



Triexo 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
N/0017	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	23/11/2023		PL	
WS/2521	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008.	19/10/2023	n/a		

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).



	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation				
WS/2457/G	<p>This was an application for a group of variations following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008.</p> <p>B.II.f.1.b.1 - Stability of FP - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)</p> <p>B.II.d.1.g - Change in the specification parameters and/or limits of the finished product - Addition or replacement (excluding biological or immunological product) of a specification parameter with its corresponding test method as a result of a safety or quality issue</p> <p>B.II.d.1.e - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range</p> <p>A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient</p> <p>A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient</p>	31/08/2023		SmPC	<p>The SmPC section 6.3 Annex II has been updated as follows:</p> <p>Shelf-life 3 years</p>

PSUSA/10908 /202212	Periodic Safety Update EU Single assessment - formoterol fumarate dihydrate / glycopyrronium bromide / budesonide	06/07/2023	n/a		PRAC Recommendation - maintenance
IG/1603/G	This was an application for a group of variations. 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 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 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	14/04/2023	n/a		
PSUSA/10908 /202206	Periodic Safety Update EU Single assessment - formoterol fumarate dihydrate / glycopyrronium bromide / budesonide	12/01/2023	n/a		PRAC Recommendation - maintenance
IG/1542	B.III.1.a.1 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from an already approved manufacturer	16/09/2022	n/a		
PSUSA/10908 /202112	Periodic Safety Update EU Single assessment - formoterol fumarate dihydrate / glycopyrronium	07/07/2022	n/a		PRAC Recommendation - maintenance

	bromide / budesonide				
IA/0008	A.7 - Administrative change - Deletion of manufacturing sites	19/05/2022	15/05/2023	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
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	24/06/2022	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	17/02/2021	24/06/2022	SmPC, Annex II and PL	

	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				
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