Apoquel

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/0016	C.I.3.z - Change(s) in the SPC, Labelling or PL intended to implement the outcome of a procedure concerning PSUR or PASS or the outcome of the assessment done under A 45/46 - Other variation	17/04/2019		SPC and PL	The Agency accepted the variation to update the SPC and the package leaflet to implement the agreed wording following assessment of the 8th PSUR.
IB/0015	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	20/02/2019	n/a		The Agency accepted the variation to increase the re-test period of the active substance.
R/0013	Renewal of the marketing authorisation.	25/05/2018	26/07/2018	SPC, Labelling and PL	The European Commission renewed the marketing authorisation for Apoquel.
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).
IB/0012	B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation	13/10/2017	n/a		The Agency accepted the variation for an additional supplier of a starting material used in the manufacture of the active ingredient.

[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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IA/0011	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	06/04/2017	n/a		The Agency accepted the variation to change the name of the supplier of a regulatory starting material.
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	06/04/2018	SPC, Labelling and PL	The Agency accepted the variation to update the list of local representatives in the product information.
IB/0009/G	This was an application for a group of variations. B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation B.I.a.3.b - Change in batch size (including batch size ranges) of AS or intermediate - Downscaling down to 10-fold 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 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 B.I.c.2.z - Change in the specification parameters and/or limits of the immediate packaging of the AS - Other variation	18/03/2016	n/a		The Agency accepted the group of variations to add an additional manufacturer of the active substance and to register consequential related changes.
IA/0008	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	08/01/2016	n/a		The Agency accepted a variation to change the name of a manufacturing site.
IB/0007	B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation	29/07/2015	n/a		The Agency accepted the variation to add an additional supplier for one of the regulatory starting materials (RSMs) used in the manufacture of the active substance.
IB/0006/G	This was an application for a group of variations. B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process B.II.e.1.b.1 - Change in immediate packaging of the finished product - Change in type/addition of a new container - Solid, semi-solid and non-sterile liquid pharmaceutical forms B.II.e.1.b.1 - Change in immediate packaging of the finished product - Change in type/addition of a new container - Solid, semi-solid and non-sterile liquid pharmaceutical forms B.II.e.1.b.1 - Change in immediate packaging of the finished product - Change in type/addition of a new	08/05/2015	17/05/2016	SPC, Labelling and PL	The Agency accepted the group of variations to include additional packaging for the finished product in HDPE bottles with a child resistant container closure.

	container - Solid, semi-solid and non-sterile liquid pharmaceutical forms B.II.e.2.b - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Addition of a new specification parameter to the specification with its corresponding test method B.II.e.2.b - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Addition of a new specification parameter to the specification with its corresponding test method				
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/0004	B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation	13/03/2015	n/a		The Agency accepted the variation to add an additional supplier of the starting material.
IB/0003	B.II.a.2.b - Change in the shape or dimensions of the pharmaceutical form - Gastro-resistant, modified or prolonged release pharmaceutical forms and scored tablets intended to be divided into equal doses	06/02/2015	n/a		The Agency accepted the variation to modify the shape of the 3.6 mg film-coated tablet.
IA/0002/G	This was an application for a group of variations. 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.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process	05/11/2014	n/a		The Agency accepted the group of variations to implement a smaller blend batch size (235 kg) for the 5.4 mg and 16 mg tablets and to change to the screen size used to remove any large agglomerates of API and excipients prior to blending for all presentations.
IAIN/0001	B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes	25/10/2013	27/10/2014	SPC, Labelling and PL	The Agency accepted the variation to add an additional presentation of 50 tablets to the existing presentations of 20 and 100 tablets.