Pyzchiva

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/0006	An extension of the marketing authorisation to add a new strength of 45 mg solution for injection in a vial for partial use in paediatric patients. Annex I_2.(c) Change or addition of a new strength/potency	19/06/2025	14/08/2025	SmPC, Labelling 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).

II/0005/G	This was an application for a group of variations. Type II B.IV.1.c To add a new presentation of 45 mg and 90 mg solution for injection in Pre-filled Pen (PFP) (EU/1/24/1801/004-005). Type IB C.I.2.a To update section 4.6 Fertility, Pregnancy and lactation of the SmPC of all presentations to update information on pregnancy following assessment of the same change for the reference product Stelara (EMEA/H/C/000958). An updated RMP (version 4.1) is provided. The requested group of variations proposed amendments to the Summary of Product Characteristics, Labelling and Package Leaflet and to the Risk Management Plan (RMP). 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 B.IV.1.c - Change of a measuring or administration device - Addition or replacement of a device which is an integrated part of the primary packaging	30/01/2025	14/08/2025	SmPC, Labelling and PL	The Summary of Product Characteristics, Labelling and Package Leaflet are updated to include the new presentations 45 mg and 90 mg solution for injection in Pre-filled Pen (PFP).
IB/0007/G	This was an application for a group of variations. C.I.2.a - Change in the SPC, Labelling or PL of a	03/12/2024	14/08/2025	SmPC and PL	

	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				
IB/0004/G	This was an application for a group of variations. B.II.f.1.e - Stability of FP - Change to an approved stability protocol B.II.f.1.e - Stability of FP - Change to an approved stability protocol 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 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	08/10/2024	14/08/2025	SmPC and PL	
IB/0003	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	02/08/2024	n/a		

IB/0002	B.I.a.2.z - Changes in the manufacturing process of the AS - Other variation	24/06/2024	n/a		
IB/0001	C.I.6.b - Change(s) to therapeutic indication(s) - Deletion of a therapeutic indication	24/06/2024	24/07/2024	SmPC, Labelling and PL	