Trydonis

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/0039	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	04/11/2024		Labelling and PL	
WS/2659/G	This was an application for a group of variations following a worksharing procedure according to Article 20 of Commission Regulation (EC) No	19/09/2024	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).

	1234/2008. B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation B.II.a.3.b.2 - Changes in the composition (excipients) of the finished product - Other excipients - Qualitative or quantitative changes in one or more excipients that may have a significant impact on the safety, quality or efficacy of the product B.II.b.5.a - Change to in-process tests or limits applied during the manufacture of the finished product - Tightening of in-process limits				
IA/0037	B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	24/04/2024	n/a		
PSUSA/10617 /202307	Periodic Safety Update EU Single assessment - beclometasone / formoterol / glycopyrronium bromide	08/02/2024	n/a		PRAC Recommendation - maintenance
IG/1701	B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation	02/02/2024	n/a		
WS/2604	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	25/01/2024	n/a		

IB/0033/G	This was an application for a group of variations. B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process B.III.1.a.3 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from a new manufacturer (replacement or addition) B.I.b.1.c - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Addition of a new specification parameter to the specification with its corresponding test method	03/01/2024	n/a		
WS/2408	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.III.1.a.3 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from a new manufacturer (replacement or addition)	14/12/2023	n/a		
IA/0031	B.II.e.7.b - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier	31/07/2023	n/a		
WS/2440/G	This was an application for a group of variations following a worksharing procedure according to Article 20 of Commission Regulation (EC) No	04/05/2023	n/a		

	1234/2008. 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.b.1.b - Replacement or addition of a manufacturing site for the FP - Primary packaging site B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure B.II.b.1.e - Replacement or addition of a manufacturing site for the FP - Site where any manufacturing operation(s) take place, except batch-release, batch control, primary and secondary packaging, for non-sterile medicinal products				
IG/1592/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites B.III.2.b - Change to comply with Ph. Eur. or with 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	13/02/2023	n/a		
IG/1590	B.III.2.b - Change to comply with Ph. Eur. or with 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	09/02/2023	n/a		

	Member State				
PSUSA/10617 /202207	Periodic Safety Update EU Single assessment - beclometasone / formoterol / glycopyrronium bromide	09/02/2023	n/a		PRAC Recommendation - maintenance
R/0025	Renewal of the marketing authorisation.	13/10/2022	02/12/2022	SmPC, Annex II, Labelling and PL	Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of Trydonis in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
IB/0024	B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation	30/03/2022	n/a		
IG/1494/G	This was an application for a group of variations. B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation 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	18/03/2022	n/a		
N/0022	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	07/03/2022	02/12/2022	PL	
IB/0021	B.II.b.3.z - Change in the manufacturing process of	02/03/2022	n/a		

	the finished or intermediate product - Other variation				
PSUSA/10617 /202107	Periodic Safety Update EU Single assessment - beclometasone / formoterol / glycopyrronium bromide	10/02/2022	n/a		PRAC Recommendation - maintenance
IG/1478	B.II.e.7.b - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier	01/02/2022	n/a		
X/0015	Annex I_2.(c) Change or addition of a new strength/potency Annex I_2.(d) Change or addition of a new pharmaceutical form	14/10/2021	06/01/2022	SmPC, Labelling and PL	
IG/1469	A.5.b - Administrative change - Change in the name and/or address of a manufacturer/importer of the finished product, including quality control sites (excluding manufacturer for batch release)	03/12/2021	n/a		
PSUSA/10617 /202101	Periodic Safety Update EU Single assessment - beclometasone / formoterol / glycopyrronium bromide	02/09/2021	n/a		PRAC Recommendation - maintenance
IG/1422/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	13/07/2021	n/a		

	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				
WS/2075	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.II.e.1.a.2 - Change in immediate packaging of the finished product - Qualitative and quantitative composition - Semi-solid and non-sterile liquid pharmaceutical forms	08/07/2021	n/a		
WS/2074	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.II.d.1.e - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range	24/06/2021	n/a		
IG/1385	B.II.e.7.a - Change in supplier of packaging components or devices (when mentioned in the dossier) - Deletion of a supplier	03/05/2021	n/a		

PSUSA/10617 /202007	Periodic Safety Update EU Single assessment - beclometasone / formoterol / glycopyrronium bromide	11/02/2021	n/a		PRAC Recommendation - maintenance
IG/1285/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	18/09/2020	n/a		
PSUSA/10617 /202001	Periodic Safety Update EU Single assessment - beclometasone / formoterol / glycopyrronium bromide	04/09/2020	n/a		PRAC Recommendation - maintenance
IAIN/0008	A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer responsible for batch release	02/07/2020	05/07/2021	Annex II and PL	
IG/1226/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	24/03/2020	n/a		

	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				
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
PSUSA/10617 /201901	Periodic Safety Update EU Single assessment - beclometasone / formoterol / glycopyrronium bromide	11/07/2019	n/a		PRAC Recommendation - maintenance
WS/1554	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. 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	28/02/2019	09/04/2019	SmPC and PL	Please refer to the scientific discussion Riarify EMEA/H/C/004836/WS1554/0002 and Trydonis EMEA/H/C/004702/WS1554/0002.

	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. C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one				
PSUSA/10617 /201807	Periodic Safety Update EU Single assessment - beclometasone / formoterol / glycopyrronium bromide	14/02/2019	n/a		PRAC Recommendation - maintenance