EMA/511051/2020

Lumark

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/10391 /201912	Periodic Safety Update EU Single assessment - lutetium (177Lu) chloride	23/07/2020	17/09/2020	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/10391/201912.
R/0014	Renewal of the marketing authorisation.	27/02/2020	23/04/2020	SmPC, Annex II, Labelling and PL	Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of Lumark in the approved indication remains favourable and therefore recommended the renewal of the marketing

[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).

					authorisation with unlimited validity.
IB/0015	B.II.e.1.z - Change in immediate packaging of the finished product - Other variation	28/11/2019	n/a		
PSUSA/10391 /201812	Periodic Safety Update EU Single assessment - lutetium (177Lu) chloride	25/07/2019	19/09/2019	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/10391/201812.
IB/0012	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	03/04/2019	n/a		
PSUSA/10391 /201806	Periodic Safety Update EU Single assessment - lutetium (177Lu) chloride	31/01/2019	02/04/2019	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/10391/201806.
N/0010	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	02/10/2018	02/04/2019	Labelling	
PSUSA/10391 /201712	Periodic Safety Update EU Single assessment - lutetium (177Lu) chloride	26/07/2018	20/09/2018	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/10391/201712.
IB/0009/G	This was an application for a group of variations. B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation B.II.c.1.z - Change in the specification parameters and/or limits of an excipient - Other variation	21/08/2018	n/a		

PSUSA/10391 /201706	Periodic Safety Update EU Single assessment - lutetium (177Lu) chloride	25/01/2018	04/04/2018		Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/10391/201706.
IB/0007	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	09/02/2018	n/a		
PSUSA/10391 /201612	Periodic Safety Update EU Single assessment - lutetium (177Lu) chloride	20/07/2017	18/09/2017	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/10391/201612.
PSUSA/10391 /201606	Periodic Safety Update EU Single assessment - lutetium (177Lu) chloride	12/01/2017	n/a		PRAC Recommendation - maintenance
IAIN/0004	A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer responsible for batch release	11/01/2017	18/09/2017	Annex II, Labelling and PL	
T/0002	Transfer of Marketing Authorisation	03/08/2016	22/08/2016	SmPC, Labelling and PL	
PSUSA/10391 /201512	Periodic Safety Update EU Single assessment - lutetium (177Lu) chloride	07/07/2016	n/a		PRAC Recommendation - maintenance