ALTUVOCT

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
PSUSA/11062 /202408	Periodic Safety Update EU Single assessment - efanesoctocog alfa	13/03/2025	n/a		PRAC Recommendation - maintenance
IB/0006	B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)	03/02/2025	n/a		

[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).

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IAIN/0005	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	09/12/2024	12/12/2025	Annex II and PL	
IAIN/0003/G	This was an application for a group of variations. B.II.f.1.e - Stability of FP - Change to an approved stability protocol A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer responsible for batch release	29/10/2024	n/a		
IB/0002	B.II.d.1.c - Change in the specification parameters and/or limits of the finished product - Addition of a new specification parameter to the specification with its corresponding test method	21/10/2024	n/a		
IB/0001	B.II.g.5.c - Implementation of changes foreseen in an approved change management protocol - For a biological/immunological medicinal product	29/08/2024	n/a		