LUTATHERA

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/0005	Update of the SmPC section 5.1 to include information on the quality of life based on relevant analyses of NETTER-I study data. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	31/01/2019	25/03/2019	SmPC	Health Related Quality of Life (HRQOL) was assessed using the European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-C30) (generic instrument) and its neuroendocrine tumour module (EORTC QLQ-GI.NET-21). The results indicate an improvement in the overall global health-related quality of life up to week 84, for patients on Lutathera treatment as compared to patients on Octreotide

[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/10643 /201806	Periodic Safety Update EU Single assessment - lutetium (177Lu) oxodotreotide	17/01/2019	n/a		PRAC Recommendation - maintenance
N/0008	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	17/12/2018	25/03/2019	PL	
IB/0007	B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation	05/12/2018	n/a		
PSUSA/10643 /201712	Periodic Safety Update EU Single assessment - lutetium (177Lu) oxodotreotide	12/07/2018	n/a		PRAC Recommendation - maintenance
IAIN/0004	B.I.a.1.a - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The proposed manufacturer is part of the same pharmaceutical group as the currently approved manufacturer	18/05/2018	n/a		
IAIN/0003	A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer responsible for batch release	21/03/2018	25/03/2019	Annex II, Labelling and PL	
IB/0001	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	21/02/2018	n/a		