Jubbonti

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
PSUSA/954/202409	Periodic Safety Update EU Single assessment - denosumab (indicated for osteoporosis and for bone loss associated with hormone ablation in prostate cancer)	22/05/2025	17/07/2025	SmPC	Please refer to PSUSA/00000954/202409 EPAR: Scientific conclusions and grounds recommending the variation to the terms of the marketing authorisation
N/0006	Minor change in labelling or package leaflet not	09/01/2025	17/07/2025	Labelling and	

[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).

	connected with the SPC (Art. 61.3 Notification)			PL	
IB/0005	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	20/11/2024	17/07/2025	SmPC, Annex II, Labelling and PL	To update sections 4.4 and 4.8 of the SmPC in order to update a warning regarding hypocalcaemia and to include reports of life-threatening events and fatal cases occurred in the post marketing setting based on the cumulative review of the MAH of the reference products safety database and literature. The Package Leaflet is updated accordingly. In addition the MAH has taken this opportunity to update the details for the local representatives in CZ, LU, DK, NO, SV and UK (NI).
WS/2772	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.I.b.z - Change in control of the AS - Other variation	07/11/2024	n/a		
II/0002/G	This was an application for a group of variations. B.I.a.3.c - Change in batch size (including batch size ranges) of AS or intermediate - The change requires assessment of the comparability of a biological/immunological AS B.I.a.4.z - Change to in-process tests or limits applied during the manufacture of the AS - Other variation	31/10/2024	n/a		
IB/0003/G	This was an application for a group of variations. B.II.e.3.z - Change in test procedure for the	08/10/2024	n/a		

	immediate packaging of the finished product - Other variation B.II.e.3.z - Change in test procedure for the immediate packaging of the finished product - Other variation				
IA/0001	B.II.b.5.a - Change to in-process tests or limits applied during the manufacture of the finished product - Tightening of in-process limits	01/08/2024	n/a		