EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Tasermity

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/0006	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	15/12/2017		Labelling and PL	
PSUSA/2697/ 201610	Periodic Safety Update EU Single assessment - sevelamer	09/06/2017	n/a		PRAC Recommendation - maintenance
PSUSA/2697/ 201510	Periodic Safety Update EU Single assessment - sevelamer	23/06/2016	25/08/2016	SmPC	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for

[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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					PSUSA/2697/201510.
WS/0867	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. Update of section 4.5 of the SmPC regarding drug-drug interaction between sevelamer and proton pump inhibitors. The Package Leaflet has been updated accordingly. In addition, the MAH took the opportunity to implement editorial changes in section 4.8 of the SmPC of Renvela and Sevelamer carbonate Zentiva in order to harmonize the wording for all Sevelamer compounds. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	11/02/2016	25/08/2016	SmPC and PL	Changes in gastric acidity with acid suppressants may potentially alter the efficacy of sevelamer HCL. During post-marketing experience, very rare cases of increased phosphate levels have been reported in patients taking proton pump inhibitors co-administered with sevelamer hydrochloride.
WS/0803	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. C.I.11.b - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH where significant assessment is required	19/11/2015	n/a		
WS/0770	This was an application for a variation following a worksharing procedure according to Article 20 of	01/10/2015	25/08/2016	SmPC and PL	

	Commission Regulation (EC) No 1234/2008. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data				