GoResp Digihaler

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
R/0016	Renewal of the marketing authorisation.	12/12/2024	10/02/2025	SmPC, Labelling and PL	Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of GoResp Digihaler in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
IA/0015	A.7 - Administrative change - Deletion of manufacturing sites	07/06/2024	10/02/2025	Annex II 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).

IA/0014	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	03/04/2024	n/a		
IAIN/0013	A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer responsible for batch release	03/04/2024	10/02/2025	Annex II and PL	
II/0012/G	This was an application for a group of variations. 1. Type II, B.IV.1.c, to replace the multidose dry powder inhaler with an inhaler including an electronic sensor to be used for the delivery of Budesonide/Formoterol fumarate dihydrate inhalation powder, as well as to detect, record, store and transfer inhaler usage information to a mobile application (App), the data is stored in the cloud and can be shared with the health care provider; the App can be used as patient diary and gives notifications (reminders and alerts) for the patient. The inhaler is an integral drug device combination. Additionally, the number of doses is increased from 120 to 180 doses for the 160/4.5 mcg product and from 60 to 90 doses for the 320/9 mcg product, by increasing the blend fill weight for each of the strength. 2. Type IAIN, A.2.a, to change the name of the medicinal product from Budesonide/Formoterol Teva Pharma B.V. to the invented name GoResp Digihaler. 3. Type IA, B.II.d.2.a, to introduce an	21/03/2024	10/02/2025	SmPC, Labelling and PL	The SmPC was updated in order to add information on the new inhaler that includes an electronic sensor and to reflect the new name (GoResp Digihaler). In addition, the MAH took the opportunity to align the SmPC section 4.8 with the reference medicinal product. The Labelling and the PL have been updated accordingly.

	automated New Generation Impactor (NGI) sample preparation and recovery unit (ANSPRU) APSD test method for NGI plate recovery with consequential minor changes to the Aerodynamic Particle Size Distribution (APSD) test procedure for the finished product. 4. Type IB, C.I.2.a to update sections 4.2 and 4.4 of the SmPC to reorganise the flow of information within these sections (as approved for DuoResp Spiromax EMEA/H/C/002348), following assessment of the same change for the reference product Symbicort Turbohaler. 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 A.2.a - Administrative change - Change in the (invented) name of the medicinal product for CAPs B.IV.1.c - Change of a measuring or administration device - Addition or replacement of a device which is an integrated part of the primary packaging B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure				
PSUSA/10585 /202208	Periodic Safety Update EU Single assessment - budesonide / formoterol	14/04/2023	n/a		PRAC Recommendation - maintenance

IG/1579	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	19/12/2022	n/a		
IG/1560	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)	08/12/2022	n/a		
IG/1510/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	26/05/2022	n/a		
IG/1491/G	This was an application for a group of variations. B.II.d.2.f - Change in test procedure for the finished product - To reflect compliance with the Ph. Eur. and remove reference to the outdated internal test method and test method number 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	22/03/2022	n/a		

	product - Minor changes to an approved test procedure A.7 - Administrative change - Deletion of manufacturing sites A.7 - Administrative change - Deletion of manufacturing sites				
IG/1472	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	14/01/2022	n/a		
N/0005	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	07/12/2021	10/02/2025	PL	
IAIN/0004	C.I.11.a - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Implementation of wording agreed by the competent authority	14/06/2021	n/a		
IA/0003	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	18/05/2021	n/a		
IA/0002	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	05/05/2021	n/a		
II/0001/G	This was an application for a group of variations. C.I.3.z - Change(s) in the SPC, Labelling or PL	11/02/2021	18/03/2021	SmPC, Labelling and	In section 4.2 of the SmPC, information related to the use of Budesonide/Formoterol Teva Pharma B.V. as reliever therapy for allergen- and exercise-induced

	intended to implement the outcome of a procedure concerning PSUR or PASS or the outcome of the assessment done under A 45/46 - Other variation 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			PL	bronchoconstriction was added to inform that preventative use of Budesonide/Formoterol Teva Pharma B.V. 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 4.8 of the SmPC is updated to add 'dysphonia' as an adverse drug reaction with a frequency 'common' following DuoResp Spiromax PSUR (PSUSA/00010585/201908). 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.