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
N/0027	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	15/07/2022		PL	
IB/0026/G	This was an application for a group of variations. B.II.b.1.a - Replacement or addition of a	09/03/2022	n/a		

[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).

	manufacturing site for the FP - Secondary packaging site 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.b.1.b - Replacement or addition of a manufacturing site for the FP - Primary packaging site B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process				
PSUSA/10614 /202106	Periodic Safety Update EU Single assessment - pentosan polysulfate sodium (for centrally authorised product)	13/01/2022	n/a		PRAC Recommendation - maintenance
R/0024	Renewal of the marketing authorisation.	11/11/2021	11/01/2022	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 elmiron in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
N/0023	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	21/07/2021	29/09/2021	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	04/05/2021	n/a		

PSUSA/10614 /202006	Periodic Safety Update EU Single assessment - pentosan polysulfate sodium (for centrally authorised product)	14/01/2021	n/a		PRAC Recommendation - maintenance
IA/0021	A.5.b - Administrative change - Change in the name and/or address of a manufacturer/importer of the finished product, including quality control sites (excluding manufacturer for batch release)	10/12/2020	n/a		
IB/0019	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	26/08/2020	29/09/2021	SmPC and PL	
N/0018	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	22/04/2020	29/09/2021	PL	
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	29/09/2021	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	27/09/2019	n/a		

	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				
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	16/11/2018	31/01/2019	SmPC,	

	life of the finished product - After first opening (supported by real time data)			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 procedure	27/02/2018	n/a		
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	