Enerzair Breezhaler

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/0029	Renewal of the marketing authorisation.	12/12/2024	14/02/2025	SmPC and PL	Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of Enerzair Breezhaler in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity

[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).

PSUSA/10861 /202407	Periodic Safety Update EU Single assessment - indacaterol / glycopyrronium / mometasone	16/01/2025	n/a		PRAC Recommendation - maintenance
IG/1790	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	21/11/2024	14/02/2025	Annex II and PL	
IB/0028	B.II.f.1.b.1 - Stability of FP - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)	04/09/2024	14/02/2025	SmPC	
IG/1782/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.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.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.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP -	16/08/2024	n/a		

	Replacement/addition of a site where batch control/testing takes place 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 A.7 - Administrative change - Deletion of manufacturing sites A.7 - Administrative change - Deletion of manufacturing sites A.7 - Administrative change - Deletion of manufacturing sites A.7 - Administrative change - Deletion of manufacturing sites				
IB/0026/G	This was an application for a group of variations. B.I.b.2.e - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure (including replacement or addition) for the AS or a starting material/intermediate 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	21/06/2024	n/a		
IG/1749/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of	11/06/2024	n/a		

	manufacturing sites A.7 - Administrative change - Deletion of manufacturing sites				
IG/1706	B.I.c.1.a - Change in immediate packaging of the AS - Qualitative and/or quantitative composition	27/05/2024	n/a		
N/0023	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	21/05/2024	16/09/2024	PL	
IG/1727	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	19/03/2024	n/a		
PSUSA/10861 /202307	Periodic Safety Update EU Single assessment - indacaterol / glycopyrronium / mometasone	08/02/2024	n/a		PRAC Recommendation - maintenance
IB/0021/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.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.III.1.a.3 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from a	08/01/2024	n/a		

	new manufacturer (replacement or addition) 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.e - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure (including replacement or addition) for the AS or a starting material/intermediate 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.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 B.I.b.2.e - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure (including replacement or addition) for the AS or a starting material/intermediate B.I.b.2.e - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure (including replacement				

	or addition) for the AS or a starting material/intermediate 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.II.b.1.e - Replacement or addition of a manufacturing site for the FP - Site where any manufacturing operation(s) take place, except batch-release, batch control, primary and secondary packaging, for non-sterile medicinal products B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation				
IG/1642/G	This was an application for a group of variations. 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) 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	11/09/2023	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				
WS/2523	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 5.3 and 6.6 of the SmPC in order to include a statement regarding the risk to the environment based on results from ERA study Mometasone furoate – Fish Sexual Development Test with Zebrafish (Danio rerio). The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	07/09/2023	16/09/2024	SmPC and PL	Mometasone is considered an endocrine active substance (EAS) and is therefore potentially harmful to aquatic life at a Predicted Environmental Concentration in surface water (PECsw) below the action limit of 0.01 µg/L. A GLP-compliant OECD 234 Fish Sexual Development study was carried out and as a result section 5.3 was updated to indicate that 'Environmental risk assessment studies have shown that mometasone may pose a risk to surface water.' and section 6.6. that "This medicinal product may pose a risk to the environment (See section 5.3). Any unused medicinal product or waste material should be disposed of in accordance with local requirements.' The Package Leaflet (PL) (section 5) is updated accordingly. For more information, please refer to the Summary of Product Characteristics.
N/0017	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	16/06/2023	16/09/2024	PL	
IB/0016/G	This was an application for a group of variations. B.I.d.1.b.1 - Stability of AS - Change in the storage conditions - Change to more restrictive storage conditions of the AS B.I.d.1.a.4 - Stability of AS - Change in the re-test	28/04/2023	n/a		

	period/storage period - Extension or introduction of a re-test period/storage period supported by real time data				
PSUSA/10861 /202207	Periodic Safety Update EU Single assessment - indacaterol / glycopyrronium / mometasone	09/02/2023	n/a		PRAC Recommendation - maintenance
N/0013	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	21/06/2022	16/09/2024	PL	
IG/1511	B.II.e.7.b - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier	16/05/2022	n/a		
PSUSA/10861 /202107	Periodic Safety Update EU Single assessment - indacaterol / glycopyrronium / mometasone	10/02/2022	n/a		PRAC Recommendation - maintenance
IG/1473	B.II.e.7.b - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier	22/12/2021	n/a		
IG/1453	B.II.e.7.b - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier	15/12/2021	n/a		
IB/0010/G	This was an application for a group of variations. B.II.b.1.e - Replacement or addition of a manufacturing site for the FP - Site where any manufacturing operation(s) take place, except batch-release, batch control, primary and secondary packaging, for non-sterile medicinal products	12/11/2021	05/05/2022	SmPC, Labelling and PL	To introduce the revised storage conditions of "Do not store above 30 °C" in section 6.4 of the Summary of Product Characteristics, section 9 of the Labelling and section 5 of the Package Leaflet.

	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 B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process 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 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 B.II.f.1.d - Stability of FP - Change in storage conditions of the finished product or the diluted/reconstituted product				
PSUSA/10861 /202101	Periodic Safety Update EU Single assessment - indacaterol / glycopyrronium / mometasone	02/09/2021	n/a		PRAC Recommendation - maintenance
WS/2054	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	22/07/2021	05/05/2022	SmPC and PL	The MAH submitted with this variation an update of the Summary of Product Characteristics (SmPC) based on the final results from the ARGON study. As a result, section 5.1. has been updated accordingly to state under the "Comparison of Enerzair Breezhaler to the concurrent open-label administration of salmeterol/fluticasone + tiotropium" heading that a randomised, partially blinded, active treatment controlled, non inferiority study (ARGON) comparing Enerzair Breezhaler 114 mcg/46 mcg/136 mcg

					once daily and 114 mcg/46 mcg/68 mcg once daily to the concurrent administration of salmeterol/fluticasone propionate 50 mcg/500 mcg twice daily + tiotropium 5 mcg once daily over 24 weeks of treatment was conducted. Enerzair Breezhaler demonstrated non inferiority to salmeterol/fluticasone + tiotropium for the primary endpoint (change from baseline for Asthma Quality of Life Questionnaire [AQLQ S]), in previously symptomatic patients on ICS and LABA therapy with a difference of 0.073 (one sided lower 97.5% confidence limit [CL]: 0.027). For more information, please refer to the Summary of Product Characteristics.
IG/1404/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 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)	05/07/2021	n/a		
N/0006	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	23/06/2021	n/a		
IG/1391	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	22/04/2021	05/05/2022	SmPC, Annex II and PL	

	responsible for importation and/or batch release - Not including batch control/testing				
IG/1376/G	This was an application for a group of variations. A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer responsible for batch release 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)	14/04/2021	n/a		
IG/1344	B.I.b.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits	22/03/2021	n/a		
IG/1301/G	This was an application for a group of variations. B.I.c.1.a - Change in immediate packaging of the AS - Qualitative and/or quantitative composition 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) 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	29/10/2020	n/a		