



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Privigen

Procedural steps taken and scientific information after the authorisation*

*Due to the Agency`s update of its procedure management systems, an additional document, reflecting the historical lifecycle may be available in the 'Assessment history' section. For the complete product lifecycle procedures, you may need to also refer to **EPAR - Procedural steps taken and scientific information after authorisation (archive)**.

Application number	Scope	Opinion/ Notification ¹ issued on	Commission Decision Issued ² / amended on	Product Information affected ³	Summary
Variation type II /	Outcome:	23/04/2026	26/05/2026	SmPC and PL	

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).



EMA/VR/0000304719	<p>This was an application for a group of variations.</p> <p>C.I.6 Change(s) to therapeutic indication(s) - C.I.6.a Addition of a new therapeutic indication or modification of an approved one - Accepted</p> <p>B.II.d.1 Change in the specification parameters and/or limits of the finished product - B.II.d.1.c Addition of a new specification parameter to the specification with its corresponding test method - Accepted</p> <p>A grouped application consisting of: C.I.6: Extension of indication to include treatment of patients with measles pre/post-exposure prophylaxis in whom active immunisation is contraindicated or not advised, for PRIVIGEN, in alignment with the IVIg core SmPC (EMA/CHMP/BPWP/94038/2007 Rev); As a consequence, sections 2, 4.1, 4.2 and 5.2 of the SmPC. The Package Leaflet is updated accordingly. The RMP version 9 has also been submitted. B.II.d.1.c: To add anti-measles as immunological requirement to the specifications of the finished product with its corresponding test method.</p>				
Variation type IA / EMA/VR/0000332008	Outcome: Q.V.a.1 Inclusion of a new, updated or amended Plasma Master File in the	10/04/2026			

	marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Q.V.a.1.d) Inclusion of an updated/amended Plasma Master File when changes do not affect the properties of the finished product - Accepted				
Variation type IB / EMA/VR/0000333989	Outcome: Q.I.e.5 Implementation of changes foreseen in post-approval change management protocol (PACMP) - Q.I.e.5.c) Implementation of changes foreseen in a PACMP via Type IB notification - Accepted	20/03/2026			
Variation type IA / EMA/VR/0000332806	Outcome: Q.I.a.2 Change in the manufacturing process of the active substance, intermediate of an active substance or starting materials for biological active substance - Q.I.a.2.a) Minor change in the manufacturing process - Accepted	20/02/2026			
Variation type II / EMA/VR/0000312980	Outcome: This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.II.b.3 Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the	12/02/2026			

	finished product - B.II.b.3.b Substantial changes to a manufacturing process that may have a significant impact on the quality, safety and efficacy of the medicinal product - Accepted				
PSUR / EMA/PSUR/0000296525	EURD: PSUSA/00001633/202505 Active substance: human normal immunoglobulin (IgG) Outcome: Maintenance	29/01/2026			Variation
Variation type IB / EMA/VR/0000312989	Outcome: This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.II.f.1 Change in the shelf-life or storage conditions of the finished product - B.II.f.1.e Change to an approved stability protocol - Accepted	15/01/2026			
Variation type II / EMA/VR/0000294243	Outcome: This was an application for a group of variations. B.I.a.2 Changes in the manufacturing process of the active substance - B.I.a.2.a Minor change in the manufacturing process of the active substance - Accepted	13/11/2025			N/A

	<p>B.I.a.2 Changes in the manufacturing process of the active substance - B.I.a.2.c The change refers to a biological / immunological substance or use of a different chemically derived substance in the manufacture of a biological/immunological substance, which may have a significant impact on the quality, safety and efficacy of the medicinal product and is not related to a protocol - Accepted</p> <p>B.I.a.2 Changes in the manufacturing process of the active substance - B.I.a.2.z Other variation - Accepted</p>				
Variation type IB / EMA/VR/0000301683	<p>Outcome: B.I.e.5 Implementation of changes foreseen in an approved change management protocol - B.I.e.5.c Implementation of a change for a biological/immunological medicinal product - Accepted</p>	04/11/2025			
Variation type IB / EMA/VR/0000269786	<p>Outcome: This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008.</p> <p>B.II.d.2 Change in test procedure for the finished product - B.II.d.2.d Other changes to a test procedure (including replacement</p>	26/06/2025			

	or addition) - Accepted				
Variation type IB / EMA/VR/0000264780	<p>Outcome: This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008.</p> <p>B.I.a.2 Changes in the manufacturing process of the active substance - B.I.a.2.a Minor change in the manufacturing process of the active substance - Accepted</p>	05/06/2025			
Variation type II / EMA/VR/0000256879	<p>Outcome: B.I.e) Design Space and post-approval change management protocols - B.I.e.2 Introduction of a post approval change management protocol related to the active substance - Accepted</p>	15/05/2025			
Variation type IB / EMA/VR/0000263949	<p>Outcome: B.I.e.5 Implementation of changes foreseen in an approved change management protocol - B.I.e.5.c Implementation of a change for a biological/immunological medicinal product - Accepted</p>	08/05/2025			

<p>Variation type IB / EMA/VR/0000253343</p>	<p>Outcome: This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008.</p> <p>B.II.d.2 Change in test procedure for the finished product - B.II.d.2.d Other changes to a test procedure (including replacement or addition) - Accepted</p>	<p>25/04/2025</p>			
<p>Variation type IA_IN / EMA/VR/0000249049</p>	<p>Outcome: B.V.a.1 Inclusion of a new, updated or amended Plasma Master File in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - B.V.a.1.d Inclusion of an updated/amended Plasma Master File when changes do not affect the properties of the finished product - Accepted</p>	<p>07/03/2025</p>			