



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

## Oczyesa

Procedural steps taken and scientific information after the authorisation

Application number	Scope	Opinion/ Notification <sup>1</sup> issued on	Commission Decision Issued <sup>2</sup> / amended on	Product Information affected <sup>3</sup>	Summary
Variation type IB / EMA/VR/0000313339	B.II.f.1.b Extension of the shelf life of the finished product - B.II.f.1.b.1 As packaged for sale (supported by real time data) - Accepted	02/12/2025		SmPC and PL	
Variation type IB / EMA/VR/0000293307	This was an application for a group of variations.	27/10/2025	N/A		

<sup>1</sup> 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.

<sup>2</sup> 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.

<sup>3</sup> SmPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).



	<p>B.II.c.1 Change in the specification parameters and/or limits of an excipient - B.II.c.1.a Tightening of specification limits - Accepted</p> <p>B.II.c.2 Change in test procedure for an excipient - B.II.c.2.d Other changes to a test procedure (including replacement or addition) - Accepted</p> <p>B.II.c.2 Change in test procedure for an excipient - B.II.c.2.d Other changes to a test procedure (including replacement or addition) - Accepted</p> <p>B.II.c.2 Change in test procedure for an excipient - B.II.c.2.d Other changes to a test procedure (including replacement or addition) - Accepted</p> <p>B.II.c.2 Change in test procedure for an excipient - B.II.c.2.d Other changes to a test procedure (including replacement or addition) - Accepted</p>				
Variation type IA_IN / EMA/VR/0000291855	B.II.b.1 Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - B.II.b.1.a Secondary packaging site - Accepted	13/08/2025	N/A		