



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Spevigo

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
X/0011	An extension application for a new strength of 300 mg (150 mg/ml) for solution for injection in a pre-filled syringe. The RMP (version 3.0) is updated in accordance. In addition, the applicant has updated SmPC (Annex I) and Package Leaflet (Annex IIIB) for both 450 mg	19/06/2025	14/08/2025	SmPC, Labelling and PL	Please refer to Scientific Discussion "Spevigo EMEA/H/C/005874/X/0011"

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).



	concentrate for solution for infusion and 150 mg and 300 mg solution for injection in line with the new excipient guideline Annex I_2.(c) Change or addition of a new strength/potency				
PSUSA/11033/202409	Periodic Safety Update EU Single assessment - spesolimab	10/04/2025	n/a		PRAC Recommendation - maintenance
R/0008	Renewal of the marketing authorisation.	19/09/2024	14/11/2024		
IB/0010	B.II.b.4.f - Change in the batch size (including batch size ranges) of the finished product - The scale for a biological/immunological medicinal product is increased/decreased without process change (e.g. duplication of line)	05/11/2024	n/a		
PSUSA/11033/202403	Periodic Safety Update EU Single assessment - spesolimab	03/10/2024	n/a		PRAC Recommendation - maintenance
X/0006/G	This was an application for a group of variations. Extension application to introduce a new pharmaceutical form (solution for injection) associated with a new strength (150 mg) and new route of administration (subcutaneous use), for the prevention of generalised pustular psoriasis (GPP) flares in adults and adolescents from 12 years of age. This line extension is grouped with a type II variation	25/07/2024	25/09/2024	SmPC, Annex II, Labelling and PL	Please refer to Scientific Discussion "Spevigo EMEA/H/C/005874/X/0006/G"

	(C.I.6.a) indication for Spevigo 450 mg concentrate for solution for infusion to include treatment of generalised pustular psoriasis (GPP) flares in adolescents (from 12 years of age), based on final results from study 1368-0027 (Effisayil 2) and extrapolation; this is a multi-center, randomised, parallel group, double blind, placebo controlled, phase IIb dose-finding study to evaluate efficacy and safety of BI 655130 (spesolimab) compared to placebo in preventing GPP flares in patients with history of GPP. As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.6, 4.8, 4.9, 5.1 and 5.2 of the SmPC are updated. The Annex II and Package Leaflet are updated in accordance. Version 2.0 of the RMP has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to introduce editorial changes to the PI and update the list of local representatives in the Package Leaflet. 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 C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one				
PSUSA/11033 /202309	Periodic Safety Update EU Single assessment - spesolimab	11/04/2024	n/a		PRAC Recommendation - maintenance

PSUSA/11033 /202303	Periodic Safety Update EU Single assessment - spesolimab	28/09/2023	n/a		PRAC Recommendation - maintenance
R/0005	Renewal of the marketing authorisation.	20/07/2023	15/09/2023		
IA/0004/G	This was an application for a group of variations. B.II.e.7.b - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier 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)	24/05/2023	n/a		
IB/0002/G	This was an application for a group of variations. 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 B.I.a.1.k - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - New storage site of MCB and/or WCB	23/05/2023	n/a		
IB/0001	B.II.c.3.z - Change in source of an excipient or reagent with TSE risk - Other variation	28/02/2023	n/a		