EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Numient

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
T/0005	Transfer of Marketing Authorisation	24/07/2018	03/08/2018	SmPC, Labelling and PL	
IB/0004/G	This was an application for a group of variations. 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)	09/10/2017	03/08/2018	SmPC, Labelling 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).

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5520
Send a question via our website www.ema.europa.eu/contact

	B.II.f.1.b.2 - Stability of FP - Extension of the shelf life of the finished product - After first opening (supported by real time data)				
PSUSA/10479 /201611	Periodic Safety Update EU Single assessment - carbidopa / levodopa (for centrally authorised product)	09/06/2017	n/a		PRAC Recommendation - maintenance
PSUSA/10479 /201605	Periodic Safety Update EU Single assessment - carbidopa / levodopa (for centrally authorised product)	01/12/2016	n/a		PRAC Recommendation - maintenance
T/0002	Transfer of Marketing Authorisation	18/10/2016	14/11/2016	SmPC, Labelling and PL	