Yorvipath

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/0008	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	27/02/2025		PL	
PSUSA/173/202405	Periodic Safety Update EU Single assessment - palopegteriparatide	28/11/2024	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/0007/G	This was an application for a group of variations. B.IV.1.z - Change of a measuring or administration device - Other variation B.IV.1.z - Change of a measuring or administration device - Other variation B.IV.1.b - Change of a measuring or administration device - Deletion of a device B.IV.1.b - Change of a measuring or administration device - Deletion of a device	12/11/2024		SmPC, Labelling and PL	
IB/0005	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	26/07/2024		SmPC and PL	
IAIN/0004	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	11/04/2024	n/a		
IB/0002	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	09/04/2024		SmPC	
IB/0003/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.c - Stability of AS - Change in the re-test period/storage period or storage conditions - Change to an approved stability protocol	08/04/2024	n/a		

IB/0001	B.I.d.z - Stability of AS - Other variation	25/03/2024	n/a		