Kinpeygo

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
N/0015	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	06/12/2024		PL	
IB/0014	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	06/11/2024	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).

PSUSA/11007 /202312	Periodic Safety Update EU Single assessment - budesonide (for centrally authorised products indicated for primary immunoglobulin A nephropathy only)	25/07/2024	25/09/2024	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/11007/202312.
II/0008	Extension of indication to slow kidney function decline in adults with primary immunoglobulin A (IgA) nephropathy (IgAN) for KINPEYGO, based on Part B of study NefIgArd (NEF-301), listed as the final specific obligation in the Annex II in the initial MA; this is a Phase 3, randomised, double-blind, placebo-controlled, multicenter study to evaluate the efficacy, safety, and tolerability of oral Nefecon compared to matching placebo in patients with primary IgAN on a background of optimized RAS inhibitor therapy. As a consequence, sections 4.1, 4.2, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 1.3 of the RMP has been agreed. In addition, the CHMP, having considered the application as set out in the appended assessment report and having reviewed the data submitted by the marketing authorisation holder including the evidence concerning compliance with specific obligations, is of the opinion that the risk-benefit balance of the above mentioned medicinal product remains favourable, that all specific obligations laid down in Annex II have been fulfilled and that comprehensive data supports a favourable benefit-risk balance of the above mentioned medicinal product. Therefore, pursuant to Article 14-a(8) of	30/05/2024	24/07/2024	SmPC and PL	Please refer to Scientific Discussion Kinpeygo EMEA/H/C/005653/II/0008

	Regulation (EC) No 726/2004, the CHMP recommends by consensus the granting of a marketing authorisation in accordance with Article 14(1) of Regulation (EC) No 726/2004 for the above mentioned medicinal product for which the draft Summary of Product Characteristics is set out in Annex I. In addition, the CHMP, with reference to Article 8 of Regulation (EC) No 141/2000, considers by consensus Kinpeygo not to be similar (as defined in Article 3 of Commission Regulation (EC) No. 847/2000) to authorised orphan medicinal products for the same therapeutic indication. C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one				
R/0010	Renewal of the marketing authorisation.	25/04/2024	17/06/2024		
IA/0012/G	This was an application for a group of variations. 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.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.a - Change to importer, batch release arrangements and quality control testing of the FP -	10/05/2024	n/a		

	Replacement/addition of a site where batch control/testing takes place				
IB/0009/G	This was an application for a group of variations. B.II.e.4.a - Change in shape or dimensions of the container or closure (immediate packaging) - Non-sterile medicinal products B.II.e.4.a - Change in shape or dimensions of the container or closure (immediate packaging) - Non-sterile medicinal products B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes B.II.f.1.d - Stability of FP - Change in storage conditions of the finished product or the diluted/reconstituted product	08/03/2024	17/06/2024	SmPC, Labelling and PL	
PSUSA/11007 /202306	Periodic Safety Update EU Single assessment - budesonide (for centrally authorised products indicated for primary immunoglobulin A nephropathy only)	11/01/2024	n/a		PRAC Recommendation - maintenance
IAIN/0006/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 -	21/08/2023	17/06/2024	Annex II and PL	

	Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site B.II.b.1.b - Replacement or addition of a manufacturing site for the FP - Primary packaging site B.II.b.1.b - Replacement or addition of a manufacturing site for the FP - Primary packaging site 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 B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site				
R/0003	Renewal of the marketing authorisation.	25/05/2023	17/07/2023		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 Kinpeygo, subject to the Specific Obligations and Conditions as laid down in Annex II to the opinion.
N/0005	Minor change in labelling or package leaflet not	13/07/2023	17/06/2024	PL	

	connected with the SPC (Art. 61.3 Notification)				
PSUSA/11007 /202212	Periodic Safety Update EU Single assessment - budesonide (for centrally authorised products indicated for primary immunoglobulin A nephropathy only)	06/07/2023	n/a		PRAC Recommendation - maintenance
IB/0002	B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes	23/11/2022	17/07/2023	SmPC, Labelling and PL	Product information updated to add a new pack-size of 3 packs of 120 modified-release hard capsules in multipack carton for Kinpeygo 4 mg modified-release hard capsules EU/1/22/1657/002.
T/0001	Transfer of Marketing Authorisation	25/08/2022	15/09/2022	SmPC, Labelling and PL	