Pyzchiva

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 IB /	This was an application for a group of	03/11/2025		SmPC,	For the Pyzchiva 130 mg vial, the shelf-life is

[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/0000301212	variations. B.II.f.1.b Extension of the shelf life of the finished product - B.II.f.1.b.5 Extension of the shelf-life of a biological/ immunological medicinal product in accordance with an approved stability protocol - Accepted B.II.f.1.b Extension of the shelf life of the finished product - B.II.f.1.b.5 Extension of the shelf-life of a biological/ immunological medicinal product in accordance with an approved stability protocol - Accepted B.II.f.1 Change in the shelf-life or storage conditions of the finished product - B.II.f.1.d Change in storage conditions of the finished product or the diluted/reconstituted product - Accepted B.II.f.1 Change in the shelf-life or storage conditions of the finished product - B.II.f.1.d Change in storage conditions of the finished product or the diluted/reconstituted product - Accepted			Labelling and PL	extended from 24 months to 36 months when stored in a refrigerator (2°C–8°C). For the Pyzchiva 45 mg vial, the shelf-life is extended from 36 months to 42 months when stored in a refrigerator (2°C–8°C). Additionally, for both products, the storage condition of the finished drug product (DP) at room temperature is extended to 35 days.
Variation type IB / EMA/VR/0000293227	C.I.2 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - C.I.2.a	22/09/2025	24/10/2025	SmPC and PL	

	Implementation of change(s) for which no new additional data is required to be submitted by the MAH - Accepted C.I.2.a – extension of indication to add paediatric Crohn's disease following the outcome of the assessment of the same change for the reference product Stelara (EMEA/H/C/000958/II/0108). Sections 4.1, 4.2, 4.8 , 5.1, and 5.2 of the SmPC have been updated. The Package Leaflet, sections 1, 2 and 3 has been updated accordingly. A revised RMP has been submitted accordingly.				
Variation type IB / EMA/VR/0000284803	B.II.e.5.a Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - B.II.e.5.a.2 Change outside the range of the currently approved pack sizes - Accepted	24/07/2025	24/10/2025	SmPC, Labelling and PL	
Variation type IB / EMA/VR/0000279010	B.I.a.1 Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - B.I.a.1.k New storage site of Master Cell Bank and/or Working Cell Banks - Accepted	30/06/2025	N/A		

Variation type IB / EMA/VR/0000276357	B.I.d.1.a Re-test period/storage period - B.I.d.1.a.4 Extension or introduction of a re-test period/storage period supported by real time data - Accepted	23/06/2025	N/A		
Variation type IB / EMA/VR/0000272880	This was an application for a group of variations. B.II.f.1 Change in the shelf-life or storage conditions of the finished product - B.II.f.1.d Change in storage conditions of the finished product or the diluted/reconstituted product - Accepted B.II.f.1 Change in the shelf-life or storage conditions of the finished product - B.II.f.1.d Change in storage conditions of the finished product or the diluted/reconstituted product - Accepted B.II.f.1.b Extension of the shelf life of the finished product - B.II.f.1.b.5 Extension of the shelf-life of a biological/ immunological medicinal product in accordance with an approved stability protocol - Accepted B.II.f.1.b Extension of the shelf life of the finished product - B.II.f.1.b.5 Extension of the shelf-life of a biological/ immunological medicinal product in accordance with an approved stability protocol - Accepted	13/06/2025		SmPC, Labelling and PL	

Variation type IB / EMA/VR/0000267759	C.I.2 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - C.I.2.a Implementation of change(s) for which no new additional data is required to be submitted by the MAH - Accepted C.I.2.a – to update section 4.5, 4.8, 5.1 and 5.2 to align the SmPC to the SmPC of the reference product upon receipt of the CHMP adoption of the same changes. The MAH has also took the opportunity to update the PI based on the QRD template, which includes a warning on the polysorbate threshold in section 4.4 the SmPC.	26/05/2025		SmPC	
Variation type IB / EMA/VR/0000261867	B.II.e.5.a Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - B.II.e.5.a.2 Change outside the range of the currently approved pack sizes - Accepted	06/05/2025		SmPC, Labelling and PL	
Variation type IB / EMA/VR/0000264568	B.II.d.1 Change in the specification parameters and/or limits of the finished product - B.II.d.1.z Change in the specification parameters and/or limits of the finished product to more accurately describe the appearance of the drug product -	01/05/2025	N/A		

	Accepted				
Variation type IB / EMA/VR/0000263468	B.I.b.2 Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - B.I.b.2.e Other changes to a test procedure (including replacement or addition) for the active substance or a starting material/intermediate - Accepted	30/04/2025	N/A		
Variation type II / EMA/VR/0000250386	B.II.f.1 Change in the shelf-life or storage conditions of the finished product - B.II.f.1.c Change in storage conditions for biological medicinal products, when the stability studies have not been performed in accordance with an approved stability protocol - Accepted	25/04/2025		SmPC and PL	
Variation type IB / EMA/VR/0000262167	This was an application for a group of variations. B.II.f.1 Change in the shelf-life or storage conditions of the finished product - B.II.f.1.d Change in storage conditions of the finished product or the diluted/reconstituted product - Accepted B.II.f.1 Change in the shelf-life or storage	23/04/2025		SmPC, Labelling and PL	

	conditions of the finished product - B.II.f.1.d Change in storage conditions of the finished product or the diluted/reconstituted product - Accepted B.II.f.1.b Extension of the shelf life of the finished product - B.II.f.1.b.5 Extension of the shelf-life of a biological/ immunological medicinal product in accordance with an approved stability protocol - Accepted B.II.f.1.b Extension of the shelf life of the finished product - B.II.f.1.b.5 Extension of the shelf-life of a biological/ immunological medicinal product in accordance with an approved stability protocol - Accepted				