Elfabrio

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/0007	Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	29/01/2026	05/03/2026	SmPC and PL	Please refer to the "H-5618-II-07-AR-en" assessment report

[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).

PSUSA/11049 /202405	Periodic Safety Update EU Single assessment - pegunigalsidase alfa	28/11/2024	n/a		PRAC Recommendation - maintenance
IB/0006	B.II.g.5.c - Implementation of changes foreseen in an approved change management protocol - For a biological/immunological medicinal product	26/11/2024	n/a		
PSUSA/11049 /202311	Periodic Safety Update EU Single assessment - pegunigalsidase alfa	13/06/2024	n/a		PRAC Recommendation - maintenance
II/0004/G	This was an application for a group of variations. B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes B.II.e.5.c - Change in pack size of the finished product - Change in the fill weight/fill volume of sterile multidose (or single-dose, partial use) parenteral medicinal products, including biological/immunological medicinal products	23/05/2024	12/06/2025	SmPC, Labelling and PL	The SmPC sections 2, 6.5, 6.6 and 8 have been updated to include the addition of new presentations of 1, 2 and 5 vials of 2.5 ml presentation of Elfabrio 2 mg/ml concentrate for solution for infusion (EU/1/23/1724/004-006) The Labelling and PL have been updated accordingly.
II/0002	B.II.g.2 - Introduction of a post approval change management protocol related to the finished product	02/05/2024	n/a		
IB/0001/G	This was an application for a group of variations.	19/06/2023	n/a		

	B.II.g.5.c - Implementation of changes foreseen in an approved change management protocol - For a biological/immunological medicinal product B.II.g.5.c - Implementation of changes foreseen in an approved change management protocol - For a biological/immunological medicinal product B.II.g.5.c - Implementation of changes foreseen in an approved change management protocol - For a biological/immunological medicinal product B.II.g.5.c - Implementation of changes foreseen in an approved change management protocol - For a biological/immunological medicinal product				