Bevespi Aerosphere

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
N/0021	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	02/12/2024		Labelling and PL	
IA/0020	A.5.b - Administrative change - Change in the name and/or address of a manufacturer/importer of the finished product, including quality control sites	02/08/2024	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).

	(excluding manufacturer for batch release)				
II/0019/G	This was an application for a group of variations. B.II.d.1.e - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range B.II.d.1.g - Change in the specification parameters and/or limits of the finished product - Addition or replacement (excluding biological or immunological product) of a specification parameter wit its corresponding test method as a result of a safety or quality issue 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 B.II.c.1.c - Change in the specification parameters and/or limits of an excipient - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) B.II.c.2.d - Change in test procedure for an excipient - Other changes to a test procedure (including replacement or addition)	22/02/2024		Annex II and PL	Annex II has been updated as follows: • Delete AstraZeneca GmbH, Wedel, Germany from the list of the manufacturers responsible for batch release; Package Leaflet has been updated accordingly.

PSUSA/10739 /202304	Periodic Safety Update EU Single assessment - glycopyrronium bromide / formoterol	30/11/2023	n/a		PRAC Recommendation - maintenance
R/0017	Renewal of the marketing authorisation.	20/07/2023	15/09/2023	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 Bevespi Aerosphere in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
PSUSA/10739 /202204	Periodic Safety Update EU Single assessment - glycopyrronium bromide / formoterol	01/12/2022	n/a		PRAC Recommendation - maintenance
N/0015	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	13/07/2022	15/09/2023	PL	
N/0013	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	11/05/2022	15/09/2023	Labelling and PL	
IA/0014	A.7 - Administrative change - Deletion of manufacturing sites	24/03/2022	n/a		
PSUSA/10739 /202104	Periodic Safety Update EU Single assessment - glycopyrronium bromide / formoterol	02/12/2021	n/a		PRAC Recommendation - maintenance
IA/0012/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	26/07/2021	n/a		

	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				
PSUSA/10739 /202010	Periodic Safety Update EU Single assessment - glycopyrronium bromide / formoterol	10/06/2021	n/a		PRAC Recommendation - maintenance
IA/0009	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	02/12/2020	n/a		
PSUSA/10739 /202004	Periodic Safety Update EU Single assessment - glycopyrronium bromide / formoterol	26/11/2020	n/a		PRAC Recommendation - maintenance
II/0006	C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	17/09/2020	16/07/2021	SmPC, Annex II, Labelling and PL	Urinary tract infection (UTI) has been commonly reported in several studies including glycopyrronium. Urinary tract infection is an expected ADR for other inhaled LAMA as well. UTI is therefore included as an adverse drug reaction in the SmPC, section 4.8 with the frequency common. The Patient Leaflet, section 4 is updated accordingly.
IA/0008	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	28/07/2020	n/a		

PSUSA/10739 /201910	Periodic Safety Update EU Single assessment - glycopyrronium bromide / formoterol	14/05/2020	n/a		PRAC Recommendation - maintenance
IB/0005	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)	15/04/2020	16/07/2021	SmPC	
IB/0004/G	This was an application for a group of variations. B.I.a.1.i - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Introduction of a new site of micronisation 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	08/04/2020	n/a		
PSUSA/10739 /201904	Periodic Safety Update EU Single assessment - glycopyrronium bromide / formoterol	31/10/2019	n/a		PRAC Recommendation - maintenance
IB/0001/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)	10/05/2019	23/04/2020	SmPC, Annex II, Labelling and PL	

	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site 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 B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes C.I.12 - Inclusion or deletion of black symbol and explanatory statements for medicinal products in the list of medicinal products that are subject to additional monitoring				