Otulfi

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/0001/G	This was an application for a group of variations. Type II - B.II.e.1.b.2 - Change in the immediate packaging of the sterile biological finished product Otulfi to add a new container (vial) for the 90 mg/mL solution for injection (EU/1/24/1863/004). Type II - B.II.b.3.c - Changes in the manufacturing	10/04/2025		SmPC, Labelling and PL	The SmPC has been updated to reflect the new new 45 mg vial presentation for subcutaneous injection, including a new Table 2 weight-based dosage calculations for patients < 60 kg in SmPC section 4.2 in line with the reference medicinal product. The Labelling and PL have been updated accordingly. The RMP is updated consequentially to include the information specific to the new PFS presentation and

[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).

	process of the biological finished product to introduce consequential changes in the filling step of the manufacturing process due to the addition of a new container (vial). Type IB - B.II.d.1.z - To add container specific specifications (appearance, extractable volume, container closure integrity) to the specifications of the finished product. Type IAIN - B.II.b.1.a - To add 'Fresenius Kabi Austria GmbH, Am Gewerbepark 6, 8402 Werndorf' as an alternative site responsible for secondary packaging of the finished product Otulfi 45 mg solution for injection in a vial. Module 3 have been updated, as well as certain overarching Module 2 and 3 documents previously submitted for the vial dosage form. The product information and the RMP (v 1.0) is updated consequentially to include the information specific to the new 45 mg vial presentation, including a new Table 2 weight-based dosage calculations for patients < 60 kg in SmPC section 4.2 in line with the reference medicinal product, and some editorial changes. The requested group of variations proposed amendments to the Summary of Product Characteristics, Labelling, Package Leaflet and Annex A and to the Risk Management Plan (RMP). B.II.b.3.c - Change in the manufacturing process of the finished or intermediate product - The product is				some editorial changes (final version 1.2).

	a biological/immunological medicinal product and the change requires an assessment of comparability B.II.d.1.z - Change in the specification parameters and/or limits of the finished product - Other variation B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site 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/0003/G	This was an application for a group of variations. C.I.3.z - Change(s) in the SPC, Labelling or PL intended to implement the outcome of a procedure concerning PSUR or PASS or the outcome of the assessment done under A 45/46 - Other variation 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	13/01/2025		SmPC and PL	To update section 4.4 of the SmPC to remove the wording `non-melanoma' from the safety information on malignancies, following the assessment of the same change for the reference product. To update sections 4.4, 4.5 and 4.6 of the SmPC and section 2 of the PL to revise a warning on administration of live vaccines in infants exposed to ustekinumab in utero. The RMP is updated accordingly.
IB/0002	B.II.f.1.b.1 - Stability of FP - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)	18/12/2024		SmPC	