Revinty 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
WS/2438/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.13 - Other variations not specifically covered	06/07/2023		SmPC, Labelling and PL	

[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).

	elsewhere in this Annex which involve the submission of studies to the competent authority C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data				
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/1577/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	06/01/2023	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 - 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	26/09/2022	n/a		

	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				
WS/2274	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. Submission of the final report from study HZA114971 listed as a category 3 study in the RMP. This is a multicentre randomised, double-blind, placebo-controlled, parallel-group study to evaluate the effects of a one-year regimen of orally inhaled fluticasone furoate 50 mcg once daily on growth velocity in prepubertal, paediatric subjects with asthma. The RMP version 11.1 has also been submitted. C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority	15/09/2022	n/a		
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		
IG/1517	B.I.b.2.a - Change in test procedure for AS or	06/07/2022	n/a		

	starting material/reagent/intermediate - Minor changes to an approved test procedure				
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 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	24/01/2022	n/a		
PSUSA/10099 /202105	Periodic Safety Update EU Single assessment - fluticasone furoate / vilanterol	13/01/2022	n/a		PRAC Recommendation - maintenance
WS/2137	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	21/10/2021	02/12/2021	SmPC and PL	
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/1341/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites A.7 - Administrative change - Deletion of manufacturing sites	16/02/2021	02/12/2021	Annex II and PL	
IG/1339	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	27/01/2021	n/a		
WS/1968	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation	14/01/2021	n/a		
WS/1822	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	26/11/2020	02/12/2021	SmPC, Labelling and PL	
IG/1273	B.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP -	07/09/2020	n/a		

	Replacement/addition of a site where batch control/testing takes place				
WS/1568	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority	14/06/2019	n/a		
N/0042	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	24/04/2019	16/12/2019	Labelling	
WS/1522/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 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 A.7 - Administrative change - Deletion of manufacturing sites	07/02/2019	n/a		

	B.I.c.1.a - Change in immediate packaging of the AS - Qualitative and/or quantitative composition				
IG/1016	B.II.b.2.c.2 - Change to importer, batch release arrangements and quality control testing of the FP - Including batch control/testing	16/01/2019	16/12/2019	Annex II and PL	
T/0038	Transfer of Marketing Authorisation	27/11/2018	12/12/2018	SmPC, Labelling and PL	
PSUSA/10099 /201805	Periodic Safety Update EU Single assessment - fluticasone furoate / vilanterol	29/11/2018	n/a		PRAC Recommendation - maintenance
WS/1449	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	13/09/2018	12/12/2018	SmPC and PL	
N/0037	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	21/08/2018	12/12/2018	PL	
R/0033	Renewal of the marketing authorisation.	31/05/2018	26/07/2018	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 Revinty Ellipta in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
WS/1343	This was an application for a variation following a	14/06/2018	12/12/2018	Annex II	

	worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. Submission of final results of study HZA115150 (SLS-Asthma, Salford Asthma); this is an interventional post-authorisation safety Category 1 study to further investigate the risk of pneumonia (ANX005). Consequently, Annex II condition of the product information is updated. Moreover, an updated RMP version 10 is submitted to add information from the study, to update the important identified risk of pneumonia based on findings from the study, and to provide justifications for removal of the important potential risk of asthma related intubations and deaths and of missing information related to long term use in asthma (>1 year). C.I.11.b - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH where significant assessment is required				
WS/1283	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority	12/04/2018	n/a		

N/0034	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	10/04/2018	26/07/2018	PL	
PSUSA/10099 /201705	Periodic Safety Update EU Single assessment - fluticasone furoate / vilanterol	30/11/2017	n/a		PRAC Recommendation - maintenance
WS/1263/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.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	16/11/2017	n/a		
WS/1224	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	14/09/2017	07/03/2018	SmPC and PL	
WS/1157	This was an application for a variation following a worksharing procedure according to Article 20 of	18/05/2017	21/09/2017	SmPC and PL	

	Commission Regulation (EC) No 1234/2008. C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation				
WS/1101	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. Submission of HZC115151 study (A 12-month, open label, randomised, effectiveness study to evaluate fluticasone furoate (FF, GW685698)/vilanterol (VI, GW642444) Inhalation Powder delivered once daily via a Novel Dry Powder Inhaler (NDPI) compared with the existing COPD maintenance therapy alone in subjects with Chronic Obstructive Pulmonary Disease (COPD)) in order to update the safety information. Consequently the Annex II of the Product Information and the RMP version 9.0 are updated. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	21/04/2017	21/09/2017	Annex II	
WS/1030	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	21/04/2017	21/09/2017	SmPC, Labelling and PL	

WS/0992/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. Type II C.I.4: Update of sections 4.4, 4.8 and 5.1 of the SmPC in order to update the safety information and include data from the HZC113782 (SUMMIT) study (designed to investigate whether FF/VI-Furoate/Vilanterol could improve survival in patients with moderate chronic obstructive pulmonary disease (COPD) who had, or were at increased risk for cardiovascular disease (CV)). The Package Leaflet and Labelling are updated accordingly. The RMP v.9 is updated accordingly. Type II C.I.4: Update of section 4.8 of the SmPC in order to add "paradoxical bronchospasm" to the list of adverse reactions. The Package Leaflet and Labelling are updated accordingly. Type IB C.I.z: Update of section 5.1 the SmPC in order to correct an error identified in the pharmacodynamics section. C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation 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	21/04/2017	21/09/2017	SmPC, Labelling and PL	SUMMIT was a multi-centre, randomised, double-blind study evaluating the effect on survival of fluticasone furoate/vilanterol 92/22 micrograms compared with placebo in 16,485 subjects. The primary endpoint was all-cause mortality and a secondary endpoint was a composite of cardiovascular events. Prior to randomization, subjects were required to discontinue previous COPD medications used at baseline. Subjects were then randomized to receive either fluticasone furoate/vilanterol 92/22 micrograms, fluticasone furoate 92 micrograms, vilanterol 22 micrograms, or placebo, and treated for a mean of 1.7 years (SD = 0.9 years). Subjects had moderate COPD (mean percent post-bronchodilator screening FEV1 of 60% [SD = 6%]), and a history of, or an increased risk of cardiovascular disease. Mortality risk with fluticasone furoate/vilanterol was not significantly different compared with placebo (HR 0.88; 95% CI: 0.74 to 1.04; p=0.137), fluticasone furoate (HR 0.96; 95% CI: 0.81 to 1.15; p=0.681) or vilanterol (HR 0.91; 95% CI: 0.77 to 1.09; p=0.299). The risk of the cardiovascular composite event with fluticasone furoate/vilanterol was not significantly different compared with placebo (HR 0.93; 95% CI: 0.75 to 1.14), fluticasone furoate (HR 1.03; 95% CI: 0.83 to 1.28) or vilanterol (HR 0.94; 95% CI: 0.76 to 1.16). For more information on the SUMMIT study, please refer to the Summary of Product Characteristics. In peripheral blood mononuclear cells from subjects with COPD, a larger anti-inflammatory effect was seen in the presence of the combination of fluticasone furoate/vilanterol compared with fluticasone furoate alone at concentrations achieved with clinical doses. The

					enhanced anti-inflammatory effect of the LABA component was similar to that obtained with other ICS/LABA combinations.
WS/1028	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority	15/12/2016	n/a		
PSUSA/10099 /201605	Periodic Safety Update EU Single assessment - fluticasone furoate / vilanterol	01/12/2016	n/a		PRAC Recommendation - maintenance
N/0021	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	18/10/2016	21/09/2017	Labelling and PL	
WS/1025	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. C.I.1.b - Change(s) in the SPC, Labelling or PL intended to implement the outcome of a Union referral procedure - The product is not covered by the defined scope of the procedure but the change(s) implements the outcome of the procedure and no new additional data is required to be submitted by the MAH	13/10/2016	21/09/2017	SmPC	
WS/0986	This was an application for a variation following a worksharing procedure according to Article 20 of	29/09/2016	n/a		

	Commission Regulation (EC) No 1234/2008. B.I.d.1.a.4 - Stability of AS - Change in the re-test period/storage period - Extension or introduction of a re-test period/storage period supported by real time data				
IG/0715	B.II.e.6.b - Change in any part of the (primary) packaging material not in contact with the finished product formulation - Change that does not affect the product information	26/07/2016	n/a		
A31/0010	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 recommendation whether the marketing authorisation of these products should be maintained, varied, suspended or revoked.	28/04/2016	24/06/2016	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
WS/0957	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008.	23/06/2016	n/a		

	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation				
PSUSA/10099 /201511	Periodic Safety Update EU Single assessment - fluticasone furoate / vilanterol	09/06/2016	n/a		PRAC Recommendation - maintenance
WS/0863/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.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	14/01/2016	24/06/2016	Annex II and PL	
WS/0850	This was an application for a variation following a	17/12/2015	24/06/2016	SmPC, Annex	

	worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. Update of section 4.8 of the SmPC in order to add new ADR, muscle spasm, identified following routine pharmacovigilance with the frequency common. The Package Leaflet is updated accordingly. In addition, the Worksharing applicant (WSA) took the opportunity to update the details of local representatives in Iceland in the Package Leaflet, and to bring the PI in line with the latest QRD template version 9.1. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data			II and PL	
PSUSA/10099 /201505	Periodic Safety Update EU Single assessment - fluticasone furoate / vilanterol	03/12/2015	n/a		PRAC Recommendation - maintenance
WS/0772	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. Update of section 4.8 of the SmPC to include the terms anxiety and tremor with the frequency 'rare'. The Package Leaflet is updated accordingly. Additionally, the MAH took the opportunity to introduce minor editorial updates in the PI. C.I.4 - Change(s) in the SPC, Labelling or PL due to	24/09/2015	27/11/2015	SmPC, Labelling and PL	

	new quality, preclinical, clinical or pharmacovigilance data				
WS/0694	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. Update of SmPC sections: 4.4 to include medical conditions predisposing to cardiac arrhythmias e.g. heart rhythm abnormalities, thyrotoxicosis, uncorrected hypokalaemia, and section 4.8 to include palpitations and tachycardia as rare adverse reactions based on the analysis of safety data. The Package Leaflet is updated accordingly. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	25/06/2015	27/11/2015	SmPC and PL	
PSUSA/10099 /201411	Periodic Safety Update EU Single assessment - fluticasone furoate / vilanterol	11/06/2015	n/a		PRAC Recommendation - maintenance
IG/0554/G	This was an application for a group of variations. 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	19/05/2015	n/a		

	proposed manufacturer is part of the same pharmaceutical group as the currently approved manufacturer				
WS/0713/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. Update of the SmPC, Annex II and the RMP to revise due dates of commitments within the Pharmacovigilance plan; furthermore, updates to the MedDRA terms and additional information have been added to section SVI 4.4 and SVII 3.1.4 of the RMP. The requested grouped worksharing procedure proposed amendments to the Annex II and RMP. C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation C.I.11.b - Introduction of, or change(s) to, the obligations and conditions of a marketing	23/04/2015	27/11/2015	Annex II	

	authorisation, including the RMP - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH where significant assessment is required				
WS/0602/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. Grouped variation application as follows: - Type II variation to add the ADR 'hypersensitivity' to section 4.8 of the SmPC. The Package Leaflet has been updated accordingly. Further, editorial changes have been implemented in the SmPC and labelling. - Type IB variation to amend the due date in Annex II and the RMP for the provision of the CSR for Study HZC115151. The application included a revised RMP version 7.0. C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	18/12/2014	27/11/2015	SmPC, Annex II, Labelling and PL	This is a worksharing variation to amend the product information and RMP to include "Hypersensitivity" and amend the timelines for study HZC115151. The changes are appilcable for Relvar Ellipta and its duplicate product Revinty Ellipta.
PSUV/0002	Periodic Safety Update	04/12/2014	n/a		PRAC Recommendation - maintenance
IG/0496	B.II.e.6.a - Change in any part of the (primary) packaging material not in contact with the finished	20/11/2014	27/11/2015	SmPC, Labelling and	

	product formulation - Change that affects the product information			PL	