



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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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
IAIN/0006	A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer responsible for batch release	18/10/2023		Annex II and PL	
IB/0005	B.II.f.1.b.1 - Stability of FP - Extension of the shelf life of the finished product - As packaged for sale	15/02/2023		SmPC, Labelling and	

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).



	(supported by real time data)			PL	
IB/0004/G	<p>This was an application for a group of variations.</p> <p>B.II.d.1.z - Change in the specification parameters and/or limits of the finished product - Other variation</p> <p>B.II.d.1.z - Change in the specification parameters and/or limits of the finished product - Other variation</p> <p>B.II.d.1.z - Change in the specification parameters and/or limits of the finished product - Other variation</p> <p>B.II.d.1.z - Change in the specification parameters and/or limits of the finished product - Other variation</p>	30/08/2022	n/a		
PSUSA/2932/202103	Periodic Safety Update EU Single assessment - thiotepa	02/12/2021	n/a		PRAC Recommendation - maintenance
IAIN/0003/G	<p>This was an application for a group of variations.</p> <p>A.7 - Administrative change - Deletion of manufacturing sites</p> <p>A.1 - Administrative change - Change in the name and/or address of the MAH</p>	01/12/2021	08/07/2022	SmPC, Annex II, Labelling and PL	
IAIN/0002	<p>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</p>	07/07/2021	08/07/2022	SmPC, Annex II and PL	