DuoResp Spiromax

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
II/0033/G	This was an application for a group of variations. Extension of Indication to include adolescents (12 years and older) for the regular treatment of asthma, where use of a combination (inhaled corticosteroid and long-acting β2 adrenoceptor agonist) is	22/04/2021	21/05/2021	SmPC, Annex II, Labelling and PL	Please refer to Scientific Discussion 'DuoResp Spiromax EMEA/H/C/002348/II/0033'.

[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).

	appropriate: in patients not adequately controlled with inhaled corticosteroids and "as needed" inhaled short-acting β2 adrenoceptor agonists; or in patients already adequately controlled on both inhaled corticosteroids and long-acting β2 adrenoceptor agonists. As a consequence, sections 4.1, 4.2, and 5.1 of the SmPC have been updated and the labelling and Package Leaflet have been updated accordingly. In addition, Changes were made to sections 4.4 and 4.8 of the SmPC to align information with the reference medicinal product, Symbicort Turbohaler. The MAH also took the opportunity to make administrative updates to the Greek, Islandic, Irish and Maltese local representatives phone numbers in the Package Leaflet. Furthermore, the PI is brought in line with the latest QRD template version 10.2. RMP version 3.3 is considered acceptable. C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one				
PSUSA/10585 /201908	Periodic Safety Update EU Single assessment - budesonide / formoterol	30/04/2020	13/07/2020	SmPC	Please refer to PSUSA-10585-201908 EPAR: Scientific conclusions and grounds recommending the variation to the terms of the marketing authorisation.
IA/0034	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	29/06/2020	n/a		

II/0030	Updates of section 4.2 to add information on the use as reliever for allergen- and exercise-induced bronchoconstriction, section 4.4 to revise the general warning on complete withdrawal of inhaled corticosteroids; and section 6.6 to update the statement on special precautions for disposal and other handling following assessment of the same changes for the reference product Symbicort Turbohaler 160 mcg/4.5 mcg. The Package Leaflet (PL) and Labelling are updated accordingly. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the PL and to introduce some minor editorial amendments in the PI for the following languages: FR, NO and PT. C.I.2.b - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Change(s) require to be further substantiated by new additional data to be submitted by the MAH	30/01/2020	09/03/2020	SmPC and PL	In section 4.2 of the SmPC, information related to the use of DuoResp Spiromax as reliever therapy for allergen- and exercise-induced bronchoconstriction was added to inform that preventative use of DuoResp Spiromax should be discussed between physician and patient; the recommended use should take into consideration the frequency of need. In case of frequent need of bronchodilation without corresponding need for an increased dose of inhaled corticosteroids, an alternative reliever should be used. Section 4.4 of the SmPC is updated to inform healthcare professionals that the complete withdrawal of inhaled corticosteroids should not be considered unless it is temporarily required to confirm diagnosis of asthma. Section 6.6 of the SmPC is updated to reflect that any unused medicinal product or waste material should be disposed of in accordance with local requirements. The PL is updated accordingly.
IA/0032	B.II.b.5.b - Change to in-process tests or limits applied during the manufacture of the finished product - Addition of a new test(s) and limits	31/01/2020	n/a		
IA/0029/G	This was an application for a group of variations. B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor	28/06/2019	n/a		

	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.II.c.2.a - Change in test procedure for an excipient - 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 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				
N/0028	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	12/06/2019	09/03/2020	PL	
R/0027	Renewal of the marketing authorisation.	31/01/2019	08/04/2019	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 DuoResp Spiromax in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
II/0026	B.II.d.1.e - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range	08/11/2018	n/a		
II/0024/G	This was an application for a group of variations. B.II.b.3.b - Change in the manufacturing process of the finished or intermediate product - Substantial changes to a manufacturing process that may have a	26/07/2018	n/a		

	significant impact on the quality, safety and efficacy of the medicinal product B.II.b.4.d - Change in the batch size (including batch size ranges) of the finished product - The change relates to all other pharmaceutical forms manufactured by complex manufacturing processes				
IB/0025	C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH	10/07/2018	08/04/2019	SmPC	
IA/0023	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	08/03/2018	n/a		
IAIN/0021	C.I.3.a - Change(s) in the SPC, Labelling or PL intended to implement the outcome of a procedure concerning PSUR or PASS or the outcome of the assessment done under A 45/46 - Implementation of wording agreed by the competent authority	08/06/2017	12/03/2018	SmPC and PL	
IB/0019	B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation	19/04/2017	n/a		
IB/0020/G	This was an application for a group of variations. B.II.e.6.a - Change in any part of the (primary)	24/03/2017	12/03/2018	SmPC, Labelling and PL	

	packaging material not in contact with the finished product formulation - Change that affects the product information C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH				
IA/0018	B.II.e.1.a.1 - Change in immediate packaging of the finished product - Qualitative and quantitative composition - Solid pharmaceutical forms	24/02/2017	n/a		
PSUSA/10202 /201604	Periodic Safety Update EU Single assessment - budesonide / formoterol (only centrally authorised products)	01/12/2016	n/a		PRAC Recommendation - maintenance
IB/0016/G	This was an application for a group of variations. 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 B.II.e.7.z. - Change in supplier of packaging components or devices (when mentioned in the dossier) - Other variation	17/10/2016	n/a		
IAIN/0017	C.I.11.a - Introduction of, or change(s) to, the	07/10/2016	n/a		

	obligations and conditions of a marketing authorisation, including the RMP - Implementation of wording agreed by the competent authority				
A31/0008	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	04/07/2016	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
IB/0014/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 B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)	14/06/2016	n/a		

PSUSA/10202 /201510	Periodic Safety Update EU Single assessment - budesonide / formoterol (only centrally authorised products)	13/05/2016	n/a		PRAC Recommendation - maintenance
IB/0013	B.II.e.1.z - Change in immediate packaging of the finished product - Other variation	22/04/2016	n/a		
PSUSA/10202 /201504	Periodic Safety Update EU Single assessment - budesonide / formoterol (only centrally authorised products)	06/11/2015	n/a		PRAC Recommendation - maintenance
IB/0011/G	This was an application for a group of variations. A.1 - Administrative change - Change in the name and/or address of the MAH B.II.f.1.z - Stability of FP - Change in the shelf-life or storage conditions of the finished product - Other variation	17/09/2015		SmPC, Annex II, Labelling and PL	
IA/0009/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 B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	24/07/2015	n/a		

PSUSA/10202 /201410	Periodic Safety Update EU Single assessment - budesonide / formoterol (only centrally authorised products)	07/05/2015	n/a		PRAC Recommendation - maintenance
IAIN/0007	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	13/03/2015	n/a		
II/0002/G	This was an application for a group of variations. additional finished product manufacturer 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.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	18/12/2014	n/a		
IA/0004	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	27/08/2014	n/a		
IAIN/0003/G	This was an application for a group of variations. B.II.b.1.a - Replacement or addition of a	18/08/2014	n/a		

	manufacturing site for the FP - Secondary packaging site 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				
IAIN/0001	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	21/07/2014	08/07/2015	Annex II and PL	