Porcilis PCV M Hyo

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
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 takes the opportunity to make some editorial changes in the dossier Part 3 and 4 and align 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 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	05/10/2017		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 were accepted.

[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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	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				
IB/0005	C.I.4.z - Change(s) in the SPC, Labelling or package leaflet further to a veterinary PSUR	17/02/2017		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		The Agency accepted the group of variations to update the Detailed Description of the Pharmacovigilance System (DDPS).
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.