Fotivda

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/0026	A.1 - Administrative change - Change in the name and/or address of the MAH	17/07/2023		SmPC, Labelling and PL	
IB/0024/G	This was an application for a group of variations.	13/02/2023	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).

	B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation				
IB/0023	B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	17/01/2023	n/a		
PSUSA/10636 /202202	Periodic Safety Update EU Single assessment - tivozanib	29/09/2022	n/a		PRAC Recommendation - maintenance
R/0021	Renewal of the marketing authorisation.	19/05/2022	15/07/2022	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 Fotivda in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
IA/0020	A.7 - Administrative change - Deletion of manufacturing sites	14/10/2021	n/a		
IA/0019	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	14/10/2021	n/a		
II/0018	Submission of an updated RMP version 4.0 in order to include interim data from the phase III Study TIVO-3, a randomised, controlled, multi-centre,	30/09/2021	n/a		

	open-label study to compare tivozanib with sorafenib in subjects with advanced Renal Cell Carcinoma. Addtional updates to the RMP include new information from clinical studies and postmarketing exposure. 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 by new additional data to be submitted by the MAH where significant assessment is required				
PSUSA/10636 /202102	Periodic Safety Update EU Single assessment - tivozanib	30/09/2021	n/a		PRAC Recommendation - maintenance
IA/0017	To change the ATC Code of tivozanib from L01XE34 to L01EK03. A.6 - Administrative change - Change in ATC Code/ATC Vet Code	01/06/2021	24/01/2022	SmPC	
IAIN/0015	A.1 - Administrative change - Change in the name and/or address of the MAH	26/01/2021	24/01/2022	SmPC, Labelling and PL	
PSUSA/10636 /202002	Periodic Safety Update EU Single assessment - tivozanib	01/10/2020	n/a		PRAC Recommendation - maintenance
II/0012	C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority	17/09/2020	n/a		

IB/0014/G	This was an application for a group of variations. B.I.a.2.z - Changes in the manufacturing process of the AS - Other variation B.I.a.3.b - Change in batch size (including batch size ranges) of AS or intermediate - Downscaling down to 10-fold B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation	03/08/2020	n/a		
PSUSA/10636 /201908	Periodic Safety Update EU Single assessment - tivozanib	12/03/2020	n/a		PRAC Recommendation - maintenance
IAIN/0010	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	31/10/2019	10/08/2020	SmPC and PL	
IB/0009	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	05/10/2019	n/a		
PSUSA/10636 /201902	Periodic Safety Update EU Single assessment - tivozanib	05/09/2019	n/a		PRAC Recommendation - maintenance
IAIN/0008	B.II.b.1.b - Replacement or addition of a manufacturing site for the FP - Primary packaging site	26/08/2019	n/a		
IAIN/0007/G	This was an application for a group of variations.	26/08/2019	10/08/2020	Annex II and PL	

	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site 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.c.2 - Change to importer, batch release arrangements and quality control testing of the FP - Including batch control/testing				
PSUSA/10636 /201808	Periodic Safety Update EU Single assessment - tivozanib	14/03/2019	n/a		PRAC Recommendation - maintenance
T/0005	Transfer of Marketing Authorisation	20/12/2018	14/02/2019	SmPC, Labelling and PL	
PSUSA/10636 /201802	Periodic Safety Update EU Single assessment - tivozanib	06/09/2018	n/a		PRAC Recommendation - maintenance
II/0002	Update of the section 5.2 of the SmPC with additional information on transporter proteins based on the results of an in vitro interaction transporter study. The updated RMP version 2.0 was also submitted. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	08/02/2018	14/02/2019	SmPC	In vitro studies have shown that tivozanib is neither a substrate nor inhibitor of the transporter proteins MDR1 (P-gp), OCT1, OATP1B1, OATP1B3 and BSEP. Furthermore, tivozanib was not an in vitro inhibitor of OAT1, OAT3, OCT2, MATE1 and MATE2-K or substrate of MRP2 and BCRP.

II/0001	B.II.d.1.e - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range	07/12/2017	n/a		