RYBREVANT

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/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	20/09/2023		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).

	B.II.f.1.b.5 - Stability of FP - Extension of the shelf life of the finished product - Biological/immunological medicinal product in accordance with an approved stability protocol				
R/0007	Renewal of the marketing authorisation.	20/07/2023	11/09/2023		
PSUSA/10977 /202211	Periodic Safety Update EU Single assessment - amivantamab	08/06/2023	n/a		PRAC Recommendation - maintenance
PSUSA/10977 /202205	Periodic Safety Update EU Single assessment - amivantamab	12/01/2023	n/a		PRAC Recommendation - maintenance
IB/0004	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	30/11/2022	n/a		
IB/0005	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	29/11/2022	11/09/2023	SmPC and Annex II	
R/0002	Renewal of the marketing authorisation.	21/07/2022	26/09/2022		
II/0001	Update of section 4.8 of the SmPC in order to add hypokalaemia and hypomagnesaemia to the list of adverse drug reactions (ADRs), with the frequency common, based on an updated analysis of data submitted during the marketing authorisation procedure. The Package Leaflet is updated accordingly. In addition, the MAH proposed to update	07/07/2022	26/09/2022	SmPC and PL	Section 4.8 of the SmPC has been updated to add hypokalaemia and hypomagnesaemia to the list of adverse drug reactions (ADRs), with the frequency common, based on a reanalysis of data submitted during the initial marketing authorisation procedure. Section 4.2 of the SmPC has been updated to clarify recommendations for dose reductions. Sections 4.2 and 4.4 of the SmPC were

	the current information in section 4.2 of the SmPC to improve clarity and provide more specific guidance. Section 4.4 was updated to also reflect ILD-like adverse reactions. The MAH also took the opportunity to introduce editorial changes in section 4.8 of the SmPC. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data				harmonized to reflect consistently ILD and ILD-like reactions. In addition, examples of Grade 4 skin reactions were removed from section 4.2 of the SmPC. Finally, in Section 4.8 of the SmPC, the word "paronychia" has been replaced by "nail toxicity". For more information, please refer to the Summary of Product Characteristics.