Elebrato Ellipta

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
IG/1656/G	This was an application for a group of variations. B.I.a.1.f - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Changes to quality control testing arrangements for the AS -replacement or addition of a site where	22/09/2023	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).

	batch control/testing takes place B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure B.I.a.1.i - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Introduction of a new site of micronisation				
IG/1653/G	This was an application for a group of variations. B.I.a.1.i - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Introduction of a new site of micronisation B.I.a.1.f - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Changes to quality control testing arrangements for the AS -replacement or addition of a site where batch control/testing takes place	18/09/2023	n/a		
WS/2460	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance	31/08/2023		SmPC, Labelling and PL	

	data				
WS/2504/G	This was an application for a group of variations following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.I.b.2.z - Change in test procedure for AS or starting material/reagent/intermediate - Other variation B.I.b.2.z - Change in test procedure for AS or starting material/reagent/intermediate - Other variation	20/07/2023	n/a		
IG/1633/G	This was an application for a group of variations. B.I.a.1.f - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Changes to quality control testing arrangements for the AS -replacement or addition of a site where batch control/testing takes place 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 B.I.a.1.a - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The proposed manufacturer is part of the same pharmaceutical group as the currently approved manufacturer	18/07/2023	n/a		

	B.I.a.1.a - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The proposed manufacturer is part of the same pharmaceutical group as the currently approved manufacturer				
WS/2358	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. Update of sections 4.4 and 4.8 of the SmPC in order to add 'urinary retention' and 'dysuria' to the list of adverse drug reactions (ADRs) with frequency rare and to amend a warning regarding urinary retention ; the Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI and bring it in line with the latest QRD template. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	16/02/2023		SmPC and PL	Based on the cumulative review of cases of Dysuria and Urinary retention reported in the post-marketing setting, and observed in clinical trial data, a causal association between Elebrato Ellipta and Trelegy Ellipta and the adverse effects "Dysuria" and "Urinary retention" is considered a possibility. Therefore, these events are added as new undesirable effects under section 4.8 of the SmPC with the frequency "rare". As cases of acute urinary retention have been observed in a post-marketing setting, a warning regarding the prescription of this product to patients with urinary retention or risk factors of urinary retention was also added. For more information, please refer to the Summary of Product Characteristics.
IG/1546	B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	25/01/2023	n/a		
IG/1541/G	This was an application for a group of variations. B.I.a.1.f - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS -	26/09/2022	n/a		

	Changes to quality control testing arrangements for the AS -replacement or addition of a site where batch control/testing takes place B.I.a.4.z - Change to in-process tests or limits applied during the manufacture of the AS - Other variation B.I.a.1.a - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The proposed manufacturer is part of the same pharmaceutical group as the currently approved manufacturer				
IG/1540	B.I.b.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits	01/09/2022	n/a		
R/0026	Renewal of the marketing authorisation.	19/05/2022	15/07/2022	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 Elebrato Ellipta in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
IG/1517	B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	06/07/2022	n/a		
IG/1461/G	This was an application for a group of variations. B.I.a.1.f - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Changes to quality control testing arrangements for	24/01/2022	n/a		

	the AS -replacement or addition of a site where batch control/testing takes place B.I.a.1.a - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The proposed manufacturer is part of the same pharmaceutical group as the currently approved manufacturer				
WS/2130/G	This was an application for a group of variations following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	11/11/2021	15/07/2022	SmPC and PL	Following an update of the Company Core Safety Information (CCSI) of the Global Datasheet (GDS), dysgeusia was added as an adverse drug reaction (ADR) at a frequency of uncommon. Dysgeusia was not previously identified as an ADR for combination inhaled fluticasone furoate/umeclidinium bromide/vilanterol trifenatate (FF/UMEC/VI) in Chronic Obstructive Pulmonary Disease (COPD) clinical trial safety database but mainly supported by reference to the safety profile FF/UMEC/VI from asthma studies, literature case reports and review of cases of dysgeusia observed for the mono (UMEC) and dual constituents (UMEC/VI) of FF/UMEC/VI, both authorised for use in COPD. Frequency of dysgeusia was calculated based on the incidence in the triple therapy COPD clinical trials (CTT116855, CTT116853, 200812). Furthermore, based on assessment of study CTT116855 and postmarketing safety data for FF/UMEC/VI, intraocular pressure increased with frequency rare and vision blurred, glaucoma and eye pain with frequency uncommon were identified as new ADRS. For more information, please refer to the Summary of Product Characteristics.

PSUSA/10653 /202103	Periodic Safety Update EU Single assessment - fluticasone furoate / umeclidinium / vilanterol	30/09/2021	n/a		PRAC Recommendation - maintenance
IG/1443	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	13/09/2021	n/a		
IG/1340	A.7 - Administrative change - Deletion of manufacturing sites	16/02/2021	16/09/2021	Annex II and PL	
IG/1330	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 responsible for importation and/or batch release - Not including batch control/testing	22/01/2021	n/a		
PSUSA/10653 /202003	Periodic Safety Update EU Single assessment - fluticasone furoate / umeclidinium / vilanterol	01/10/2020	n/a		PRAC Recommendation - maintenance
WS/1814	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	10/09/2020	16/09/2021	SmPC and PL	
WS/1899/G	This was an application for a group of variations following a worksharing procedure according to	03/09/2020	n/a		

	Article 20 of Commission Regulation (EC) No 1234/2008. 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 B.I.a.1.a - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The proposed manufacturer is part of the same pharmaceutical group as the currently approved manufacturer B.I.a.3.a - Change in batch size (including batch size ranges) of AS or intermediate - Up to 10-fold increase compared to the originally approved batch size				
WS/1736/G	This was an application for a group of variations following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site B.II.b.1.b - Replacement or addition of a manufacturing site for the FP - Primary packaging site B.II.b.1.c - Replacement or addition of a manufacturing site for the FP - Site where any	25/06/2020	n/a		

	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.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				
N/0016	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	17/03/2020	16/09/2021	PL	
IG/1159	A.1 - Administrative change - Change in the name and/or address of the MAH	29/11/2019	09/01/2020	SmPC, Annex II, Labelling and PL	
PSUSA/10653 /201903	Periodic Safety Update EU Single assessment - fluticasone furoate / umeclidinium / vilanterol	03/10/2019	n/a		PRAC Recommendation - maintenance
PSUSA/10653 /201809	Periodic Safety Update EU Single assessment - fluticasone furoate / umeclidinium / vilanterol	11/04/2019	n/a		PRAC Recommendation - maintenance
N/0010	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	29/03/2019	09/01/2020	Labelling	
IG/1052	B.II.b.2.c.2 - Change to importer, batch release arrangements and quality control testing of the FP - Including batch control/testing	22/01/2019	09/01/2020	Annex II and PL	
N/0007	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	11/12/2018	09/01/2020	PL	

WS/1369	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. To modify the approved current COPD therapeutic indication to include the possibility to use Trelegy Ellipta and Elebrato Ellipta as maintenance treatment in patients not adequately treated by dual LABA/LAMA therapy. Additionally cross reference to the effects on symptoms is added. This is based on the results of study CTT116855 and study 200812 and the population PK report 208059. As a consequence, the indication section (4.1), Undesirable effects section (4.8), Pharmacodynamic Properties section (5.1), Pharmacokinetic properties section (5.2) and Preclinical Safety data section (5.3) of the SmPC have been updated. The package leaflet has been updated accordingly. A minor amendment in annex II is also introduced to bring it in line with the QRD template. Additionally, minor changes have been introduced to the RMP to bring it in line with the new template (revision 2). C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one	20/09/2018	31/10/2018	SmPC and PL	Please refer to the published assessment report Elebrato Ellipta-Trelegy Ellipta-WS-1369: EPAR - Assessment Report – Variation
IG/0987/G	This was an application for a group of variations. A.4 - Administrative change - Change in the name	24/10/2018	n/a		

	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 A.7 - Administrative change - Deletion of manufacturing sites A.7 - Administrative change - Deletion of manufacturing sites A.7 - Administrative change - Deletion of manufacturing sites				
PSUSA/10653 /201803	Periodic Safety Update EU Single assessment - fluticasone furoate / umeclidinium / vilanterol	04/10/2018	n/a		PRAC Recommendation - maintenance
WS/1437/G	This was an application for a group of variations following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. 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 B.I.c.1.a - Change in immediate packaging of the AS - Qualitative and/or quantitative composition	20/09/2018	n/a		
N/0005	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	21/08/2018	31/10/2018	PL	
IG/0931	A.6 - Administrative change - Change in ATC	30/05/2018	31/10/2018	SmPC,	

	Code/ATC Vet Code			Labelling and PL	