Palladia

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/0014	B.II.a.1.a - Change or addition of imprints, bossing or other markings including replacement, or addition of inks used for product marking - Changes in imprints, bossing or other markings	23/01/2019		SPC, Labelling and PL	The Agency accepted the variation to remove the logo from the tablets. With this variation MAH also took the opportunity to delete the local representatives from the package leaflet.
II/0012/G	This was an application for a group of variations. B.I.a.1.g - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Introduction of a new manufacturer of the AS that is not supported by an ASMF and requires significant update to the relevant AS section in the dossier A.7 - Administrative change - Deletion of manufacturing sites B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation	19/07/2018	n/a		The Agency accepted the group of variations to include an alternative manufacture of the active substance and consequential changes. The removal of one supplier of a starting material and its replacement with an alternative supplier was also accepted within this grouping.
IG/0951	C.I.9.b - Changes to an existing pharmacovigilance system as described in the DDPS - Change(s) in the	05/07/2018	n/a		The Agency accepted the variation to update the current detailed description of the pharmacovigilance system

[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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	safety database and/or major contractual arrangements for the fulfilment of PhV obligations, and/or change of the site undergoing PhV activities				(DDPS).
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	23/03/2018	SPC, Labelling and PL	The Agency accepted the variation to update the list of local representatives in the product information.
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/0009	B.II.f.1.b.1 - Stability of FP - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)	06/03/2015	08/03/2016	SPC	The Agency accepted a variation to extend the shelf life of the finished product from 24 months to 36 months.
IB/0008	B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation	20/11/2014	n/a		The Agency accepted a variation to replace the manufacturer for a starting material.
R/0007	Renewal of the marketing authorisation.	05/06/2014	31/07/2014	SPC, Annex II, Labelling and PL	The European Commission renewed the marketing authorisation for Palladia.
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.
T/0005	Transfer of Marketing Authorisation	26/04/2013	27/05/2013	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'.
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.
IB/0002	B.II.f.1.b.1 - Stability of FP - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)	16/02/2011	07/07/2011	SPC	The Agency accepted a variation to extend the shelf life from 18 months to 2 years.
IG/0002/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 responsible for batch release A.5.b - Administrative change - Change in the name and/or address of a manufacturer of the finished product, including quality control sites (excluding manufacturer for batch release)	03/12/2010	07/07/2011	Annex II and PL	The Agency accepted a group of variations to change the postcode of the manufacturing site for batch release and amend the name of the manufacturer, as well as changing the legal seat address.
IB/0001	B.II.f.1.b.1 - Stability of FP - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)	25/05/2010	13/01/2011	SPC and Labelling	The Agency accepted a variation extending the shelf life from 12 to 18 months.