Nexpovio

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/0016	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	14/08/2023		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	03/07/2023	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).

IAIN/0013	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	19/04/2023	n/a		
PSUSA/10926 /202209	Periodic Safety Update EU Single assessment - selinexor	14/04/2023	n/a		PRAC Recommendation - maintenance
II/0011	Update of section 4.5 of the SmPC in order to add drug-drug interaction information regarding the strong CYP3A4 inhibitor, clarithromycin, based on results from the drug-drug interaction (DDI) pharmacokinetic (PK) portion of Study KCP 330-017 (STOMP) following procedure EMEA/H/C/005127/REC/003.1. This is a Phase 1b/2, multi-center, open-label, clinical study with Dose Escalation (Phase 1) and Expansion (Phase 2) to independently assess the MTD, efficacy, and safety of 10 combination therapies in 11 arms in patients with RRMM (Relapsed/Refractory Multiple Myeloma) and NDMM (Newly Diagnosed Multiple Myeloma). C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	26/01/2023		SmPC	Not applicable
IAIN/0010/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	11/11/2022		Annex II and PL	

	responsible for importation and/or batch release - 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				
PSUSA/10926 /202203	Periodic Safety Update EU Single assessment - selinexor	27/10/2022	n/a		PRAC Recommendation - maintenance
IAIN/0009/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.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.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	22/09/2022		Annex II and PL	
T/0007	Transfer of Marketing Authorisation	24/06/2022	22/07/2022	SmPC, Labelling and PL	

II/0001/G	This was an application for a group of variations. • Extension of indication for Nexpovio in combination with bortezomib and dexamethasone for the treatment of adult patients with multiple myeloma who have received at least one prior therapy and, • Addition of a new pack size (8 tablets) to align with the dose modification guidance for the new indication. Accordingly, Sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1 and 6.5 of the SmPC are updated to reflect the new indication and the new pack size. • Fulfilment of the Specific Obligation agreed in the context of the CMA of Nexpovio via the submission of results from the confirmatory Phase 3 study, KCP-330-023, thereby supporting the granting of a marketing authorisation not subject to specific obligations. Annex II is updated to reflect the completion of the Specific Obligation. The Labelling and Package Leaflet are amended accordingly. The RMP (v 2.0) is amended consequently. C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one B.II.z - Quality change - Finished product - Other variation	19/05/2022	18/07/2022	SmPC, Annex II, Labelling and PL	Please refer to Scientific Discussion 'Nexpovio-H-C-5127-II-0001/G'
IB/0006/G	This was an application for a group of variations.	25/05/2022	22/07/2022	SmPC and PL	C.I.z - To update the PL to include the name and address of the site responsible for batch release of the finished

	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 B.I.b.2.z - Change in test procedure for AS or starting material/reagent/intermediate - Other variation C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation 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) 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)				product. B.II.f.1.b.1 - To extend the shelf-life of the finished product as packaged for sale from 48 months to 60 months.
R/0005	Renewal of the marketing authorisation.	24/03/2022	13/05/2022		Positive Opinion adopted by consensus together with the CHMP assessment report ‹and translation timetable›. The CHMP was of the opinion that the renewal for this conditional Marketing Authorisation can be granted. The Marketing Authorisation remains conditional. The Icelandic and Norwegian CHMP Members were in agreement with the CHMP Opinion.
PSUSA/10926 /202109	Periodic Safety Update EU Single assessment - selinexor	05/05/2022	n/a		PRAC Recommendation - maintenance
IA/0003/G	This was an application for a group of variations. B.I.b.2.c - Change in test procedure for AS or starting material/reagent/intermediate - Other	16/11/2021	n/a		

	changes to a test procedure for a reagent, which does not have a significant effect on the overall quality of the AS B.II.b.5.a - Change to in-process tests or limits applied during the manufacture of the finished product - Tightening of in-process limits A.z - Administrative change - 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 B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - 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/0002/G	This was an application for a group of variations. B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition) B.I.c.z - Container closure system of the AS - Other variation B.I.b.z - Change in control of the AS - Other variation B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition) B.II.f.1.b.1 - Stability of FP - Extension of the shelf life of the finished product - As packaged for sale	10/09/2021	13/05/2022	SmPC	

	(supported by real time data)				