Entacapone Teva

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
N/0018	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	10/09/2021		PL	
IA/0017	A.7 - Administrative change - Deletion of manufacturing sites	01/02/2021		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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IA/0016/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.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	23/08/2019	n/a		
N/0015	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	14/11/2018		Labelling	
IA/0014/G	This was an application for a group of variations. B.II.e.4.a - Change in shape or dimensions of the container or closure (immediate packaging) - Non-sterile medicinal products 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	31/05/2018	n/a		
IA/0013	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	10/10/2016	n/a		
IA/0012	B.III.1.a.2 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph.	24/06/2016	n/a		

	Eur. Monograph - Updated certificate from an already approved manufacturer				
IA/0011	A.7 - Administrative change - Deletion of manufacturing sites	30/03/2016	20/03/2017	Annex II and PL	
R/0010	Renewal of the marketing authorisation.	24/09/2015	19/11/2015	SmPC, Annex II, Labelling and PL	Based on the review of the available information the CHMP is of the opinion that the quality, the safety and the efficacy of this medicinal product continues to be adequately and sufficiently demonstrated and therefore considers that the benefit/risk profile of Entacapone Teva continues to be favourable. The CHMP is of the opinion that the renewal can be granted with unlimited validity.
T/0009	Transfer of Marketing Authorisation	30/09/2014	27/10/2014	SmPC, Labelling and PL	
IB/0008	B.I.d.1.z - Stability of AS - Change in the re-test period/storage period or storage conditions - Other variation	16/07/2014	n/a		
IAIN/0007	B.III.1.a.3 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from a new manufacturer (replacement or addition)	26/06/2014	n/a		
IAIN/0006	B.III.1.a.1 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from an already approved manufacturer	18/03/2014	n/a		

N/0005	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	20/02/2014	21/03/2014	PL	
IAIN/0004	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	21/05/2013	n/a		
IB/0003	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	04/03/2013	21/03/2014	SmPC, Annex II, Labelling and PL	The Applicant proposes to update the Product Information to incorporate the below discussed safety updates adopted for the reference product Comtess through a work sharing procedure EMEA/H/C/xxxx/WS/0331 and aligment with the revised QRD template (version 8). The safety update consist of updates to sections 4.4 and 4.8 of the SmPC to implement a class labelling on the risk of impulse control disorder and consequential changes to sections 2 and 4 of the Package Leaflet. In addition, alignment in accordance with the requirements set out in the list of Union Reference Dates (EURD list) have been made in Annex II. The Applicant would also like to take the opportunity to propose some minor amendments to the translated Product Information in some languages due to readability and compliance with the reference product text.
IB/0001/G	This was an application for a group of variations. B.I.a.3.a - Change in batch size (including batch size ranges) of AS or intermediate - Up to 10-fold increase compared to the currently approved batch size B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS B.III.2.a.1 - Change of specification('s) of a former	12/03/2012	n/a		

	non Pharmacopoeial substance to comply with the Ph. Eur. or with a national pharmacopoeia of a Member State - AS B.I.d.1.z - Stability of AS - Change in the re-test period/storage period or storage conditions - Other variation				
IAIN/0002	A.5.a - Administrative change - Change in the name and/or address of a manufacturer responsible for batch release	23/01/2012	10/09/2012	Annex II and PL	