



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

AREXVY

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/0004	C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	27/06/2024		SmPC	
PSUSA/31/20 2311	Periodic Safety Update EU Single assessment - respiratory syncytial virus, glycoprotein f,	16/05/2024	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, stabilised in the pre-fusion conformation, adjuvanted with as01e				
II/0009/G	<p>This was an application for a group of variations.</p> <p>B.II.b.1.c - Replacement or addition of a manufacturing site for the FP - Site where any manufacturing operation(s) take place, except batch release/control, and secondary packaging, for biol/immunol medicinal products or pharmaceutical forms manufactured by complex manufacturing processes</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.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</p>	02/05/2024	n/a		
II/0002/G	<p>This was an application for a group of variations.</p> <p>Update of section 4.5 of the SmPC in order to update information on the co-administration with inactivated seasonal quadrivalent influenza vaccines: with a high dose unadjuvanted influenza vaccine (QIV-HD) and a standard dose adjuvanted influenza vaccine (aQIV) based on final results from studies ADJ-008 and ADJ-017. These are Phase III studies intended to evaluate the immune response, safety and reactogenicity of Arexvy when co-administered with</p>	11/04/2024		SmPC	<p>Information added to section 4.5 of SmPC (Interaction with other medicinal products and other forms of interaction) (cursive)</p> <p>Use with other vaccines</p> <p>Arexvy may be administered concomitantly with inactivated seasonal influenza vaccines (standard dose unadjuvanted, high dose unadjuvanted, or standard dose adjuvanted). Upon concomitant administration of Arexvy with seasonal influenza vaccines, numerically lower RSV A and B neutralising titres and numerically lower influenza A and B haemagglutination inhibition titres were observed as</p>

	<p>a high dose unadjuvanted quadrivalent influenza vaccine (QIV-HD, study ADJ-008) and a standard dose adjuvanted influenza vaccine (aQIV, study ADJ-017), respectively.</p> <p>C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data</p> <p>C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data</p>				<p>compared to the separate administration. This was not observed consistently across studies. The clinical relevance of these findings is unknown.</p> <p>If Arexvy is to be given at the same time as another injectable vaccine, the vaccines should always be administered at different injection sites.</p> <p>Concomitant administration of Arexvy with other vaccines than those listed above has not been studied.</p> <p>For more information, please refer to the Summary of Product Characteristics.</p>
IB/0006/G	<p>This was an application for a group of variations.</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.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>	01/02/2024		SmPC	
IB/0003/G	<p>This was an application for a group of variations.</p> <p>B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation</p> <p>B.II.b.4.z - Change in the batch size (including batch size ranges) of the finished product - Other variation</p>	19/12/2023	n/a		

IG/1677	B.III.2.z - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Other variation	27/11/2023	n/a		
IB/0001	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	07/07/2023	n/a		