Vizimpro

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/0012	A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer responsible for batch release	11/12/2024		Annex II and PL	
R/0011	Renewal of the marketing authorisation.	12/10/2023	07/12/2023	SmPC 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).

					Vizimpro in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
PSUSA/10757 /202209	Periodic Safety Update EU Single assessment - dacomitinib	14/04/2023	n/a		PRAC Recommendation - maintenance
IA/0010/G	This was an application for a group of variations. 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 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 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 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	27/02/2023	n/a		
PSUSA/10757 /202109	Periodic Safety Update EU Single assessment - dacomitinib	05/05/2022	n/a		PRAC Recommendation - maintenance

PSUSA/10757 /202103	Periodic Safety Update EU Single assessment - dacomitinib	28/10/2021	n/a		PRAC Recommendation - maintenance
IA/0007	A.6 - Administrative change - Change in ATC Code/ATC Vet Code	02/07/2021	29/06/2022	SmPC and PL	
PSUSA/10757 /202009	Periodic Safety Update EU Single assessment - dacomitinib	06/05/2021	n/a		PRAC Recommendation - maintenance
II/0003/G	This was an application for a group of variations. Update of sections 4.2 and 5.2 of the SmPC in order to revise the dosing recommendation for patients with hepatic impairment and include relevant pharmacokinetics data based on results of Study A7471058, evaluating the effect of severe hepatic impairment on the plasma PK, safety and tolerability after a single dose of dacomitinib. As a consequence, the MAH is proposing to remove the missing information "Safety in Patient with Severe Hepatic Impairment" from the list of safety concerns in the RMP v2.0. In addition, the MAH took the opportunity to bring the PI in line with the latest QRD template version 10.1. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data C.I.11.b - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Implementation of	10/12/2020	22/01/2021	SmPC, Labelling and PL	Based on results of study A7471058, a dedicated hepatic impairment trial, following a single oral dose of 30 mg Vizimpro, dacomitinib exposure was unchanged for AUCinf and increased by 31% for Cmax in subjects with severe hepatic impairment (Child-Pugh class C; N=8), when compared to subjects with normal hepatic function (N=8). As a consequence, the starting dose of Vizimpro should be adjusted to 30 mg once daily in patients with severe (Child-Pugh class C) hepatic impairment. The dose may be increased to 45 mg once daily based on individual safety and tolerability after at least 4 weeks of treatment.

	change(s) which require to be further substantiated by new additional data to be submitted by the MAH where significant assessment is required				
N/0004	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	27/11/2020	22/01/2021	PL	
PSUSA/10757 /202003	Periodic Safety Update EU Single assessment - dacomitinib	29/10/2020	n/a		PRAC Recommendation - maintenance
PSUSA/10757 /201909	Periodic Safety Update EU Single assessment - dacomitinib	17/04/2020	n/a		PRAC Recommendation - maintenance