EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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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/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 the AS -replacement or addition of a site where batch	24/01/2022	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).

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	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	16/02/2022	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	16/02/2022	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	07/01/2021	SmPC and PL	
WS/1899/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.	03/09/2020	n/a		

	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 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	25/06/2020	n/a		

	arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place				
IG/1159	A.1 - Administrative change - Change in the name and/or address of the MAH	29/11/2019	07/01/2021	SmPC, Annex II, Labelling and PL	