Abrysvo

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/0012	Update of section 5.1 of the SmPC in order to update information based on end-of-season 2 data from clinical study C3671013. This is an ongoing Phase 3, randomised, double-blind, placebo-controlled study to evaluate safety, immunogenicity and efficacy of Abrysvo in prevention of lower respiratory tract	10/04/2025		SmPC and Labelling	

[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).

	disease in adults 60 years of age and older during the first respiratory syncytial virus (RSV) season and the immunogenicity and efficacy of Abrysvo in the second RSV season and across 2 RSV seasons. In addition, the MAH took the opportunity to introduce minor changes to the PI based on the final clinical study report C3671008, which was already submitted under Article 46, and to update the list of local representatives in the Package Leaflet. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data				
II/0007	Extension of indication to include active immunisation of individuals 18 through 59 years of age for ABRYSVO, based on final results from C3671023 Substudy A; this is a Phase 3 double-blinded, randomised, placebo-controlled study of safety, tolerability and immunogenicity of Abrysvo in participants ≥18 to <60 years of age at high risk of severe RSV disease due to certain chronic medical conditions. As a consequence, sections 4.1, 4.2, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 1.1 of the RMP has also been approved. In addition, the MAH took the opportunity to implement editorial changes to the SmPC. Furthermore, the CHMP reviewed the data submitted by the marketing authorisation holder, taking into account the provisions of Article 14(11) of Regulation (EC) No 726/2004 and considers by consensus that	27/02/2025	28/03/2025	SmPC and PL	

	the new therapeutic indication brings significant clinical benefit in comparison with existing therapies, as set out in Annex IV. C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one				
II/0014	C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	13/02/2025	28/03/2025	SmPC and PL	
PSUSA/102/202405	Periodic Safety Update EU Single assessment - respiratory syncytial virus vaccine (bivalent, recombinant)	16/01/2025	n/a		PRAC Recommendation - maintenance
II/0010/G	This was an application for a group of variations. B.II.b.4.c - Change in the batch size (including batch size ranges) of the finished product - The change requires assessment of the comparability of a biological/immunological medicinal product or a new bioequivalence study B.II.b.3.c - Change in the manufacturing process of the finished or intermediate product - The product is a biological/immunological medicinal product and the change requires an assessment of comparability B.II.e.7.a - Change in supplier of packaging components or devices (when mentioned in the dossier) - Deletion of a supplier B.II.e.3.b - Change in test procedure for the immediate packaging of the finished product - Other	12/12/2024	28/03/2025	SmPC and Labelling	Section 6.5 of the SmPC (Module 1.3.1) is updated to reflect the proposed alternative stopper material (of bromobutyl rubber).

	changes to a test procedure (including replacement or addition) B.II.b.3.c - Change in the manufacturing process of the finished or intermediate product - The product is a biological/immunological medicinal product and the change requires an assessment of comparability B.II.e.1.a.3 - Change in immediate packaging of the finished product - Qualitative and quantitative composition - Sterile medicinal products and biological/immunological medicinal products B.II.b.2.b - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place for a biol/immunol product and any of the test methods at the site is a biol/immunol method B.II.b.3.c - Change in the manufacturing process of the finished or intermediate product - The product is a biological/immunological medicinal product and the change requires an assessment of comparability B.II.b.4.c - Change in the batch size (including batch size ranges) of the finished product - The change requires assessment of the comparability of a biological/immunological medicinal product or a new bioequivalence study B.II.b.3.c - Change in the manufacturing process of the finished or intermediate product - The product is a biological/immunological medicinal product and the change requires an assessment of comparability B.II.e.1.a.3 - Change in immediate packaging of the finished product - Qualitative and quantitative				

	composition - Sterile medicinal products and biological/immunological medicinal products B.II.b.2.b - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place for a biol/immunol product and any of the test methods at the site is a biol/immunol method B.II.e.3.b - Change in test procedure for the immediate packaging of the finished product - Other changes to a test procedure (including replacement or addition) B.II.e.7.a - Change in supplier of packaging components or devices (when mentioned in the dossier) - Deletion of a supplier				
IB/0013	B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation	11/10/2024	n/a		
IB/0011/G	This was an application for a group of variations. B.I.b.2.c - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure for a reagent, which does not have a significant effect on the overall quality of the AS B.I.b.2.c - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure for a reagent, which does not have a significant effect on the overall quality of the AS B.I.z - Quality change - Active substance - Other	19/09/2024	n/a		

	variation				
PSUSA/102/202311	Periodic Safety Update EU Single assessment - respiratory syncytial virus vaccine (bivalent, recombinant)	27/06/2024	16/08/2024	SmPC	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/102/202311.
IB/0008/G	This was an application for a group of variations. 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 B.II.z - Quality change - Finished product - Other variation B.II.f.1.b.5 - Stability of FP - Extension of the shelf life of the finished product - Biological/immunological medicinal product in accordance with an approved stability protocol B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process	17/07/2024	28/03/2025	SmPC, Labelling and PL	
IB/0006/G	This was an application for a group of variations. B.I.z - Quality change - Active substance - Other variation B.I.d.1.c - Stability of AS - Change in the re-test period/storage period or storage conditions - Change to an approved stability protocol 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	14/06/2024	n/a		

	data 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				
IB/0005/G	This was an application for a group of variations. B.II.z - Quality change - Finished product - Other variation B.II.f.1.b.5 - Stability of FP - Extension of the shelf life of the finished product - Biological/immunological medicinal product in accordance with an approved stability protocol	29/04/2024	16/08/2024	SmPC and PL	
IB/0003/G	This was an application for a group of variations. B.II.e.7.a - Change in supplier of packaging components or devices (when mentioned in the dossier) - Deletion of a supplier B.II.e.7.a - Change in supplier of packaging components or devices (when mentioned in the dossier) - Deletion of a supplier B.II.e.z - Change in container closure system of the Finished Product - Other variation B.II.b.1.z - Replacement or addition of a manufacturing site for the FP - Other variation	18/03/2024	n/a		
IA/0004	B.II.f.1.e - Stability of FP - Change to an approved stability protocol	07/03/2024	n/a		

II/0001	B.II.e.1.b.2 - Change in immediate packaging of the finished product - Change in type/addition of a new container - Sterile medicinal products and biological/immunological medicinal products B.II.e.1.b.2 - Change in immediate packaging of the finished product - Change in type/addition of a new container - Sterile medicinal products and biological/immunological medicinal products	22/02/2024	16/08/2024	SmPC, Labelling and PL	The SmPC sections 6.5, 6.6 and 8 have been updated as follows: Addition of a new presentation of Abrysvo powder and solvent for solution for injection (EU/1/23/1752/007) with the new container closure (glass vial) and the pack size of 5 diluent vials + 5 antigen vials. The Labelling and PL have been updated accordingly.