



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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/0014	C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	13/02/2025		SmPC and PL	
PSUSA/102/2 02405	Periodic Safety Update EU Single assessment - respiratory syncytial virus vaccine (bivalent,	16/01/2025	n/a		PRAC Recommendation - maintenance

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).



	recombinant)				
II/0010/G	<p>This was an application for a group of variations.</p> <p>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</p> <p>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</p> <p>B.II.e.7.a - Change in supplier of packaging components or devices (when mentioned in the dossier) - Deletion of a supplier</p> <p>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)</p> <p>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</p> <p>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</p> <p>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</p>	12/12/2024		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).

<p>product and any of the test methods at the site is a biol/immunol method</p> <p>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</p> <p>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</p> <p>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</p> <p>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</p> <p>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</p> <p>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)</p> <p>B.II.e.7.a - Change in supplier of packaging components or devices (when mentioned in the</p>					
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	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	<p>This was an application for a group of variations.</p> <p>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</p> <p>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</p> <p>B.I.z - Quality change - Active substance - Other variation</p>	19/09/2024	n/a		
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	<p>This was an application for a group of variations.</p> <p>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</p> <p>B.II.z - Quality change - Finished product - Other variation</p>	17/07/2024		SmPC, Labelling and PL	

	<p>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</p> <p>B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process</p>				
IB/0006/G	<p>This was an application for a group of variations.</p> <p>B.I.z - Quality change - Active substance - Other variation</p> <p>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</p> <p>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</p> <p>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</p>	14/06/2024	n/a		
IB/0005/G	<p>This was an application for a group of variations.</p> <p>B.II.z - Quality change - Finished product - Other variation</p> <p>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</p>	29/04/2024	16/08/2024	SmPC and PL	

IB/0003/G	<p>This was an application for a group of variations.</p> <p>B.II.e.7.a - Change in supplier of packaging components or devices (when mentioned in the dossier) - Deletion of a supplier</p> <p>B.II.e.7.a - Change in supplier of packaging components or devices (when mentioned in the dossier) - Deletion of a supplier</p> <p>B.II.e.z - Change in container closure system of the Finished Product - Other variation</p> <p>B.II.b.1.z - Replacement or addition of a manufacturing site for the FP - Other variation</p>	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	<p>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</p> <p>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</p>	22/02/2024	16/08/2024	SmPC, Labelling and PL	<p>The SmPC sections 6.5, 6.6 and 8 have been updated as follows:</p> <p>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.</p> <p>The Labelling and PL have been updated accordingly.</p>