantial change to or replacement of a biol/immunol/immunochemical test method or a method using a biol. reagent or replacement of a biol. reference preparation not covered by an approved protocol 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	15/07/2021		SPC, Labelling and PL	The Agency accepted the group of variations to replace the in-process control test and the finished product potency test of the active substance of Porcilis PCV.
IA/0013	B.II.d.1.d - Change in the specification parameters and/or limits of the finished product - Deletion of a non-significant specification parameter	09/12/2020	n/a		n/a
IG/0967/G	This was an application for a group of variations. C.I.9.b - Changes to an existing pharmacovigilance	26/07/2018	n/a		n/a

[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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	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				
II/0011/G	This was an application for a group of variations. B.II.d.1.d - Change in the specification parameters and/or limits of the finished product - Deletion of a non-significant specification parameter 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 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 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 B.II.d.1.d - Change in the specification parameters and/or limits of the finished product - Deletion of a non-significant specification parameter B.I.a.4.d - Change to in-process tests or limits applied during the manufacture of the AS - Widening of the approved in-process test limits, which may have a significant effect on the overall quality of the AS	15/06/2017	n/a		The Agency approved the grouped variation to update the manufacturing and the quality control of the active substance of Porcilis PCV.
IB/0010	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
IG/0465	C.I.9.a - Changes to an existing pharmacovigilance	20/08/2014	n/a		The Agency accepted the variation to change the qualified

	system as described in the DDPS - Change in the QPPV and/or QPPV contact details and/or back-up procedure				person for pharmacovigilance (QPPV).
R/0007	Renewal of the marketing authorisation.	10/10/2013	13/12/2013	SPC, Annex II, Labelling and PL	The European Commission renewed the marketing authorisation for Porcilis PCV.
II/0005	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	13/12/2012	13/12/2013	Annex II	The Agency accepted the variation to add a manufacturing site for the production of the active substance.
IA/0006	A.4 - Administrative change - Change in the name and/or address of a manufacturer or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS	04/12/2012	13/12/2013	Annex II	The Agency accepted the variation to change the name of the manufacturer of the active substance.
IB/0003	B.II.f.1.b.5 - Stability of FP - Extension of the shelf life of the finished product - Extension of storage period of a biological/immunological medicinal product in accordance with an approved stability protocol	21/02/2012	11/09/2012	SPC	The Agency accepted the variation to extend the shelf life of the finished product from 2 years to 3 years.
IG/0128	A.5.b - Administrative change - Change in the name and/or address of a manufacturer of the finished product, including quality control sites (excluding manufacturer for batch release)	06/01/2012	n/a		The Agency accepted a group of type IA variations to change the name and address of a manufacturer of the finished product.
IAIN/0002/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 C.I.9.h - 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 pharmacovigilance system	23/03/2010	23/03/2010		The Agency accepted a grouping of type IAIN variations to update the DDPS and QPPV.
II/0001	II - Other quality changes	09/12/2009	12/01/2010	SPC and PL	The European Commission amended the decision granting the marketing authorisation to add a single shot administration to pigs from 3 weeks onwards and to extend the indications to include reduction of mortality.