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
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	08/03/2024		SmPC, Labelling 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).

	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				
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 - 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	21/08/2023		Annex II and PL	

	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 connected with the SPC (Art. 61.3 Notification)	13/07/2023		PL	
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	