TOOKAD

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/0020	A.1 - Administrative change - Change in the name and/or address of the MAH	07/12/2022		SmPC, Labelling and PL	
R/0019	Renewal of the marketing authorisation.	21/07/2022	26/09/2022	SmPC, Annex II and PL	Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of

[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).

					TOOKAD in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
PSUSA/10654 /202111	Periodic Safety Update EU Single assessment - padeliporfin	10/06/2022	n/a		PRAC Recommendation - maintenance
IA/0018/G	This was an application for a group of variations. A.5.b - Administrative change - Change in the name and/or address of a manufacturer/importer of the finished product, including quality control sites (excluding manufacturer for batch release) A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient	14/02/2022	n/a		
II/0015	Submission of the Clinical Study Report for Category 1 study: Post-authorisation efficacy study (PAES) CLIN1001 PCM301FU5, A European Randomised Phase 3 Study to Assess the Efficacy and Safety of TOOKAD Soluble for Localised Prostate Cancer compared to Active Surveillance. The Annex II has been updated to remove reference to this study. The RMP version 8.0 is approved. C.I.11.b - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Implementation of change(s) which require to be further substantiated	10/02/2022	21/06/2022	Annex II	The Clinical Study Report for Category 1 study CLIN1001 PCM301FU5 has been submitted and the Annex II has been updated to remove reference to this study.

	by new additional data to be submitted by the MAH where significant assessment is required				
PSUSA/10654 /202105	Periodic Safety Update EU Single assessment - padeliporfin	02/12/2021	n/a		PRAC Recommendation - maintenance
PSUSA/10654 /202011	Periodic Safety Update EU Single assessment - padeliporfin	10/06/2021	n/a		PRAC Recommendation - maintenance
IB/0014	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	25/05/2021	21/06/2022	Annex II	
IB/0011	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	17/12/2020	04/02/2021	Annex II	
PSUSA/10654 /202005	Periodic Safety Update EU Single assessment - padeliporfin	26/11/2020	n/a		PRAC Recommendation - maintenance
IB/0008/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.2.z - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Other variation	08/09/2020	n/a		
IA/0010	B.II.e.2.c - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Deletion of a non-significant	07/09/2020	n/a		

	specification parameter (e.g. deletion of an obsolete parameter)				
IB/0009	B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation	12/08/2020	n/a		
IB/0007	B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation	12/08/2020	n/a		
PSUSA/10654 /201911	Periodic Safety Update EU Single assessment - padeliporfin	11/06/2020	n/a		PRAC Recommendation - maintenance
IAIN/0005	A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer responsible for batch release	20/02/2020	04/02/2021	Annex II and PL	
PSUSA/10654 /201905	Periodic Safety Update EU Single assessment - padeliporfin	28/11/2019	n/a		PRAC Recommendation - maintenance
PSUSA/10654 /201811	Periodic Safety Update EU Single assessment - padeliporfin	14/06/2019	n/a		PRAC Recommendation - maintenance
PSUSA/10654 /201805	Periodic Safety Update EU Single assessment - padeliporfin	29/11/2018	n/a		PRAC Recommendation - maintenance