Pemazyre

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/10923 /202210	Periodic Safety Update EU Single assessment - pemigatinib	25/05/2023	26/07/2023	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/10923/202210.
IA/0011	A.5.b - Administrative change - Change in the name and/or address of a manufacturer/importer of the	24/03/2023	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).

	finished product, including quality control sites (excluding manufacturer for batch release)				
PSUSA/10923 /202204	Periodic Safety Update EU Single assessment - pemigatinib	15/12/2022	24/02/2023	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/10923/202204.
R/0007	Renewal of the marketing authorisation.	15/12/2022	23/02/2023		The CHMP, having reviewed the available information on the status of the fulfilment of Specific Obligations and having confirmed the positive benefit risk balance, is of the opinion that the quality, safety and efficacy of this medicinal product continue to be adequately and sufficiently demonstrated and therefore recommends the renewal of the conditional MA for Pemazyre, subject to the Specific Obligations and Conditions as laid down in Annex II to the opinion.
IB/0009/G	This was an application for a group of variations. B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition) B.II.b.4.b - Change in the batch size (including batch size ranges) of the finished product - Downscaling down to 10-fold B.II.f.1.b.1 - Stability of FP - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data) B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure B.II.d.2.a - Change in test procedure for the finished	02/12/2022	23/02/2023	SmPC	

	product - Minor changes to an approved test procedure				
IB/0008/G	This was an application for a group of variations. B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure B.I.d.1.a.4 - Stability of AS - Change in the re-test period/storage period - Extension or introduction of a re-test period/storage period supported by real time data B.I.a.3.a - Change in batch size (including batch size ranges) of AS or intermediate - Up to 10-fold increase compared to the originally approved batch size B.I.b.1.d - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) B.I.d.1.z - Stability of AS - Change in the re-test period/storage period or storage conditions - Other variation B.I.b.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	01/12/2022	n/a		

PSUSA/10923 /202110	Periodic Safety Update EU Single assessment - pemigatinib	10/06/2022	n/a		PRAC Recommendation - maintenance
II/0005	Update of sections 4.4, 4.8 and 5.1 of the SmPC based on the final results from study INCB054828 (FIGHT-202) listed as a specific obligation in the Annex II (SOB/002); this is a phase 2 study investigating the efficacy and safety of pemigatinib in adults with advanced/metastatic or surgically unresectable cholangiocarcinoma including FGFR2 translocations who failed previous therapy. The Annex II has been updated accordingly. RMP version 2.0 has also been submitted. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	19/05/2022	23/02/2023	SmPC and Annex II	The main proposed changes in the SmPC are as follows: - Section 4.4: update of data on Hyperphosphatemia and Hypophosphatemia based on INCB 54828-202 final CSR - Section 4.8: update of frequency of AEs and description of Hyperphosphatemia and Serious retinal detachment based on INCB 54828-202 final CSR - Section 5.1: update of efficacy results based on INCB 54828-202 final CSR For more information, please refer to the Summary of Product Characteristics.
R/0003	Renewal of the marketing authorisation.	16/12/2021	16/02/2022	SmPC and PL	The CHMP, having reviewed the available information on the status of the fulfilment of Specific Obligations and having confirmed the positive benefit risk balance, is of the opinion that the quality, safety and efficacy of this medicinal product continue to be adequately and sufficiently demonstrated and therefore recommends the renewal of the conditional MA for Pemazyre, subject to the Specific Obligations and Conditions as laid down in Annex II to the opinion.
PSUSA/10923 /202104	Periodic Safety Update EU Single assessment - pemigatinib	02/12/2021	n/a		PRAC Recommendation - maintenance

IB/0001	B.II.f.1.b.1 - Stability of FP - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)	03/08/2021	16/02/2022	SmPC	