STEQEYMA

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/G	This was an application for a group of variations. Type II (B.II.e.1.b.2) - Change to the immediate packaging of the biological finished product, by addition of 45 mg solution for injection in a vial (EU/1/24/1844/004).	27/03/2025		SmPC, Labelling and PL	The SmPC sections 1, 2, 3, 4.2, 4.4, 5.1, 6.3, 6.4, 6.5, 6.6, 8 have been updated as follows: To include details of the 45 mg vial presentation. Annex A, Labelling and Package Leaflet have been updated accordingly.

[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).

	Type II (B.II.b.1.c) - To add Patheon Italia S.p.A. (Viale Gian Battista Stucchi 110, Monza, 20900, Italy) as an alternative site responsible for the production and release testing (endotoxin and sterility) of the finished product, 45 mg solution for injection in a vial (EU/1/24/1844/004). The requested group of variations proposed amendments to the Summary of Product Characteristics, Labelling and Package Leaflet and Annex A. 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 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				
IB/0006/G	This was an application for a group of variations. C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH	17/01/2025		SmPC and PL	C.I.2.a To update SmPC sections 4.4, 4.5 and 4.6 to revise a warning on administration of live vaccines in infants exposed to ustekinumab in utero. The Package leaflet is updated accordingly. C.I.2.a To update SmPC Section 4.6 to update information on

	C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH				pregnancy based on the outcome of a study for the reference product. C.I.2.a To update SmPC section 4.4 with removing "non-melanoma" following the outcome of a study for the reference product.
IB/0005	B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation	16/12/2024	n/a		
IB/0003	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	22/11/2024	n/a		
IB/0001	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	26/09/2024	n/a		
IAIN/0002/G	This was an application for a group of variations. B.II.b.2.c.1 - Change to importer, batch release arrangements and quality control testing of the FP - Replacement or addition of a manufacturer	24/09/2024		SmPC, Annex II, Labelling and PL	

	responsible for importation and/or batch release - Not including batch control/testing B.II.b.2.c.1 - Change to importer, batch release arrangements and quality control testing of the FP - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing				