ZULVAC 1 Ovis

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
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		SPC, Labelling and PL	The Agency accepted the variation to update the list of local representatives.
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.
R/0011	Renewal of the marketing authorisation.	18/02/2016	18/04/2016	SPC, Annex II, Labelling and PL	The European Commission renewed the marketing authorisation for ZULVAC 1 Ovis.
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.
WS/0597	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008.	06/11/2014	n/a		The Agency accepted a variation to make changes to 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] 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.a.2.z - Changes in the manufacturing process of the AS - Other variation				
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 a variation to add a manufacturing site for secondary packaging of the finished product.
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	09/09/2014	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 a variation to update the contact details of the QPPV.
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/0005	Transfer of Marketing Authorisation	26/04/2013	16/05/2013	SPC, Labelling and PL	The European Commission amended the decision granting the marketing authorisation to transfer the marketing authorisation from 'Pfizer Ltd' to 'Zoetis Belgium SA'.
S/0003		13/12/2012	20/02/2013		The CVMP, having reviewed the evidence of compliance with the specific obligations submitted by the marketing authorisation holder and having re-assessed the benefit-risk profile of the veterinary medicinal product recommended the updating of the Community marketing authorisation for the veterinary medicinal product. Since all specific obligations stated in Annex II of the CVMP opinion dated 9 June 2011 have been fulfilled, there are no remaining grounds for the marketing authorisation to remain under exceptional circumstances.
WS/0230	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008.	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.

	B.II.e.4.c - Change in shape or dimensions of the container or closure (immediate packaging) - Sterile medicinal products				
WS/0005 (V)	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	10/11/2011	n/a		The European Medicines Agency accepted a variation for a change to the 20ml vial dimensions.