Naxcel

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).
WS/1241	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.I.z - Quality change - Active substance - Other variation	15/03/2018	n/a		The Agency accepted the variation to implement changes in the Active Substance Master File for an intermediate.
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.
IA/0033/G	This was an application for a group of variations.	11/08/2017	n/a		The Agency accepted the grouped variation to delete four

[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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	A.7 - Administrative change - Deletion of manufacturing sites A.7 - Administrative change - Deletion of manufacturing sites A.7 - Administrative change - Deletion of manufacturing sites A.7 - Administrative change - Deletion of manufacturing sites				manufacturing sites of the active substance intermediates.
IAIN/0032	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	07/04/2017	n/a		The Agency accepted the variation to add an additional alternative secondary packaging site for Naxcel 100 mg/ml and 200 mg/ml suspension for injection.
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	26/04/2018	SPC, Labelling and PL	The Agency accepted the variation to update the list of local representatives in the package leaflet.
IAIN/0030	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	12/12/2016	n/a		The Agency accepted the variation to add an alternative site responsible for secondary packaging.
IB/0029	B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation	09/10/2015	n/a		The Agency accepted the variation to implement a change in the manufacturing process of the finished product.
IG/0542	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)	03/07/2015	n/a		The Agency accepted the variation to change the name of the site for the manufacturing of the finished product.
IA/0027/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites A.7 - Administrative change - Deletion of manufacturing sites	24/04/2015	27/04/2016	SPC, Annex II, Labelling and PL	The Agency accepted the variation to delete two batch release sites.
IB/0025	B.II.b.4.a - Change in the batch size (including batch size ranges) of the finished product - Up to 10-fold compared to the originally approved batch size	01/04/2015	n/a		The Agency accepted the variation to add an additional batch size of the finished product.
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.
IB/0024	B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation	08/01/2015	n/a		The Agency accepted the variation to introduce minor changes to the manufacturing process of the finished product.
IA/0023	B.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place	12/09/2014	n/a		The Agency accepted the variation on the replacement of the batch testing/control manufacturing site for the finished products.
IAIN/0021/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)	05/09/2013	26/08/2014	SPC, Annex II, Labelling and PL	The Agency accepted the grouped type IA and type IAIN variation to change the name of the manufacturer of the finished product from 'Pharmacia & Upjohn' to 'Zoetis P&U LLC' and to add 'Zoetis Belgium SA' as an additional site for batch release.

	B.II.b.2.c.1 - Change to importer, batch release arrangements and quality control testing of the FP - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing				
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/0326	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	09/08/2013	n/a		The Agency accepted the variation to add a manufcturing site for part of the manufacturing process of the finished product - secondary packaging.
IA/0019	B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	29/05/2013	n/a		The Agency accepted a quality variation
T/0018	Transfer of Marketing Authorisation	26/04/2013	23/05/2013	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'.
IA/0017	A.7 - Administrative change - Deletion of manufacturing sites	15/02/2013	n/a		The Agency accepted a variation to delete a finished product sterilization site
IB/0016	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	11/01/2013	23/05/2013	SPC and PL	The Agency accepted a variation, following CVMP assessment of a PSUR, to modify the text in section 4.9 of the SPC and section 9 of the package leaflet to reduce the possibility of intravascular injections. The opportunity was also taken to update the product information in line with the latest version of the QRD template
IAIN/0015	B.II.b.2.b.1 - Change to batch release arrangements and quality control testing of the FP - Not including batch control/testing	16/05/2012	29/10/2012	Annex II and PL	The Agency accepted a type IA(IN) variation to add a new manufacturer responsible for batch release.
IG/0005/G	This was an application for a group of variations. C.I.9.g - Changes to an existing pharmacovigilance system as described in the DDPS - Change of the site undertaking pharmacovigilance activities	05/08/2011	05/08/2011		The Agency accepted a group of variations to change the location of the Qualified Person for Pharmacovigilance.
II/0012	C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one	05/05/2011	14/06/2011	SPC, Labelling and PL	The European Commission approved a type II variation for the addition of an acute post-partum (puerperal) metritis indication for Naxcel 200 mg/ml suspension for injection for cattle.
R/0011	Renewal of the marketing authorisation.	10/03/2010	26/05/2010	SPC, Annex II, Labelling and PL	The European Commission approved an indefinite renewal of the product.
II/0010	II - Other quality changes	14/04/2010	21/04/2010		The European Commission approved a type II variation to add a new supplier of an intermediate. This variation does not require any amendment to the marketing authorisation issued by the European Commission.
X/0007	X-3-V New route of administration X-4-I Addition or change of target species X-3-III Extension to a new strength	15/07/2009	08/10/2009	SPC, Labelling and PL	The European Commission approved an extension for the addition of a new target species (cattle).

IB/0009	1B-14-b Change in manufacturer active substance or starting material-new manufacturer	05/08/2009	05/08/2009		The Agency accepted an additional manufacturer for the intermediate product.
IB/0005	1B-37-a Change in specification of the finished product-tightening of specification limits	19/12/2007	19/12/2007		The Agency approved a change in the specification of the finished product (tightening of specification limits) of the finished product.
IB/0006	1B-33 Minor change in the manufacture of the finished product	22/11/2007	22/11/2007		The Agency approved a minor change in the manufacture of the finished product.
II/0004	II - New presentation	19/07/2006	21/08/2006	SPC, Labelling and PL	The European Commission approved a type II variation adding a new pack size (50 ml glass vial).
IB/0003	1B-14-b Change in manufacturer active substance or starting material-new manufacturer	09/02/2006	n/a		The Agency accepted a type IB variation concerning the addition of a new manufacturer of the intermediate in the manufacturing process of the active substance.
IB/0002	1B-13-b Change in test procedure for active substance or starting material-other changes test procedure	09/02/2006	09/02/2006		The Agency accepted a type IB variation concerning a change in the test procedure for the active substance together with a consequential type IA variation regarding a change in the specification of the active substance.
IA/0001	1A-04 Change in name and/or address of a manufacturer of the active substance	22/12/2005	22/12/2005		The EME approved a type IA variation regarding the name of the manufacturer of an intermediate of the active substance from "Biochemie" to "Sandoz".