EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Celdoxome pegylated liposomal

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
T/0004	Transfer of Marketing Authorisation	19/02/2024	21/03/2024	SmPC, Labelling and PL	
PSUSA/1172/ 202211	Periodic Safety Update EU Single assessment - doxorubicin	22/06/2023	23/08/2023	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for

[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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					PSUSA/1172/202211.
IA/0003	B.II.b.5.c - Change to in-process tests or limits applied during the manufacture of the finished product - Deletion of a non-significant in-process test	08/08/2023	n/a		
IAIN/0002	A.1 - Administrative change - Change in the name and/or address of the MAH	13/04/2023	23/08/2023	SmPC, Labelling and PL	