Nimvastid

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/0024	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	09/01/2024		SmPC 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).

N/0023	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	26/01/2023		PL	
IB/0022	B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation	11/07/2022	n/a		
IB/0021	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	07/02/2022	03/02/2023	SmPC, Annex II, Labelling and PL	To amend SmPC section 2 for the orodispersible to essentially align with the wording given in the excipient guidance for Sorbitol (E420). The package leaflet has been updated accordingly. The marketing authorisation holder took the opportunity to align the PI to the latest QRD template (version 10.2). This includes merging the SmPCs for hard capsules and orodispersible tables respectively. Also the contact details of the local representatives in Cyprus, Greece, Ireland, Iceland and United Kingdom (Northern Ireland).
IA/0020	B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process	06/04/2021	n/a		
IA/0019	B.II.b.4.a - Change in the batch size (including batch size ranges) of the finished product - Up to 10-fold compared to the originally approved batch size	25/03/2021	n/a		
IA/0018/G	This was an application for a group of variations. B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor	12/11/2020	n/a		

	changes to an approved test procedure B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure 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 originally approved batch size				
IA/0017	B.II.b.4.b - Change in the batch size (including batch size ranges) of the finished product - Downscaling down to 10-fold	30/01/2020	n/a		
N/0016	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	18/01/2018	03/02/2023	Labelling and PL	
IB/0014	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)	18/12/2015	05/09/2016	SmPC	
IB/0015	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	10/12/2015	05/09/2016	SmPC, Annex II and PL	
IB/0013	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	18/08/2015	05/09/2016	SmPC, Labelling and PL	

	new additional data is required to be submitted by the MAH				
R/0012	Renewal of the marketing authorisation.	21/11/2013	16/01/2014	SmPC, Annex II, Labelling and PL	Based on the review of the cumulative quality, efficacy and safety data from clinical trials and post-marketing studies conducted with the reference medicinal product Exelon as well as from spontaneous reports and the scientific literature, the CHMP concluded that there were no changes to the known benefits and safety concerns associated with Nimvastid when used in the approved indications. The CHMP therefore concluded that the benefit/risk balance of Nimvastid remained favourable and recommended the renewal of the marketing authorisation with unlimited validity.
IA/0011	B.II.d.1.a - Change in the specification parameters and/or limits of the finished product - Tightening of specification limits	15/07/2013	n/a		
IB/0010	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	27/06/2012	29/10/2012	SmPC and PL	Following the procedure for the originator product Exelon EMEA/H/C/xxxx/WS/0132 Section 4.8 of the SmPC was updated to reflect the safety findings of the open-label safety study in patients with Parkinson’s disease dementia. Additionally, sections 4.3 and 4.4 were updated with information on skin application site reactions and skin hypersensitivity, recommendations on formulation switching and treatment discontinuation. The Package Leaflet was updated in accordance. Minor editorial changes were introduced throughout the Product Information. Additionally local representatives were updated.

IB/0009	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)	05/06/2012	29/10/2012	SmPC	
N/0008	The Marketing Authorisation Holder (MAH) took the opportunity to update details of local representatives in Annex IIIB. Furthermore, minor corrections were made in Annex IIIA of Romanian PI and in Annex IIIB of Slovakian PI. Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	14/11/2011	26/03/2012	PL	The Marketing Authorisation Holder (MAH) took the opportunity to update details of local representatives in Annex IIIB. Furthermore, minor corrections were made in Annex IIIA of Romanian PI and in Annex IIIB of Slovakian PI.
IB/0007/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 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	31/08/2011	n/a	SmPC and PL	Update sections 4.3 and 4.4 of Nimvastid SmPC to change the contraindication for patients with severe hepatic impairment into a warning. Section 4.4 of the SmPC is also revised to reflect that patients with clinically significant renal or hepatic impairment might experience more adverse reactions. Section 4.2 is amended accordingly. In addition, minor linguistic amendments have been introduced in the SmPC. The Package Leaflet of has been revised based on the results of a user testing of the reference product. In addition, section 4.8 of the SmPC has been amended to include new adverse reactions: dehydration, hepatitis, aggression, restlessness, sick sinus syndromes and anxiety. The whole section 4.8 has been revised according to the current MedDRA terminology. Furthermore, Section 4.4 of the SmPC has also been amended to include that gastrointestinal disorders may occur when in patients treated with rivastigmine and to

					include a warning for patients with low body weight. The Package Leaflet has been amended to reflect those changes, and the local representative section has also been updated.
IB/0006	Updated information on skin reactions has been included in section 4.8 of the SPC and the corresponding section 4 of the Package Leaflet. In addition, minor amendments have been made throughout the Annexes and the Product information has been brought in line with current QRD requirements. This followed a wider update to the Product information of Exelon (the reference medicinal product) which included updates of other formulations (i.e. patches) via procedure EMEA/H/C/000169/II/0055. 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	21/06/2010	n/a	SmPC and PL	
IA/0005	IA_41_a_01_Change in pack size - change in no. of units within range of appr. pack size	20/07/2009	20/07/2009	SmPC, Labelling and PL	
IA/0004	IA_41_a_01_Change in pack size - change in no. of units within range of appr. pack size	20/07/2009	20/07/2009	SmPC, Labelling and PL	

IA/0003	IA_41_a_01_Change in pack size - change in no. of units within range of appr. pack size	20/07/2009	20/07/2009	SmPC, Labelling and PL	
IA/0002	IA_41_a_01_Change in pack size - change in no. of units within range of appr. pack size	20/07/2009	20/07/2009	SmPC, Labelling and PL	
IA/0001	IA_35_a_Change in weight of coating/capsule shells - immediate release pharm. forms	17/06/2009	n/a		