Koselugo

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
PSUSA/10936 /202304	Periodic Safety Update EU Single assessment - selumetinib	26/10/2023	n/a		PRAC Recommendation - maintenance
II/0013	Update of sections 4.2 and 5.2 of the SmPC in order to update the recommended dosage regimen to remove the fasting state and update pharmacokinetic	14/09/2023	19/10/2023	SmPC, Annex II and PL	For more information, please refer to the Summary of Product Characteristics.

[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).

	information, based on the final results from study D1346C00015; this is a phase 1, single-arm, sequential study to evaluate the effect of food on the gastrointestinal tolerability and pharmacokinetics of selumetinib after multiple doses in adolescent children with neurofibromatosis type 1 (NF1) related plexiform neurofibromas (PN). The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data				
R/0010	Renewal of the marketing authorisation.	30/03/2023	31/05/2023	SmPC, Annex II and PL	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 Koselugo, subject to the Specific Obligations and Conditions as laid down in Annex II to the opinion.
PSUSA/10936 /202210	Periodic Safety Update EU Single assessment - selumetinib	12/05/2023	n/a		PRAC Recommendation - maintenance
N/0012	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	13/01/2023	31/05/2023	PL	

PSUSA/10936 /202204	Periodic Safety Update EU Single assessment - selumetinib	27/10/2022	n/a		PRAC Recommendation - maintenance
II/0006/G	This was an application for a group of variations. C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority	13/10/2022	n/a		
IA/0009	B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	30/08/2022	n/a		
N/0008	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	18/07/2022	31/05/2023	PL	
N/0005	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	29/06/2022	31/05/2023	PL	
PSUSA/10936 /202110	Periodic Safety Update EU Single assessment - selumetinib	05/05/2022	n/a		PRAC Recommendation - maintenance
R/0003	Renewal of the marketing authorisation.	24/02/2022	25/04/2022	Annex II	
IB/0002	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	19/10/2021	25/04/2022	Annex II	

IB/0001	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	03/08/2021	n/a		