QINLOCK

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
IA/0022/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)	09/12/2024	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).

	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)				
PSUSA/10962 /202405	Periodic Safety Update EU Single assessment - ripretinib	28/11/2024	n/a		PRAC Recommendation - maintenance
IB/0020	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	17/09/2024	n/a		
IB/0019	B.I.b.2.e - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure (including replacement or addition) for the AS or a starting material/intermediate	17/09/2024	n/a		
IB/0021	B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)	16/09/2024	n/a		
N/0017	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	27/06/2024		PL	
PSUSA/10962 /202305	Periodic Safety Update EU Single assessment - ripretinib	30/11/2023	n/a		PRAC Recommendation - maintenance
IA/0016/G	This was an application for a group of variations. B.I.a.2.a - Changes in the manufacturing process of	28/11/2023	n/a		

	the AS - Minor change in the manufacturing process of the AS 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				
IB/0014	B.II.f.z - Stability of FP - Other variation	14/09/2023	n/a		
IAIN/0015/G	This was an application for a group of variations. B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site 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.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)	17/08/2023	n/a		
IB/0012	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)	21/06/2023	08/02/2024	SmPC	
PSUSA/10962 /202211	Periodic Safety Update EU Single assessment - ripretinib	08/06/2023	n/a		PRAC Recommendation - maintenance
IB/0011	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing	11/05/2023	n/a		

	authorisation, including the RMP - Other variation				
PSUSA/10962 /202205	Periodic Safety Update EU Single assessment - ripretinib	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/10962/202205.
IB/0009	B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation	31/01/2023	n/a		
II/0004	Update of sections 4.2 and 5.2 of the SmPC in order to change posology recommendations in patients with hepatic impairment and update the description of pharmacokinetics based on final results from Study DCC-2618-01-004; a Phase 1 study of the Pharmacokinetics, Safety, and Tolerability of Ripretinib in Subjects With Hepatic Impairment Compared to Healthy Control Subjects. The Package Leaflet is updated accordingly. The RMP version 2.2 has also been submitted. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	26/01/2023	08/02/2024	SmPC and PL	SmPC new text
IB/0008	B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)	08/11/2022	n/a		
IA/0007/G	This was an application for a group of variations. B.II.d.2.a - Change in test procedure for the finished	27/10/2022	n/a		

	product - Minor changes to an approved test procedure B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure				
IB/0005	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	18/08/2022	n/a		
IB/0003	B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation	17/05/2022	n/a		
II/0002	C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority	10/03/2022	n/a		
IAIN/0001/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) B.II.b.2.c.1 - Change to importer, batch release arrangements and quality control testing of the FP - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing	13/12/2021	02/12/2022	SmPC, Annex II, Labelling and PL	