EMA/487898/2020

elmiron

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/0019	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	26/08/2020		SmPC and PL	
N/0018	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	22/04/2020		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).

PSUSA/10614 /201906	Periodic Safety Update EU Single assessment - pentosan polysulfate sodium (for centrally authorised product)	30/01/2020	03/04/2020		Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/10614/201906.
N/0017	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	26/02/2020		PL	
IB/0016/G	This was an application for a group of variations. A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient B.I.a.2.e - Changes in the manufacturing process of the AS - Minor change to the restricted part of an ASMF B.I.b.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits 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.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	27/09/2019	n/a		
N/0014	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	29/08/2019	03/04/2020	PL	

PSUSA/10614 /201812	Periodic Safety Update EU Single assessment - pentosan polysulfate sodium (for centrally authorised product)	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/10614/201812.
N/0013	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	25/03/2019	23/08/2019	PL	
IA/0011	B.II.e.1.a.1 - Change in immediate packaging of the finished product - Qualitative and quantitative composition - Solid pharmaceutical forms	15/02/2019	n/a		
PSUSA/10614 /201806	Periodic Safety Update EU Single assessment - pentosan polysulfate sodium (for centrally authorised product)	17/01/2019	n/a		PRAC Recommendation - maintenance
IB/0010	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)	16/11/2018	31/01/2019	SmPC, Labelling and PL	
IB/0008	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	14/08/2018	31/01/2019	SmPC, Labelling and PL	
PSUSA/10614 /201712	Periodic Safety Update EU Single assessment - pentosan polysulfate sodium (for centrally authorised product)	14/06/2018	n/a		PRAC Recommendation - maintenance
IB/0006	B.II.f.z - Stability of FP - Other variation	27/03/2018	31/01/2019	SmPC and PL	
IA/0005	B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test	27/02/2018	n/a		

	procedure				
IB/0003	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	05/02/2018	31/01/2019	SmPC, Labelling and PL	
N/0002	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	23/10/2017	31/01/2019	PL	
N/0001	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	30/08/2017	31/01/2019	PL	