Trixeo Aerosphere

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
IA/0008	A.7 - Administrative change - Deletion of manufacturing sites	19/05/2022		Annex II and PL	
PSUSA/10908 /202106	Periodic Safety Update EU Single assessment - formoterol fumarate dihydrate / glycopyrronium bromide / budesonide	13/01/2022	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/0004/G	This was an application for a group of variations. B.II.e.5.b - Change in pack size of the finished product - Deletion of a pack size(s) B.II.g.5.b - Implementation of changes foreseen in an approved change management protocol - Requires further supporting data	01/10/2021		SmPC, Labelling and PL	
IA/0006	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	22/09/2021	n/a		
PSUSA/10908 /202012	Periodic Safety Update EU Single assessment - formoterol fumarate dihydrate / glycopyrronium bromide / budesonide	08/07/2021	n/a		PRAC Recommendation - maintenance
IAIN/0001/G	This was an application for a group of variations. B.II.b.2.c.1 - Change to importer, batch release arrangements and quality control testing of the FP - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	17/02/2021		SmPC, Annex II and PL	