Kengrexal

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/0034/G	This was an application for a group of variations. 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 -	22/11/2024		Annex II and PL	

[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).

	Not including batch control/testing 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				
II/0033	B.I.a.1.b - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Introduction of a manufacturer of the AS supported by an ASMF	14/11/2024	n/a		
IB/0032	B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation	09/04/2024	n/a		
II/0031	C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority	31/08/2023	n/a		
IAIN/0030	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	16/01/2023	08/06/2023	Annex II and PL	
IA/0029/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 A.4 - Administrative change - Change in the name	14/12/2022	n/a		

	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 B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure				
N/0028	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	15/11/2022	08/06/2023	PL	
PSUSA/10360 /202203	Periodic Safety Update EU Single assessment - cangrelor	27/10/2022	n/a		PRAC Recommendation - maintenance
IB/0026	C.I.3.z - Change(s) in the SPC, Labelling or PL intended to implement the outcome of a procedure concerning PSUR or PASS or the outcome of the assessment done under A 45/46 - Other variation	23/04/2022	08/06/2023	SmPC	
IB/0024	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	21/12/2021	n/a		
N/0025	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	09/12/2021	08/06/2023	PL	
IB/0023/G	This was an application for a group of variations. B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation B.I.b.1.b - Change in the specification parameters	22/06/2021	n/a		

	and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - 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				
IB/0022/G	This was an application for a group of variations. B.I.a.1.f - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Changes to quality control testing arrangements for the AS -replacement or addition of a site where batch control/testing takes place 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.7 - Administrative change - Deletion of manufacturing sites B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation B.I.b.1.z - Change in the specification parameters	04/02/2021	n/a		

	and/or limits of an AS, starting material/intermediate/reagent - Other variation B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation B.I.b.1.c - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Addition of a new specification parameter to the specification with its corresponding test method B.I.a.2.e - Changes in the manufacturing process of the AS - Minor change to the restricted part of an ASMF B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation B.I.c.z - Container closure system of the AS - Other variation B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure				
N/0021	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	03/12/2020	08/06/2023	PL	
R/0020	Renewal of the marketing authorisation.	17/10/2019	16/12/2019	SmPC, Annex II, Labelling and PL	Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of Kengrexal in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
PSUSA/10360	Periodic Safety Update EU Single assessment -	03/10/2019	n/a		PRAC Recommendation - maintenance

/201903	cangrelor				
IB/0018/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites 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.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	05/08/2019	n/a		
II/0015	Submission of an updated RMP (version 3.1) in order to revise the objectives, the safety concerns to address and the milestones for a study listed as category 3 in the RMP: a multicentre retrospective observational study of patients undergoing percutaneous coronary intervention (PCI) who receive cangrelor and transition to either clopidogrel, prasugrel or ticagrelo (ARCANGELO – Italian prospective study on cangrelor). The protocol synopsis of the PASS is included in the Annex to the RMP. In addition, the RMP and the list of safety concerns are revised in accordance with the GVP Module V guideline (rev. 2). C.I.11.b - Introduction of, or change(s) to, the obligations and conditions of a marketing	11/04/2019	n/a		The MAH's proposal to waive the requirement to conduct a multicentre retrospective observational study of patients undergoing percutaneous coronary intervention (PCI) who receive cangrelor and transition to either clopidogrel, prasugrel or ticagrelo is not accepted by PRAC. The objectives, the safety concerns to address and milestones of the study are revised. The study will assess the safety of cangrelor in a real world setting in Italy, when administered in patients with acute coronary syndromes undergoing PCI who have not received an oral P2Y12 inhibitor prior to the PCI procedure and in whom oral therapy with P2Y12 inhibitors is not feasible or desirable. The safety of cangrelor will be based on the incidence of bleeding and transfusion outcomes in the 30 days post-PCI. In addition, the list of safety concerns in the RMP is updated in accordance with Guideline on good

	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				pharmacovigilance practices (GVP) Module V, revision 2.
IA/0017/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites A.7 - Administrative change - Deletion of manufacturing sites	05/04/2019	n/a		
N/0016	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	20/11/2018	16/12/2019	PL	
PSUSA/10360 /201803	Periodic Safety Update EU Single assessment - cangrelor	04/10/2018	n/a		PRAC Recommendation - maintenance
N/0013	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	12/04/2018	12/12/2018	Labelling and PL	
N/0012	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	31/01/2018	12/12/2018	PL	
IAIN/0010	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	10/11/2017	12/12/2018	Annex II and PL	
PSUSA/10360 /201703	Periodic Safety Update EU Single assessment - cangrelor	26/10/2017	n/a		PRAC Recommendation - maintenance

N/0007	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	21/04/2017	12/12/2018	PL	
PSUSA/10360 /201609	Periodic Safety Update EU Single assessment - cangrelor	06/04/2017	n/a		PRAC Recommendation - maintenance
IAIN/0006	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	05/01/2017	n/a		
PSUSA/10360 /201603	Periodic Safety Update EU Single assessment - cangrelor	29/09/2016	n/a		PRAC Recommendation - maintenance
T/0004	Transfer of Marketing Authorisation	02/08/2016	02/09/2016	SmPC, Labelling and PL	
PSUSA/10360 /201509	Periodic Safety Update EU Single assessment - cangrelor	14/04/2016	n/a		PRAC Recommendation - maintenance
IB/0002/G	This was an application for a group of variations. 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.b.5.b - Change to in-process tests or limits applied during the manufacture of the finished product - Addition of a new test(s) and limits	03/02/2016	02/09/2016	SmPC, Labelling and PL	