EMA/473428/2020

Trimbow

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/10617 /202001	Periodic Safety Update EU Single assessment - beclometasone / formoterol / glycopyrronium bromide	04/09/2020	n/a		PRAC Recommendation - maintenance
IAIN/0014	A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer	02/07/2020		Annex II and	

[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).

	responsible for batch release			PL	
WS/1734	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	27/02/2020	n/a		
PSUSA/10617 /201907	Periodic Safety Update EU Single assessment - beclometasone / formoterol / glycopyrronium bromide	13/02/2020	n/a		PRAC Recommendation - maintenance
IA/0011	B.II.e.7.b - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier	25/10/2019	n/a		
IA/0007/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	13/08/2019	n/a		

PSUSA/10617 /201901	Periodic Safety Update EU Single assessment - beclometasone / formoterol / glycopyrronium bromide	11/07/2019	n/a		PRAC Recommendation - maintenance
PSUSA/10617 /201807	Periodic Safety Update EU Single assessment - beclometasone / formoterol / glycopyrronium bromide	14/02/2019	n/a		PRAC Recommendation - maintenance
II/0002	Extension of indication, based on results from two Phase III studies: Triple 7 (CCD-05993AA1-07) and Triple 8 (CCD-05993AA1-08), to include maintenance treatment in adult patients with moderate to severe chronic obstructive pulmonary disease (COPD) who are not adequately treated by combination of a long-acting beta2-agonist and a long-acting muscarinic antagonist. Sections 4.1, 4.4, 4.8 and 5.1 of the SmPC are updated accordingly to reflect the studies' results and add a new warning with regards to the risk of visual disturbance associated with beclometasone following the PSUSA recommendation PSUSA/00000306/201612. The package leaflet and the risk management plan (version 6.0) are updated accordingly. Additionally changes to annex IIIA are introduced in the Braille section to bring in line with the QRD template. C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one	13/12/2018	23/01/2019	SmPC, Labelling and PL	Please refer to the scientific discussion Trimbow EMEA/H/C/004257/II/0002.
PSUSA/10617 /201801	Periodic Safety Update EU Single assessment - beclometasone / formoterol / glycopyrronium	12/07/2018	n/a		PRAC Recommendation - maintenance

	bromide				
IA/0004/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	18/05/2018	n/a		
IA/0001/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	30/11/2017	n/a		