EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

PIRSUE

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
IB/0022/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site B.II.b.1.f - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the FP - Site where any manufacturing operation(s) take place, except batch release, batch control, and secondary packaging, for sterile medicinal products (including those that are aseptically manufactured) excluding biological/ immunological medicinal products 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	16/09/2016		Annex II and PL	The Agency accepted a group of variations relating to manufacturing activities and minor 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.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 B.II.b.4.b - Change in the batch size (including batch size ranges) of the finished product - Downscaling down to 10-fold 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 B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation				
IB/0021	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	11/12/2015	n/a		The Agency accepted a variation for a change in a test procedure for PIRSUE.
IA/0020	A.7 - Administrative change - Deletion of manufacturing sites	22/10/2014	n/a		The Agency accepted the variation to delete a manufacturing site.
IA/0019	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	09/07/2014	n/a		The Agency accepted a variation to add a site for batch control of the finished product.
IAIN/0018/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) B.II.b.2.c.1 - Change to importer, batch release arrangements and quality control testing of the FP - Not including batch control/testing	05/09/2013		SPC, Annex II, Labelling and PL	The European Medicines Agency accepted a grouped type IA and type IAIN variation to change the name and address of the finished product manufacturer from 'Pharmacia and Upjohn' to 'Zoetis P&U LLC' and to add 'Zoetis Belgium SA' as an additional site for batch release.
T/0017	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'.
IAIN/0014	B.II.b.2.b.1 - Change to batch release arrangements and quality control testing of the FP - Not including batch control/testing	13/04/2012	24/10/2012	SPC, Annex II, Labelling and PL	The European Medicines Agency accepted a variation to add a second batch release site.

Application number	Scope	Opinion / Notification[4] issued on	Commission Decision Issued[5] / amended on	Product Information affected[6]	Summary
IB/0016	B.I.d.1.a.4 - Stability of AS - Change in the re-test period/storage period - Extension or introduction of a re-test period/storage period supported by real time data	29/05/2012	n/a		The Agency accepted the variation on an extension of the re-test period for the active substance
IA/0015	B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	15/05/2012	n/a		The European Medicines Agency accepted a Type IA variation to make minor changes to a test procedure
N/0013	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	26/03/2008	26/03/2008	PL	The EMEA notified the European Commission about changes in the list of local representatives.
II/0011	II - Other quality changes	11/10/2006	18/10/2006		The European Commission approved a type II variation concerning various changes to the quality part of the dossier (test procedure and specifications for the active substance; test procedure for starting material used in the manufacturing process of the active substance).
IA/0012	1A-13-a Change in test procedure for active substance or starting material-minor changes test procedure	19/09/2006	19/09/2006		The EMEA accepted a type IA variation for minor changes to an approved test procedure.
N/0010	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	03/04/2006	03/04/2006	PL	The EMEA notified the European Commission about changes in the list of local representatives.
R/0009	Renewal of the marketing authorisation.	07/12/2005	08/02/2006		
N/0008	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	28/04/2005	19/09/2005	PL	The the EMEA notified the European Commission about changes in the list of local representatives and minor linguistic changes in the product literature.
N/0007	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	17/02/2005	19/09/2005	PL	The EMEA notified the European Commission about changes in the list of local representatives.
IA/0006	1A-05 Change in name and/or address of a manufacturer of the finished product	25/01/2005	19/09/2005	SPC, Annex II, Labelling and PL	The EMEA accepted a type IA variation changing the name of the manufacturer of the finished product.

[4] 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.
[5] 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.
[6] SPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).

Application number	Scope	Opinion / Notification[7] issued on	Commission Decision Issued[8] / amended on	Product Information affected[9]	Summary
T/0005	Transfer of Marketing Authorisation	22/10/2003	01/12/2003	SPC, Labelling and PL	The European Commission approved the transfer of the marketing authorisation from "Pharmacia n.v./s.a., Rijksweg 12, B-2870 Puurs, Belgium" to "Pfizer Ltd., Ramsgate Road, Sandwich, Kent, CT13 9NJ, UK". The name and address of the manufacturers remain unchanged.
I/0004	31_Change in container shape	22/04/2003	04/06/2003	SPC, Labelling and PL	The EMEA accepted a type I variation changing the shape of the container by replacing the approved "Flexitube" cannula with a conventional cannula for intramammary injection.
I/0003	12_Minor change of manufacturing process of the active substance	21/11/2001	27/11/2001		The EMEA accepted a type I variation for a minor change in the manufacture of the active substance.
I/0002	15_Minor changes in manufacture of the medicinal product	21/09/2001	02/10/2001		The EMEA accepted a type I variation for a minor change on manufacture changing the fill volume of the syringe.
I/0001	03_Change in the name and/or address of the marketing authorisation holder	11/04/2001	21/06/2001	SPC, Annex II, Labelling and PL	The EMEA accepted approved a type I variation changing the name of the marketing authorisation holder from "Pharmacia & Upjohn n.v./s.a." to "Pharmacia n.v./s.a."

[7] 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.
[8] 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.
[9] SPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).