Zulvac 8 Ovis

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]
IB/0025	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	03/02/2021		SPC, Labelling and PL	The Agency accepted the variation to correct translation errors in the product information in several languages following a quality defect. The MAH also took the opportunity to align the product information with the latest QRD template, correct typographical errors in the address of the manufacturer of the biological active substance and the manufacturer responsible for batch-release, delete the local representatives, revise the package leaflet and replace the word "Saponin" with "Quil A".
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).
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.
WS/1097	This was an application for a variation following a	13/07/2017	n/a		The Agency accepted a variation to amend the conduct of

[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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	worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)				the batch potency test for the Zulvac BTV range of vaccines.
WS/1039	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.I.a.1.d - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - New manufacturer of material for which an assessment is required of viral safety and/or TSE risk	12/04/2017	n/a		The Agency accepted the variation to replace the currently approved supplier of a starting material.
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	11/04/2018	SPC, Labelling and PL	The Agency accepted the variation to update the list of local representatives in the product information.
WS/1040	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. 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	19/01/2017	n/a		The Agency accepted the variation to update a 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.
R/0016	Renewal of the marketing authorisation.	11/09/2014	07/11/2014	SPC, Annex II, Labelling and PL	The European Commission renewed the marketing authorisation for Zulvac 8 Ovis.
WS/0597	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.I.a.2.z - Changes in the manufacturing process of the AS - Other variation	06/11/2014	n/a		The Agency accepted a variation to make changes to the manufacturing process.
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.
S/0009		11/04/2013	13/09/2013	SPC, Annex II, Labelling and PL	The CVMP reviewed the specific obligations and concluded that, overall, the evidence continues to support a favourable benefit-risk profile for ZULVAC 8 Ovis. Since all specific obligations stated in Annex II of the CVMP opinion dated 11 November 2009 have been fulfilled, there are no remaining grounds for the marketing authorisation to remain under exceptional circumstances.

IG/0330/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)	05/09/2013	27/06/2014	SPC, Annex II, Labelling and PL	The Agency accepted a group of variations to change the name of the manufacturer of the active substance, finished product and batch release site
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.
IG/0258	A.7 - Administrative change - Deletion of manufacturing sites	19/06/2013	27/06/2014	Annex II	The Agency accepted a variation to delete an antigen production site.
WS/0377/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.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation B.III.2.a.2 - Change of specification(s) of a former non Pharmacopoeial substance to comply with the Ph. Eur. or with a national pharmacopoeia of a Member State - Excipient/AS starting material	13/06/2013	n/a		The Agency accepted a group of variations to make changes concerning the manufacture of the active substance.
T/0011	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'.
S/0008		12/07/2012	12/07/2012		The CVMP reviewed the specific obligations and concluded that, overall, the evidence continues to support a favourable benefit/risk profile for ZULVAC 8 Ovis. Full approval will, however, remain conditional on the fulfilment of the outstanding specific obligations as outlined in Annex II E of the opinion.
WS/0230	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.II.e.4.c - Change in shape or dimensions of the container or closure (immediate packaging) - Sterile medicinal products	14/06/2012	14/06/2012		The Agency accepted a variation for a change to the dimensions of stoppers for 250 ml and 500 ml presentations.
IG/0005/G	This was an application for a group of variations.	05/08/2011	05/08/2011		The Agency accepted the group of variations to change the

	C.I.9.g - Changes to an existing pharmacovigilance system as described in the DDPS - Change of the site undertaking pharmacovigilance activities				location of the Qualified Person for Pharmacovigilance.
IG/0006/G	This was an application for a group of variations. A.5.a - Administrative change - Change in the name and/or address of a manufacturer responsible for batch release 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 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)	30/06/2011	30/06/2011	Annex II and PL	The Agency accepted a group of variations to change the name of the active substance manufacturer, the name of the batch release site and the name of the finished product manufacturer.
S/0003		04/05/2011	04/05/2011		The CVMP reviewed the specific obligations and concluded that, overall, the evidence continues to support a favourable benefit/risk profile for ZULVAC 8 Ovis. Full approval will, however, remain conditional on the fulfilment of the outstanding specific obligations as outlined in Annex II E of the opinion.
II/0001	C.I.4 - Variations related to significant modifications of the SPC due in particular to new quality, pre-clinical, clinical or pharmacovigilance data	08/12/2010	21/01/2011	SPC, Annex II, Labelling and PL	The European Commission approved a type II variation to revise section 4.2 of the SPC in order to provide precise information on duration of immunity. The proposed changes on section 4.9 and the revaccination schedule were not agreed.
WS/0001	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. C.I.8.b - Introduction of a new Pharmacovigilance system - which has been assessed by the relevant NCA/EMA for another product of the same MAH	13/10/2010	13/10/2010		The European Medicines Agency accepted a type IB worksharing variation for the provision of a new pharmacovigilance system following the transfer of the marketing authorisation from "Fort Dodge Animal Health" to "Pfizer Ltd".
T/0002	Transfer of Marketing Authorisation	02/07/2010	18/08/2010	SPC, Labelling and PL	The European Commission transferred the marketing authorisation from 'Fort Dodge Animal Health Ltd' to 'Pfizer Ltd'.