EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Budesonide/Formoterol Teva

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
A31/0002	Pursuant to Article 31 of Directive 2001/83/EC, the European Commission initiated a procedure on 27 April 2015 further to concerns over the risk of pneumonia in patients with chronic obstructive pulmonary disease when treated with inhaled corticosteroids containing medicinal products. The PRAC was requested to assess the impact thereof on the benefit-risk balance of inhaled corticosteroids containing medicinal products and to give its	28/04/2016	06/07/2016	SmPC and PL	Please refer to the assessment report: Inhaled corticosteroids containing products indicated in the treatment of chronic obstructive pulmonary disease- EMEA/H/A-31/1415

[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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	recommendation whether the marketing authorisation of these products should be maintained, varied, suspended or revoked.				
IB/0008/G	This was an application for a group of variations. B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)	14/06/2016	n/a		
PSUSA/10202 /201510	Periodic Safety Update EU Single assessment - BUDESONIDE, FORMOTEROL	13/05/2016	n/a		PRAC Recommendation - maintenance
IB/0007	B.II.e.1.z - Change in immediate packaging of the finished product - Other variation	22/04/2016	n/a		
PSUSA/10202 /201504	Periodic Safety Update EU Single assessment - BUDESONIDE, FORMOTEROL FUMARATE DIHYDRATE	06/11/2015	n/a		PRAC Recommendation - maintenance
IB/0005/G	This was an application for a group of variations. A.1 - Administrative change - Change in the name and/or address of the MAH B.II.f.1.z - Stability of FP - Change in the shelf-life or storage conditions of the finished product - Other	17/09/2015	06/07/2016	SmPC, Annex II, Labelling and PL	

	variation				
IA/0003/G	This was an application for a group of variations. B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	24/07/2015	n/a		
II/0001/G	This was an application for a group of variations. B.II.b.1.c - Replacement or addition of a manufacturing site for the FP - Site where any manufacturing operation(s) take place, except batch release/control, and secondary packaging, for biol/immunol medicinal products or pharmaceutical forms manufactured by complex manufacturing processes B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	26/03/2015	n/a		