Potactasol

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/0022	C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH	17/01/2025		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).

IG/1612	A.1 - Administrative change - Change in the name and/or address of the MAH	31/05/2023	19/04/2024	SmPC, Labelling and PL	
N/0020	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	18/07/2022	28/11/2022	PL	
IA/0019	A.6 - Administrative change - Change in ATC Code/ATC Vet Code	09/12/2021	28/11/2022	SmPC and PL	
N/0018	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	13/01/2021	28/11/2022	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.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.d.1.a.4 - Stability of AS - Change in the re-test period/storage period - Extension or introduction of a re-test period/storage period supported by real time	03/09/2018	n/a		

	data				
N/0017	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	21/08/2018	20/06/2019	Labelling and PL	
IB/0015	C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH	04/07/2018	20/06/2019	SmPC and PL	
N/0014	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	20/03/2018	20/06/2019	Labelling and PL	
IB/0013	B.I.b.2.z - Change in test procedure for AS or starting material/reagent/intermediate - Other variation	15/11/2017	n/a		
N/0012	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	12/05/2017	20/06/2019	PL	
N/0011	Deletion of a sentence in section 14 of the labelling and update of the package leaflet with revised contact details of the local representatives for BE, BG, DE, ES, FR, HR, LU and NL. In addition the MAH took the opportunity to make formatting and editorial changes in CZ, DA, IS, DE, EL, ES, ET, FI, FR, HU, IT, LT, LV, MT, NL, NO, PL, PT SI and SV package leaflets in line with the EN text. Minor change in labelling or package leaflet not	06/10/2016	20/06/2019	Labelling and PL	

	connected with the SPC (Art. 61.3 Notification)				
PSUSA/2997/ 201505	Periodic Safety Update EU Single assessment - topotecan	14/01/2016	n/a		PRAC Recommendation - maintenance
R/0009	Renewal of the marketing authorisation.	23/07/2015	05/10/2015	SmPC, Annex II, Labelling and PL	Based on the review of data on quality, safety and efficacy, including all variations introduced since the marketing authorisation was granted, the CHMP considered that the benefit-risk balance of Potactasol in the approved indications remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
IB/0005/G	This was an application for a group of variations. B.I.d.1.a.4 - Stability of AS - Change in the re-test period/storage period - Extension or introduction of a re-test period/storage period supported by real time data B.I.d.1.b.3 - Stability of AS - Change in the storage conditions - Change in storage conditions of the AS	11/08/2015	n/a		
IB/0008	B.II.f.1.b.1 - Stability of FP - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)	27/04/2015	05/10/2015	SmPC	
IB/0006	B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation	22/04/2015	n/a		
IA/0007	B.II.c.3.z - Change in source of an excipient or reagent with TSE risk - Other variation	15/04/2015	n/a		

IB/0004	C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH	17/01/2015	05/10/2015	SmPC, Annex II, Labelling and PL	
N/0003	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	13/08/2014	05/10/2015	PL	
IB/0002	B.II.b.4.a - Change in the batch size (including batch size ranges) of the finished product - Up to 10-fold compared to the currently approved batch size	10/01/2012	n/a		
IB/0001	B.II.b.3.z - Change in the manufacturing process of the finished product - Other variation	21/11/2011	04/07/2012	SmPC, Annex II and PL	