Poulvac E. coli

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/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		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).
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.
R/0012	Renewal of the marketing authorisation.	16/03/2017	15/05/2017	SPC, Annex II, Labelling and PL	The European Commission renewed the marketing authorisation for Poulvac E. coli.
X/0008	Annex I_3. Other changes specific to veterinary medicinal products to be administered to food-producing animals: change or addition of target species	18/02/2016	12/04/2016	SPC, Labelling and PL	The European Commission amended the decision granting the marketing authorisation to add a new food producing target species (turkeys).
II/0006	C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance	04/06/2015	28/07/2015	SPC, Labelling	The European Commission amended the decision granting the marketing authorisation to include drinking water as an

[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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	data			and PL	additional route of administration.
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	12/04/2016	Annex II and PL	The Agency accepted the group of variations to change the name of a manufacturing site.
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	28/07/2015	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.
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.
IAIN/0003/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	28/07/2014	SPC, Annex II, Labelling and PL	The Agency accepted the group of variations to change the name of the manufacturer of the active substance and to change the name of the finished product manufacturer 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.
IB/0002/G	This was an application for a group of variations.	12/07/2013	28/07/2014	SPC	The Agency accepted the variation to extend the current shelf life from 18 months at +2°C to +8°C to 30 months at +2°C to +8°C plus a consequential Type IAIN variation to

	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 B.II.d.1.b - Change in the specification parameters and/or limits of the finished product - Tightening of specification limits for medicinal products subject to Official Batch Release				increase the minimum release titre to maintain the end-of-shelf life specifications
T/0001	Transfer of Marketing Authorisation	26/04/2013	22/05/2013	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'.