EMA/51134/2021

Yttriga

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
N/0018	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	18/12/2020		PL	
PSUSA/3137/ 202003	Periodic Safety Update EU Single assessment - yttrium (90y) chloride	29/10/2020	n/a		PRAC Recommendation - maintenance
IA/0017	B.II.d.2.f - Change in test procedure for the	15/10/2020	n/a		

[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).

	finished product - To reflect compliance with the Ph. Eur. and remove reference to the outdated internal test method and test method number				
IA/0015/G	This was an application for a group of variations. B.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place B.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place B.I.a.1.f - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Changes to quality control testing arrangements for the AS -replacement or addition of a site where batch control/testing takes place	21/02/2019	n/a		
PSUSA/3137/ 201503	Periodic Safety Update EU Single assessment - yttrium (90y) chloride	06/11/2015	n/a		PRAC Recommendation - maintenance
IAIN/0013	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	21/07/2014	08/07/2015	SmPC and PL	
IAIN/0012	C.I.8.a - Introduction of or changes to a summary of Pharmacovigilance system - Changes in QPPV (including contact details) and/or changes in the PSMF location	30/06/2014	n/a		

N/0011	Introducing contact details for local representatives in the Package Leaflet. Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	15/11/2012	08/07/2015	PL	
IA/0010	A.4 - Administrative change - Change in the name and/or address of a manufacturer or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS	16/12/2011	n/a		
N/0009	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	21/11/2011	20/04/2012	PL	
IA/0008	A.5.a - Administrative change - Change in the name and/or address of a manufacturer responsible for batch release	28/09/2011	n/a	Annex II and PL	
T/0007	Transfer of Marketing Authorisation from Eckert&Ziegler Nuclitec GmbH to Eckert & Ziegler Radiopharma GmbH Transfer of Marketing Authorisation	08/07/2011	24/08/2011	SmPC, Labelling and PL	n/a
IB/0006/G	This was an application for a group of variations. B.II.e.1.z - Change in immediate packaging of the finished product - Other variation B.II.e.5.d - Change in pack size of the finished product - Change in the fill weight/fill volume of nonparenteral multi-dose (or single-dose, partial use) products	14/04/2011	14/04/2011	SmPC, Labelling and PL	

R/0005	Renewal of the marketing authorisation.	21/10/2010	06/01/2011	SmPC, Annex II, Labelling and PL	Based on the review of the available information the CHMP is of the opinion that the quality, the safety and the efficacy of this medicinal product continues to be adequately and sufficiently demonstrated and considers that the benefit/risk profile of Yttriga continues to be favourable. The CHMP therefore recommended that a renewal can be granted with unlimited validity. With this procedure the MAH also updated the product information (PI) to align with the current QRD requirements.
IB/0004	IB_37_a_Change in the specification of the finished product - tightening of specification limits	11/09/2009	n/a		
IA/0003	IA_01_Change in the name and/or address of the marketing authorisation holder IA_04_Change in name and/or address of a manuf. of the active substance (no Ph. Eur. cert. avail.) IA_05_Change in the name and/or address of a manufacturer of the finished product IA_08_b_02_Change in BR/QC testing - repl./add. manuf. responsible for BR - incl. BC/testing	01/07/2009	n/a	SmPC, Annex II, Labelling and PL	
IA/0002	IA_01_Change in the name and/or address of the marketing authorisation holder IA_03_Change in the name of the active substance IA_05_Change in the name and/or address of a manufacturer of the finished product	10/12/2008	n/a	SmPC, Annex II, Labelling and PL	

IA/0001	IA_01_Change in the name and/or address of the marketing authorisation holder IA_05_Change in the name and/or address of a manufacturer of the finished product	13/03/2006	n/a	SmPC, Annex II, Labelling and PL	