DECTOVA

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 /	C.I HUMAN AND VETERINARY MEDICINAL	10/11/2025		SmPC, Annex	To update Section 7 of the SmPC, Section 11 of the

[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/0000308615	PRODUCTS - C.I.z Other variation - Accepted C.I.z (Type IB) – To update Section 7 of the SmPC, Section 11 of the Labelling and Section 6 of the Package Leaflet by adding the Postal Code to the MAH address. In addition, the MAH took the opportunity to implement editorial changes by: (1) correcting typographical errors throughout the Product Information, (2) deleting the local representative for UK(NI) in line with the QRD template, (3) updating the details of the local representative for IS, (5) updating the links to Appendix V in line with the QRD template, and (6) deleting the manufacturer "Glaxo Operations UK Ltd" in the HR Package Leaflet.			II, Labelling and PL	Labelling and Section 6 of the Package Leaflet by adding the Postal Code to the MAH address. In addition, the MAH took the opportunity to implement editorial changes by: (1) correcting typographical errors throughout the Product Information, (2) deleting the local representative for UK(NI) in line with the QRD template, (3) updating the details of the local representative for IS, (5) updating the links to Appendix V in line with the QRD template, and (6) deleting the manufacturer "Glaxo Operations UK Ltd" in the HR Package Leaflet.
Annual reassessment - H / EMA/S/0000265004	- Annual Reassessment - Accepted 6th annual re-assessment	20/08/2025		Annex II	The CHMP, having reviewed the evidence of compliance with the specific obligations and the impact of the data submitted by the MAH on the benefit/risk profile of the medicinal product, concluded that marketing authorisation of DECTOVA should be maintained. Annex II of the PI is amended to update the due date for SOB1.