Macitentan Accord

Procedural steps taken and scientific information after the authorisation*

*Due to the Agency`s update of its procedure management systems, an additional document, reflecting the historical lifecycle may be available in the 'Assessment history' section. For the complete product lifecycle procedures, you may need to also refer to **EPAR - Procedural steps taken and scientific information after authorisation (archive)**.

Application number	Scope	Opinion/ Notification [1] issued on	Commission Decision Issued [2] / amended on	Product Information affected [3]	Summary
Variation type IB /	Outcome:	23/07/2026		SmPC	

[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).

EMA/VR/0000350552	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. C.2 Change(s) in the summary of product characteristics, labelling or package leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - C.2.a) Implementation of change(s) for which no new additional data is required to be submitted by the holder - Accepted Type IB, C.2.a - to submit type IB (C.2.a) variation application to update sections 4.8, 5.1 and 5.2 of the SmPC in-line with the information of the reference product following approval of same change in reference product (Opsumit via procedure number: EMA/VR/0000324354) through work-sharing procedure for Macitentan. Additionally, the MAH has updated sections 4.1, 4.2, 4.3 and 4.4 of the SmPC with editorial changes in-line information with the reference product.				