

Suvaxyn PCV

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/0028	Renewal of the marketing authorisation.	21/03/2019	29/05/2019	SPC, Annex II, Labelling and PL	The European Commission renewed the marketing authorisation for Suvaxyn PCV.
IG/0976	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	26/10/2018	29/05/2019	PL	The Agency accepted the variation to delete the list of local representatives from the product information.
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).
II/0025	B.II.d.1.e - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range	18/01/2018	n/a		The Agency accepted the variation to revise the pH limits on the finished product.
IG/0851	A.5.b - Administrative change - Change in the name and/or address of a manufacturer/importer of the finished product, including quality control sites (excluding manufacturer for batch release)	15/11/2017	n/a		The Agency accepted the variation to change the name of the secondary packaging site.
IG/0747	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	23/03/2017	22/03/2018	SPC, Labelling and PL	The Agency accepted the variation to update the list of local representatives in the product information.

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).

IG/0543/G	This was an application for a group of variations. A.5.b - Administrative change - Change in the name and/or address of a manufacturer/importer of the finished product, including quality control sites (excluding manufacturer for batch release) 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	26/06/2015	03/05/2016	Annex II and PL	The Agency accepted the group of variations to change the name of a manufacturing site.
IB/0020/G	This was an application for a group of variations. 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 B.II.b.5.a - Change to in-process tests or limits applied during the manufacture of the finished product - Tightening of in-process limits	24/04/2015	03/05/2016	SPC	The Agency accepted the variation to increase the shelf-life of the finished product as well as to make changes to the in-process limits applied during the manufacture of the finished product.
IG/0544	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	24/04/2015	03/05/2016	PL	The Agency accepted the variation to update the list of local representatives.
WS/0649/G	This was an application for a group of variations following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.I.b.2.z - Change in test procedure for AS or starting material/reagent/intermediate - Other variation B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation	10/04/2015	n/a		The Agency accepted the variation to change the site for testing of starting materials of biological origin and consequential change in test procedure.
IG/0538	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	01/04/2015	n/a		The Agency accepted the variation to change the QPPV.
II/0017/G	This was an application for a group of variations. B.I.a.1.j - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Replacement or addition of a site where batch control/testing takes place and any of the test method at the site is a biol/immunol method 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	12/02/2015	n/a		The Agency accepted the variation to reduce the serum concentration in the virus production re-feed media and to change the site of the SLCD adjuvant sterility testing including minor changes to provide additional detail to the text of the current Part II in several places, and to change from the use of water for injections to purified water in the composition of the trypsin solution.
R/0016	Renewal of the marketing authorisation.	10/04/2014	06/06/2014		The European Commission renewed the marketing authorisation for the product.

A45/0010		10/10/2013	18/12/2013		The European Commission requested on 15 May 2013, in the interests of animal health, the opinion of the CVMP on the measures necessary to ensure the quality of Suvaxyn PCV.
IB/0014	B.II.b.4.f - Change in the batch size (including batch size ranges) of the finished product - The scale for a biological/immunological medicinal product is increased/decreased without process change (e.g. duplication of line)	28/10/2013	n/a		The Agency accepted the variation to change the EU batch size from 2,600 l to 3,000 l.
IG/0359	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	25/10/2013	n/a		The Agency accepted the variation to add a manufacturing site for secondary packaging of the finished product.
II/0011/G	This was an application for a group of variations. C.I.3.a - Implementation of change(s) requested following the assessment of an USR, class labelling, a PSUR, RMP, FUM/SO, data submitted under A 45/46, or amendments to reflect a Core SPC - Changes with NO new additional data are submitted by the MAH B.I.a.2.b - Changes in the manufacturing process of the AS - Substantial change to the manufacturing process of the AS which may have a significant impact on the quality, safety or efficacy of the medicinal product	10/10/2013	18/12/2013	SPC, Annex II and PL	The Agency accepted the variation to update the description of the manufacturing process of the active substance and to amend the SPC (section 4.6) to take into account the rapporteur's comments made during the assessment of the Art 45 procedure applicant's responses.
IAIN/0012/G	This was an application for a group of variations. 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 A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer responsible for batch release A.5.b - Administrative change - Change in the name and/or address of a manufacturer/importer of the finished product, including quality control sites (excluding manufacturer for batch release) A.5.b - Administrative change - Change in the name and/or address of a manufacturer/importer of the finished product, including quality control sites (excluding manufacturer for batch release)	05/09/2013	06/06/2014	SPC, Annex II, Labelling and PL	The Agency accepted the group of variations to change the name and address of the active substance manufacturer from 'Pfizer Animal Health' to 'Zoetis WHC 2 LLC'; to change the name of the finished product manufacturers from 'Fort Dodge Animal Health' to 'Zoetis WHC 2 LLC', and from 'Fort Dodge Veterinaria SA' to 'Zoetis Manufacturing & Research Spain SL', and finally to change the name of the batch release site from 'Pfizer Olot SLU' to 'Zoetis Manufacturing & Research Spain SL'.
IG/0328	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	05/09/2013	n/a		The Agency accepted the variation to update the contact details of the QPPV.
T/0009	Transfer of Marketing Authorisation	26/04/2013	16/05/2013	SPC, Labelling and PL	The European Commission transferred the marketing authorisation from 'Pfizer Ltd' to 'Zoetis Belgium SA'.
IA/0006	A.5.a - Administrative change - Change in the name and/or address of a manufacturer responsible for batch release	20/07/2012	29/10/2012	Annex II and PL	The Agency accepted the variation to change the name of the batch release site from Fort Dodge Veterinaria S.A.

					(Spain) to Pfizer Olot S.L.U.
Z/0007		12/07/2012	10/10/2012		The European Commission adopted a decision lifting the suspension of the marketing authorisation following the approval of a type II variation.
II/0005/G	This was an application for a group of variations. 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 medicinal product and is not related to a protocol B.I.a.4.f - Change to in-process tests or limits applied during the manufacture of the AS - Addition or replacement of an in-process test as a result of a safety or quality issue B.II.b.5.f - Change to in-process tests or limits applied during the manufacture of the finished product - Addition or replacement of an in-process test as a result of a safety or quality issue 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.III.1.b.2 - Submission of a new or updated Ph. Eur. TSE Certificate of suitability - New certificate for a starting material/reagent/intermediate/or excipient from a new or an already approved manufacturer	12/07/2012	n/a		The Agency accepted the group of variations to modify the manufacturing process, to modify the in-process inactivation test, to modify the finished product second inactivation test, to increase the batch size and to add suppliers for source materials.
T/0004	Transfer of Marketing Authorisation	11/03/2011	23/05/2011	SPC, Annex II, Labelling and PL	The European Commission transferred the marketing authorisation from 'Fort Dodge Animal Health Ltd' to 'Pfizer Ltd'.
ART45/0003		14/07/2010	27/09/2010		The European Commission suspended the marketing authorisation for Suvaxyn PCV. The matter was notified to the Committee by the European Commission under Article 45 of Regulation (EC) No. 726/2004 due to concerns relating to a suspected potential for incomplete inactivation of the vaccine strain.
IA/0002	A.7 - Administrative change - Deletion of manufacturing sites	28/04/2010	28/04/2010		The Agency accepted the variation to remove one the manufacturers for the antigen.
II/0001	II - Other quality changes	10/02/2010	03/03/2010		The European Commission amended the decision granting the marketing authorisation to replace the current approved membrane filtration sterility test (Ph. Eur. 2.6.1) by a direct inoculation sterility test (Ph. Eur. 2.6.1) and to correct minor discrepancies detected in the description of the manufacturing process in Part II.