Vantobra

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/0010	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	14/10/2023		SmPC	
R/0009	Renewal of the marketing authorisation.	20/07/2023	15/09/2023	SmPC and PL	Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of Vantobra in the approved indication remains favourable 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).

					therefore recommended the renewal of the marketing authorisation with unlimited validity.
PSUSA/10370 /202209	Periodic Safety Update EU Single assessment - tobramycin (nebuliser solution) (centrally authorised product only)	25/05/2023	26/07/2023	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/10370/202209.
IA/0007/G	This was an application for a group of variations. B.II.d.1.a - Change in the specification parameters and/or limits of the finished product - Tightening of specification limits B.III.1.a.2 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer	09/02/2022	n/a		
PSUSA/10370 /202009	Periodic Safety Update EU Single assessment - tobramycin (nebuliser solution) (centrally authorised product only)	09/04/2021	n/a		PRAC Recommendation - maintenance
IB/0006	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	12/01/2021	04/02/2022	SmPC and PL	
PSUSA/10370 /201909	Periodic Safety Update EU Single assessment - tobramycin (nebuliser solution) (centrally authorised product only)	17/04/2020	n/a		PRAC Recommendation - maintenance
IA/0002	B.III.1.a.2 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer	27/09/2019	n/a		

IAIN/0001	A.2.a - Administrative change - Change in the (invented) name of the medicinal product for CAPs	12/04/2019	04/02/2022	SmPC, Labelling and PL	