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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
IAIN/0005/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/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		SPC, Annex II, Labelling and PL	The European Medicines Agency accepted a grouped type IA and type IAIN variation concerning a change in the name of the finished product manufacturer and the batch release site from 'Pfizer Olot SLU' to 'Zoetis Manufacturing & Research Spain SL'.
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 European Medicines Agency accepted a worksharing of a type IAIN variation to update the contact details of the QPPV following the transfer from 'Pfizer Ltd' to 'Zoetis Belgium SA'.
IB/0004	B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation	02/08/2013	n/a		The Agency accepted a variation to change a storage site and add an alternative/back-up location
IB/0003	C.II.6 - Changes to the labelling or the package leaflet which are not connected with the SPC	25/06/2013		PL	The Agency accepted a variation to amend local

[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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					representatives in the package leaflet
T/0002	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'.
IAIN/0001	A.5.a - Administrative change - Change in the name and/or address of a manufacturer responsible for batch release	10/02/2012	10/09/2012	Annex II and PL	The European Medicines Agency accepted a Type IA variation to change the name of the batch release site from Fort Dodge to Pfizer