EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Airexar Spiromax

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
PSUSA/10531 /201802	Periodic Safety Update EU Single assessment - fluticasone / salmeterol (for centrally authorised products)	06/09/2018	n/a		PRAC Recommendation - maintenance
PSUSA/10531 /201708	Periodic Safety Update EU Single assessment - fluticasone / salmeterol (for centrally authorised products)	08/03/2018	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).

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5520
Send a question via our website www.ema.europa.eu/contact

IA/0007	B.II.e.7.b - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier	28/02/2018	n/a		
IB/0006	B.I.z - Quality change - Active substance - Other variation	05/01/2018	n/a		
PSUSA/10531 /201702	Periodic Safety Update EU Single assessment - fluticasone / salmeterol (for centrally authorised products)	28/09/2017	n/a		PRAC Recommendation - maintenance
IA/0004/G	This was an application for a group of variations. 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 B.II.e.3.a - Change in test procedure for the immediate packaging of the finished product - Minor changes to an approved test procedure B.II.e.3.a - Change in test procedure for the immediate packaging of the finished product - Minor changes to an approved test procedure B.II.e.3.b - Change in test procedure for the immediate packaging of the finished product - Other changes to a test procedure (including replacement or addition) B.II.e.6.b - Change in any part of the (primary) packaging material not in contact with the finished product formulation - Change that does not affect the product information B.III.2.b - Change to comply with Ph. Eur. or with a	22/09/2017	n/a		

	national pharmacopoeia of a Member State - Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State				
IAIN/0003	C.I.3.a - Change(s) in the SPC, Labelling or PL intended to implement the outcome of a procedure concerning PSUR or PASS or the outcome of the assessment done under A 45/46 - Implementation of wording agreed by the competent authority	08/06/2017	19/02/2018	SmPC and PL	
IAIN/0001	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	09/03/2017	19/02/2018	SmPC, Labelling and PL	