EMA/668451/2020

Pramipexole Accord

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/0017	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	20/11/2020		Annex II and PL	

[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/0016	C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH	29/06/2020	06/08/2020	SmPC and PL	
IA/0015	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	14/03/2019	n/a		
T/0014	Transfer of Marketing Authorisation	28/01/2019	11/03/2019	SmPC, Labelling and PL	
IAIN/0013/G	This was an application for a group of variations. B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site B.II.b.1.b - Replacement or addition of a manufacturing site for the FP - Primary packaging site 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	04/10/2018	11/03/2019	Annex II and PL	
IAIN/0012	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	24/10/2017	08/05/2018	SmPC and PL	

IB/0011	C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH	21/04/2017	08/05/2018	SmPC and PL	
R/0010	Renewal of the marketing authorisation.	26/05/2016	15/07/2016	SmPC, Annex II, Labelling and PL	Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of Pramipexole Accord in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
IA/0009	B.II.e.1.a.1 - Change in immediate packaging of the finished product - Qualitative and quantitative composition - Solid pharmaceutical forms	17/02/2015	11/06/2015	SmPC, Labelling and PL	
IB/0008	Update of SmPC sections 4.4 and 4.8 to include mania and delirium as adverse drug reactions and to add a new warning to inform healthcare professionals about the possibility of these events to occur under pramipexole treatment as well as the need for monitoring patients and dose adjustment. The Package Leaflet is updated accordingly. Furthermore, the PI was brought in line with the latest QRD template version. All changes made are in order to harmonise text with the originator. C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference	04/06/2014	11/06/2015	SmPC, Annex II and PL	

	product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH				
IA/0007/G	This was an application for a group of variations. B.III.1.a.2 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer 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 B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	30/04/2014	n/a		
IAIN/0006	C.I.8.a - Introduction of or changes to a summary of Pharmacovigilance system - Changes in QPPV (including contact details) and/or changes in the PSMF location	30/08/2013	n/a		
IB/0005/G	This was an application for a group of variations. C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data are submitted by the MAH C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following	17/01/2013	08/01/2014	SmPC, Annex II, Labelling and PL	Implementation of changes approved in the reference product for procedures WS-128, WS-311 and WS-326: - Update of section 4.8 of SmPC in order to safety information related to cardiac failure. The Package Leaflet was updated accordingly. - Update of section 4.8 of the SmPC in order to include inappropriate antidiuretic hormone secretion as an adverse drug reaction based on post-marketing data. The Package Leaflet was updated accordingly. Furthermore, a more

	assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data are submitted by the MAH C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data are submitted by the MAH				detailed description of the outer appearance of the immediate release tablets was included in the Package Leaflet corresponding to the information provided in the SmPC and analogous to the description of the prolonged-release formulation. The PI was brought in line with the latest QRD template. - Update of sections 4.4 and 4.8 of the SmPC in order to update the safety information by implementing class labelling for the risk of impulse control disorders. The Package Leaflet was updated accordingly.
IAIN/0004	A.1 - Administrative change - Change in the name and/or address of the MAH	20/12/2012	08/01/2014	SmPC, Labelling and PL	
IB/0003	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)	06/11/2012	08/01/2014	SmPC	
IAIN/0002	B.III.1.a.1 - Submission of a new or updated Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from an already approved manufacturer	26/09/2012	n/a		
IB/0001	C.I.6.b - Change(s) to therapeutic indication(s) - Deletion of a therapeutic indication	16/02/2012	24/09/2012	SmPC and PL	A variation application EMEA/H/C/002291/IB/0001 is being filed for deletion of an approved indication covered by patent law. The information directly related to the patented indication has been deleted from section 4.1, section 4.2 and section 5.1 of the Summary of Product Characteristics (SmPC). Minor editorial changes have been introduced in sections 4.4 and 4.8 of the SmPC. The Package Leaflet is also revised to be in line with the revised SmPC.