Brintellix

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
R/0019	Renewal of the marketing authorisation.	20/09/2018	20/11/2018	SmPC, Labelling and PL	
IB/0020	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	18/07/2018	20/11/2018	SmPC and PL	
PSUSA/10052 /201709	Periodic Safety Update EU Single assessment - vortioxetine	12/04/2018	n/a		PRAC Recommendation - maintenance

[1] Notifications are issued for type I variations and Article 61(3) notifications (unless part of a group including a type II variation or extension application or a worksharing application). Opinions are issued for all other procedures.
[2] A Commission decision (CD) is issued for procedures that affect the terms of the marketing authorisation (e.g. summary of product characteristics, annex II, labelling, package leaflet). The CD is issued within two months of the opinion for variations falling under the scope of Article 23.1a(a) of Regulation (EU) No. 712/2012, or within one year for other procedures.
[3] SmPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).

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IB/0017	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	06/12/2017	20/11/2018	SmPC, Labelling and PL	
IB/0014	B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation	18/05/2017	n/a		
PSUSA/10052 /201609	Periodic Safety Update EU Single assessment - vortioxetine	05/05/2017	n/a		PRAC Recommendation - maintenance
IA/0016/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.I.a.1.i - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Introduction of a new site of micronisation	03/05/2017	n/a		
IB/0015	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	27/04/2017	n/a		
PSUSA/10052 /201603	Periodic Safety Update EU Single assessment - vortioxetine	10/11/2016	11/01/2017	PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/10052/201603.
IB/0011	B.II.f.1.b.1 - Stability of FP - Extension of the shelf life of the finished product - As packaged for sale	24/05/2016	11/01/2017	SmPC, Labelling and	

	(supported by real time data)			PL	
PSUSA/10052 /201509	Periodic Safety Update EU Single assessment - vortioxetine	14/04/2016	n/a		PRAC Recommendation - maintenance
PSUSA/10052 /201503	Periodic Safety Update EU Single assessment - vortioxetine	08/10/2015	n/a		PRAC Recommendation - maintenance
IB/0008	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	17/06/2015	24/02/2016	SmPC and PL	
IB/0007	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)	06/05/2015	24/02/2016	SmPC	
PSUSA/10052 /201409	Periodic Safety Update EU Single assessment - vortioxetine	10/04/2015	n/a		PRAC Recommendation - maintenance
II/0004	Update of section 5.1 of the SmPC with information on the effect of vortioxetine on certain aspects of cognitive function in Major Depressive Disorder. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	26/02/2015	24/02/2016	SmPC	Effect of vortioxetine on certain aspects of cognitive function in Major Depressive Disorder have been included in the SmPC further to data analysis, including results obtained with vortioxetine in Major Depressive Disorder (MDD) patients presenting with cognitive dysfunction.
IB/0005	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	18/12/2014	n/a		

PSUV/0003	Periodic Safety Update	23/10/2014	16/12/2014	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUV/0003.
IAIN/0002/G	This was an application for a group of variations. 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 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 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	07/03/2014	16/12/2014	SmPC, Labelling and PL	
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	07/03/2014	16/12/2014	SmPC, Labelling and PL	