



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Nexpovio

Procedural steps taken and scientific information after the authorisation*

*Due to the Agency's update of its procedure management systems, an additional document, reflecting the historical lifecycle may be available in the 'Assessment history' section. For the complete product lifecycle procedures, you may need to also refer to **EPAR - Procedural steps taken and scientific information after authorisation (archive)**.

Application number	Scope	Opinion/ Notification ¹ issued on	Commission Decision Issued ² / amended on	Product Information affected ³	Summary
Variation type IB /	Outcome:	29/07/2026			

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).



EMA/VR/0000357748	This was an application for a group of variations. Q.II.b.3 Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Q.II.b.3.e) Change in the holding time and/or storage conditions of an intermediate or bulk product used in the manufacture of the finished product - Accepted Q.II.b.3 Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - Q.II.b.3.z Other variation - Accepted				
Variation type IB / EMA/VR/0000355819	Outcome: Q.II.b.5 Change to in-process control or limits applied during the manufacture of the finished product - Q.II.b.5.z Other variation - Accepted	09/07/2026			
Variation type II / EMA/VR/0000291736	Outcome: This was an application for a group of variations. C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.4 Change(s) in the Summary of Product Characteristics,	19/02/2026	26/03/2026	SmPC and PL	

	Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data - Accepted C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.4 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data - Accepted A grouped application consisting of: C.I.4: Update of sections 4.2, and 5.2 of the SmPC in order to include the recommended dose adjustment strategy in patients with severe hepatic impairment, and update pharmacokinetic, information based on interim results from study KCP-330-027; this is an open-label, phase 1/2, interventional study assessing the effect of hepatic impairment on selinexor pharmacokinetics; the Package Leaflet is updated accordingly. The RMP version 4.0 has also been submitted. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet and to introduce editorial changes to the PI. C.I.4: Update of section 4.5 of the SmPC in order to add drug-drug interaction information with strong CYP3A4 and UGT inducer carbamazepine based on final results from study XPORT-HV-045; this is a phase 1 drug-drug interaction study in healthy				
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	volunteers to evaluate the effect of carbamazepine (a strong CYP3A4 inducer) on the pharmacokinetics of selinexor.				
Variation type IA / EMA/VR/0000322907	Outcome: This was an application for a group of variations. B.II.d.2 Change in test procedure for the finished product - B.II.d.2.a Minor changes to an approved test procedure - Accepted B.II.d.2 Change in test procedure for the finished product - B.II.d.2.a Minor changes to an approved test procedure - Accepted	15/01/2026			
Variation type IA / EMA/VR/0000317940	Outcome: B.I.b.2 Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - B.I.b.2.a Minor changes to an approved test procedure - Accepted	17/12/2025			
Variation type IA / EMA/VR/0000318969	Outcome: This was an application for a group of variations. B.I.b.2 Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - B.I.b.2.a Minor changes to an	16/12/2025			

	approved test procedure - Accepted B.I.b.2 Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - B.I.b.2.a Minor changes to an approved test procedure - Accepted				
Variation type IA / EMA/VR/0000314544	Outcome: A. ADMINISTRATIVE CHANGES - A.7 Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* - Accepted	27/11/2025			
Variation type IA / EMA/VR/0000294978	Outcome: This was an application for a group of variations. B.II.d.2 Change in test procedure for the finished product - B.II.d.2.a Minor changes to an approved test procedure - Accepted B.II.d.2 Change in test procedure for the finished product - B.II.d.2.a Minor changes to an approved test procedure - Accepted B.II.d.2 Change in test procedure for the finished product - B.II.d.2.a Minor changes to an approved test procedure - Accepted B.II.d.2 Change in test procedure for the	03/09/2025			

	finished product - B.II.d.2.a Minor changes to an approved test procedure - Accepted				
Variation type IB / EMA/VR/0000286221	Outcome: This was an application for a group of variations. B.I.b.2 Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - B.I.b.2.z Other changes - Accepted B.II.d.2 Change in test procedure for the finished product - B.II.d.2.z Other changes - Accepted	06/08/2025			
Variation type IA / EMA/VR/0000288406	Outcome: B.II.b.3 Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - B.II.b.3.z Change in the packaging material of bulk product not in contact with the bulk product formulation (including replacement or addition) - Accepted	29/07/2025			
Variation type IA / EMA/VR/0000286242	Outcome: B.I.b.2 Change in test procedure for active substance or starting material/reagent/intermediate used in the	15/07/2025			

	manufacturing process of the active substance - B.I.b.2.a Minor changes to an approved test procedure - Accepted				
Variation type IB / EMA/VR/0000262262	Outcome: B.I.b.2 Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - B.I.b.2.e Other changes to a test procedure (including replacement or addition) for the active substance or a starting material/intermediate - Accepted	06/05/2025			
Variation type IA_IN / EMA/VR/0000266528	Outcome: B.II.b.1 Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - B.II.b.1.a Secondary packaging site - Accepted	17/04/2025			
PSUR / EMA/PSUR/0000282278	EURD: PSUSA/00010926/202503 Active substance: selinexor Outcome: Maintenance	30/10/2025			Maintenance