SIBNAYAL

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/0009	B.II.f.z - Stability of FP - Other variation	27/06/2023		SmPC, Labelling and PL	
PSUSA/10932 /202210	Periodic Safety Update EU Single assessment - potassium citrate / potassium hydrogen carbonate	08/06/2023	n/a		PRAC Recommendation - maintenance

[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).

IB/0008	B.II.b.4.z - Change in the batch size (including batch size ranges) of the finished product - Other variation	13/03/2023	n/a		
IA/0006	B.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place	12/12/2022	n/a		
PSUSA/10932 /202204	Periodic Safety Update EU Single assessment - potassium citrate / potassium hydrogen carbonate	01/12/2022	n/a		PRAC Recommendation - maintenance
PSUSA/10932 /202110	Periodic Safety Update EU Single assessment - potassium citrate / potassium hydrogen carbonate	10/06/2022	n/a		PRAC Recommendation - maintenance
IAIN/0004	A.1 - Administrative change - Change in the name and/or address of the MAH	25/04/2022	24/03/2023	SmPC, Labelling and PL	
II/0002/G	This was an application for a group of variations. B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation B.II.b.3.b - Change in the manufacturing process of the finished or intermediate product - Substantial changes to a manufacturing process that may have a significant impact on the quality, safety and efficacy of the medicinal product	10/02/2022	n/a		
IA/0001	B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	15/06/2021	n/a		
