Vyvgart

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
PSUSA/11014 /202406	Periodic Safety Update EU Single assessment - efgartigimod alfa	30/01/2025	28/03/2025	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/11014/202406.
II/0022/G	This was an application for a group of variations. In view of the data submitted with the group of	13/02/2025		SmPC, Annex II, Labelling	The SmPC, labelling and package leaflet have been updated to reflect the introduction of a pre-filled syringe presentation of 5.0 ml (200 mg/ml) (1000 mg strength)

[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).

	variations, amendments to Annex(es) I, II, IIIA, IIIB and A and to the Risk Management Plan are recommended. 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.I.z - Quality change - Active substance - Other variation B.I.a.1.j - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Replacement or addition of a site where batch control/testing takes place and any of the test method at the site is a biol/immunol method B.I.a.1.e - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The change relates to a biological AS or a starting material [-] used in the manufacture of a biological/immunological product 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.a.5 - Change in concentration of a single-dose, total use parenteral product, where the amount of AS per unit dose (i.e. the strength) remains the same 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			and PL	Vyvgart solution for injection and the corresponding method of administration, changes in excipient composition as well as shelf life and storage conditions for the finished product (2 years when stored at 2-8°C and for a single period of up to 1 month at room temperature up to 30°C). The additional presentations are packs of: - 1 pre-filled syringe (EU/1/22/1674/003) - 4 pre-filled syringes (EU/1/22/1674/004)

	biol/immunol medicinal products or pharmaceutical forms manufactured by complex manufacturing processes B.II.a.3.b.5 - Changes in the composition (excipients) of the finished product - Other excipients - Change that is supported by a bioequivalence study 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				
IA/0024/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	10/12/2024	n/a		
PSUSA/11014 /202312	Periodic Safety Update EU Single assessment - efgartigimod alfa	11/07/2024	n/a		PRAC Recommendation - maintenance
II/0017	B.I.a.2.c - Changes in the manufacturing process of the AS - The change refers to a [-] substance in the manufacture of a biological/immunological substance which may have a significant impact on the medicinal product and is not related to a protocol	27/06/2024	n/a		

IA/0021	A.7 - Administrative change - Deletion of manufacturing sites	18/06/2024	n/a		
II/0016	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	30/05/2024	n/a		
IB/0019	B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process	08/05/2024	n/a		
II/0014	C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	11/04/2024	29/08/2024	SmPC and PL	
PSUSA/11014 /202306	Periodic Safety Update EU Single assessment - efgartigimod alfa	11/01/2024	n/a		PRAC Recommendation - maintenance
IB/0013	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	08/01/2024	n/a		
IB/0015	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	19/12/2023	29/08/2024	SmPC and PL	

X/0003	Annex I_2.(c) Change or addition of a new strength/potency Annex I_2.(d) Change or addition of a new pharmaceutical form Annex I_2.(e) Change or addition of a new route of administration	14/09/2023	15/11/2023	SmPC, Labelling and PL	
IA/0012	B.II.e.7.a - Change in supplier of packaging components or devices (when mentioned in the dossier) - Deletion of a supplier	06/10/2023	n/a		
II/0006	Update of sections 4.4 and 4.5 of the SmPC in order to amend an existing warning on use of vaccination and update drug-drug interaction information on vaccines based on final results from study ARGX-113-2102; this is a phase 1, randomized, open-label, placebo-controlled, parallel-group study to evaluate the immune response to PNEUMOVAX 23 in healthy participants receiving efgartigimod IV 10 mg/kg or placebo. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet. The RMP version 2.1 was adopted. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	28/09/2023	29/08/2024	SmPC and PL	Sections 4.4 and 4.5 of the SmPC are updated to inform that the safety of immunisation with live or live attenuated vaccines and the response to immunisation with these vaccines during treatment with efgartigimod alfa are unknown. For patients that are being treated with efgartigimod alfa, vaccination with live or live attenuated vaccines is generally not recommended. If vaccination with live or live attenuated vaccines is required, these vaccines should be administered at least 4 weeks before treatment and at least 2 weeks after the last dose of efgartigimod alfa. However, other vaccines may be administered as needed at any time during treatment with efgartigimod alfa.
PSUSA/11014 /202212	Periodic Safety Update EU Single assessment - efgartigimod alfa	20/07/2023	15/09/2023	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/11014/202212.
IB/0010/G	This was an application for a group of variations.	24/08/2023	n/a		

	B.I.b.1.d - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) B.I.b.1.d - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter)				
IB/0009	B.I.b.1.d - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter)	24/08/2023	n/a		
IA/0008/G	This was an application for a group of variations. B.I.b.1.d - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation	30/06/2023	n/a		
IA/0007/G	This was an application for a group of variations. B.I.b.1.z - Change in the specification parameters	30/06/2023	n/a		

	and/or limits of an AS, starting material/intermediate/reagent - Other variation B.I.b.1.d - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) B.I.b.1.d - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation				
II/0004/G	This was an application for a group of variations. 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.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	14/04/2023	n/a		

	forms manufactured by complex manufacturing processes				
IB/0002/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	22/11/2022	15/09/2023	SmPC and PL	
N/0001	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	22/09/2022	15/09/2023	PL	