Sevelamer carbonate Winthrop

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/0032/G	This was an application for a group of variations. B.II.e.2.b - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Addition of a new specification parameter to the specification with its corresponding	10/01/2023		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).

	test method B.II.e.2.b - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Addition of a new specification parameter to the specification with its corresponding test method B.II.b.1.e - Replacement or addition of a manufacturing site for the FP - Site where any manufacturing operation(s) take place, except batch-release, batch control, primary and secondary packaging, for non-sterile medicinal products B.II.c.1.g - Change in the specification parameters and/or limits of an excipient - Where there is no monograph in the European/National Ph. for the excipient, a change in specification from in-house to a non-official/third country Ph. B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site B.II.d.1.c - Change in the specification parameters and/or limits of the finished product - Addition of a new specification parameter to the specification with its corresponding test method B.II.c.1.c - Change in the specification parameters and/or limits of an excipient - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process B.II.e.2.z - Change in the specification parameters and/or limits of the immediate packaging of the				

	finished product - Other variation B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure B.II.b.2.c.2 - Change to importer, batch release arrangements and quality control testing of the FP - Including batch control/testing B.II.b.1.b - Replacement or addition of a manufacturing site for the FP - Primary packaging site				
PSUSA/2697/202110	Periodic Safety Update EU Single assessment - sevelamer	10/06/2022	n/a		PRAC Recommendation - maintenance
IA/0031	B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	13/04/2022	n/a		
IA/0030	B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	18/02/2022	n/a		
N/0028	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	10/11/2021		PL	
IA/0027/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder	02/09/2021	n/a		

	or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient				
WS/1854	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	12/11/2020	12/11/2021	SmPC, Labelling and PL	
WS/1775	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 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	17/04/2020	n/a		Removal of identified or potential risks from the list of safety concerns as these risks are fully characterized and are followed up via routine pharmacovigilance.
IA/0025	A.5.b - Administrative change - Change in the name and/or address of a manufacturer/importer of the	19/03/2020	n/a		

	finished product, including quality control sites (excluding manufacturer for batch release)				
N/0023	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	03/03/2020	12/11/2021	Labelling and PL	
R/0022	Renewal of the marketing authorisation.	19/09/2019	11/11/2019	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 Sevelamer carbonate Winthrop in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
PSUSA/2697/ 201810	Periodic Safety Update EU Single assessment - sevelamer	27/06/2019	23/08/2019	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/2697/201810.
WS/1560	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.IV.1.a.1 - Change of a measuring or administration device - Addition or replacement of a device which is not an integrated part of the primary packaging - Device with CE marking	16/05/2019	23/08/2019	SmPC, Labelling and PL	
IA/0021	A.7 - Administrative change - Deletion of manufacturing sites	23/04/2019	23/08/2019	Annex II and PL	
IAIN/0018/G	This was an application for a group of variations. A.1 - Administrative change - Change in the name	28/11/2018	23/08/2019	SmPC, Labelling and PL	

	and/or address of the MAH A.2.a - Administrative change - Change in the (invented) name of the medicinal product for CAPs				
X/0011	Annex I_2.(c) Change or addition of a new strength/potency	26/07/2018	20/09/2018	SmPC, Labelling and PL	
N/0017	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	25/07/2018	20/09/2018	PL	
PSUSA/2697/201710	Periodic Safety Update EU Single assessment - sevelamer	14/06/2018	n/a		PRAC Recommendation - maintenance
WS/1383	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.II.f.1.e - Stability of FP - Change to an approved stability protocol	07/06/2018	n/a		
IG/0926/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites B.I.b.1.d - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) B.I.c.1.a - Change in immediate packaging of the AS - Qualitative and/or quantitative composition	06/06/2018	n/a		

WS/1332	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. Update of sections 4.2 and 6.6 of the SmPC in order to include the use of food and beverage as an alternative to water for administration of sevelamer carbonate powder for oral suspension. The Package Leaflet is updated accordingly. In addition, the Worksharing applicant (WSA) took the opportunity to revise the Annex A. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	22/02/2018	20/09/2018	SmPC and PL	
N/0012	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	15/12/2017	20/09/2018	Labelling and PL	
IG/0844	C.I.11.a - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Implementation of wording agreed by the competent authority	22/09/2017	20/09/2018	SmPC, Labelling and PL	
IG/0804/G	This was an application for a group of variations. B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS B.I.a.3.a - Change in batch size (including batch size	26/06/2017	n/a		

	ranges) of AS or intermediate - Up to 10-fold increase compared to the originally approved batch size				
WS/0965	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. Extension of indication for Renvela 1.6 g and 2.4 g powder for oral suspension and Sevelamer carbonate Zentiva 2.4 g powder for oral suspension to include the control of hyperphosphataemia in paediatric patients (>6 years of age and a Body Surface Area (BSA) of >0.75 m2) with chronic kidney disease. As a consequence, sections 4.2, 4.8 and 5.1 of the SmPC are updated in order to add information on posology and safety in paediatric patients and to reflect the results of the paediatric study. The Package Leaflet is updated in accordance. C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one	18/05/2017	23/06/2017	SmPC and PL	Please refer to the Scientific Discussion of Renvela and Sevelamer carbonate Zentiva EMEA/H/C/WS0965.
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	18/08/2016	SmPC	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for 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	18/08/2016	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 Commission Regulation (EC) No 1234/2008.	01/10/2015	11/02/2016	SmPC and PL	

	C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data				
IB/0002	B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes	09/04/2015	11/02/2016	SmPC, Labelling and PL	
IAIN/0001	B.II.a.1.a - Change or addition of imprints, bossing or other markings including replacement, or addition of inks used for product marking - Changes in imprints, bossing or other markings	17/02/2015	11/02/2016	SmPC and PL	