EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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
IAIN/0011	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	20/10/2017	n/a		
PSUSA/10370 /201703	Periodic Safety Update EU Single assessment tobramycin (nebuliser solution) (centrally authorised product only)	28/09/2017	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).

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N/0010	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	21/09/2017		PL	
PSUSA/10370 /201609	Periodic Safety Update EU Single assessment - tobramycin (nebuliser solution) (centrally authorised product only)	06/04/2017	n/a		PRAC Recommendation - maintenance
IAIN/0007/G	This was an application for a group of variations. B.I.b.1.c - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Addition of a new specification parameter to the specification with its corresponding test method B.III.1.a.3 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from a new manufacturer (replacement or addition)	28/11/2016	n/a		
N/0006	Inclusion of the 2D barcode on the label of the outer carton and reduction of the label text on the printed pouch label. In addition, the MAH updated the list of local representatives at the end of the Package Leaflet to include all the member states in accordance with the QRD guidance and the MAH revised the contact details of the local representatives for NL, UK, ES and PT. Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	24/10/2016		Labelling and PL	

PSUSA/10370 /201603	Periodic Safety Update EU Single assessment - tobramycin (nebuliser solution) (centrally authorised product only)	29/09/2016	n/a		PRAC Recommendation - maintenance
IA/0005	B.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place	15/09/2016	n/a		
IA/0004	B.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place	24/08/2016	n/a		
PSUSA/10370 /201509	Periodic Safety Update EU Single assessment - tobramycin (nebuliser solution) (centrally authorised product only)	14/04/2016	n/a		PRAC Recommendation - maintenance
II/0001/G	This was an application for a group of variations. B.II.b.4.d - Change in the batch size (including batch size ranges) of the finished product - The change relates to all other pharmaceutical forms manufactured by complex manufacturing processes B.II.e.1.a.3 - Change in immediate packaging of the finished product - Qualitative and quantitative composition - Sterile medicinal products and biological/immunological medicinal products B.II.b.1.f - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the FP - Site where any manufacturing operation(s) take place, except batch	24/09/2015	30/09/2016	SmPC, Labelling and PL	

	release, batch control, and secondary packaging, for sterile medicinal products (including those that are aseptically manufactured) excluding biological/ immunological medicinal products B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site				