JEMPERLI

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 II /	Outcome:	23/04/2026	04/06/2026	SmPC and PL	Jemperli Section 4.2 'Posology and method of

[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/0000296756	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. 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 Update of sections 4.2, 4.8, 5.1 and 5.2 of the Zejula SmPC and update of sections 4.2, 5.1 and 5.2 of the Jemperli SmPC to include the final results from study 213406 (SCOOP) in order to complete the PIPs EMA/PE/0000270085 for Jemperli and EMA/PE/0000269425 for Zejula and in order to fulfil Article 46 of Regulation EC No 1901/2006. Study 213406 (SCOOP) is a phase 1, multicentre, open-label, dose escalation and cohort expansion study of niraparib and dostarlimab in paediatric participants with recurrent or refractory solid tumours. the Package Leaflet is updated accordingly. In addition, the WSA took the opportunity to implement some minor corrections throughout the Jemperli and the Zejula PIs.				administration' of the SmPC Paediatric population The safety and efficacy of JEMPERLI in children and adolescents aged below 18 years of age have not been established. Outside its authorised indications, JEMPERLI in combination with niraparib has been studied in children aged 5 to less than 18 years with recurrent or refractory solid tumours including osteosarcoma and neuroblastoma; however, the study data were limited and the results of the study did not allow to conclude that the benefits of such use outweigh the risks. Currently available data are described in sections 5.1 and 5.2. Section 5.1 'Pharmacodynamic properties 'of the SmPC Paediatric population In a Phase 1 study (SCOOP), the safety, pharmacokinetics, and antitumour activity of JEMPERLI in combination with niraparib were evaluated in 47 children and adolescents with recurrent or refractory solid tumours including osteosarcoma and neuroblastoma. Patients aged 5 to <18 years received JEMPERLI 3 mg/kg or 7.5 mg/kg (up to 500 mg) every 3 weeks. The study was terminated prematurely due to observed toxicities in conjunction with insufficient efficacy. No efficacy response was observed in the 17 patients with osteosarcoma or neuroblastoma included in the expansion part of the study. The safety profile of the combination in the paediatric population cannot be considered established due to the limited number of paediatric patients evaluated with limited exposure. See section 4.2 for information on paediatric use. Section 5.2 'Pharmacokinetic properties' of the SmPC Paediatric population In a

					Phase 1 study (SCOOP), the pharmacokinetics of dostarlimab was evaluated in 44 children and adolescents with recurrent or refractory solid tumours. The study was prematurely terminated and therefore the pharmacokinetic data obtained were limited. In the participant samples analysed at 7.5 mg/kg (N = 28), dostarlimab exposures were generally consistent with those seen in adults. Zejula Section 4.2 'Posology and method of administration' of the SmPC Paediatric population The safety and efficacy of Zejula in children and adolescents aged below 18 years of age have not been established. Outside its authorised indications, Zejula in combination with dostarlimab has been studied in children aged 5 to less than 18 years with recurrent or refractory solid tumours including osteosarcoma and neuroblastoma; however, the study data were limited and the results of the study did not allow to conclude that the benefits of such use outweigh the risks. Currently available data are described in sections 5.1 and 5.2. Section 5.1 'Pharmacodynamic properties 'of the SmPC Paediatric population The European Medicines Agency has waived the obligation to submit the results of studies with Zejula in all subsets of the paediatric population in ovarian carcinoma, excluding rhabdomyosarcoma and germ cell tumours (see section 4.2 for information on paediatric use). However, paediatric development was conducted in children and adolescents with other oncology conditions. In a Phase 1 study (SCOOP), the safety, pharmacokinetics, and

					antitumour activity of Zejula in combination with dostarlimab were evaluated in 47 children and adolescents with recurrent or refractory solid tumours including osteosarcoma and neuroblastoma. Patients aged 5 to <18 years received Zejula 75 to 200 mg daily. The study was terminated prematurely due to observed toxicities in conjunction with insufficient efficacy. No efficacy response was observed in the 17 patients with osteosarcoma or neuroblastoma included in the expansion part of the study. The safety profile of the combination in the paediatric population cannot be considered established due to the limited number of paediatric patients evaluated with limited exposure. See section 4.2 for information on paediatric use. Section 5.2 'Pharmacokinetic properties' of the SmPC Paediatric population In a Phase 1 study (SCOOP), the pharmacokinetics of niraparib was evaluated in 44 children and adolescents with recurrent or refractory solid tumours. While a clinical study was initiated to evaluate pharmacokinetics in this population, the study was prematurely terminated. Consequently, the pharmacokinetic data obtained were limited and insufficient to reliably characterise exposures in paediatric patients. For more information, please refer to the Summary of Product Characteristics.
Variation type II / EMA/VR/0000303403	Outcome: This was an application for a group of variations.	10/04/2026	04/06/2026	Annex II and PL	

	B.I.a.3 Change in batch size (including batch size ranges) of active substance or intermediate used in the manufacturing process of the active substance - B.I.a.3.c The change requires assessment of the comparability of a biological/immunological active substance - Accepted B.I.a.1 Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - B.I.a.1.e The change relates to a biological active substance or a starting material/reagent/intermediate used in the manufacture of a biological/immunological product - Accepted B.I.a.1 Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - B.I.a.1.j Changes to quality control testing arrangements for a biological active substance: replacement or addition of a site where batch control/testing including a biological / immunological / immunochemical method takes place -				

	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.e Other changes to a test procedure (including replacement or addition) for the active substance or a starting material/intermediate - Accepted B.I.c.1 Change in immediate packaging of the active substance - B.I.c.1.a Qualitative and/or quantitative composition - Accepted				
Variation type IB / EMA/VR/0000335826	Outcome: This was an application for a group of variations. Q.II.f.1.b) Extension of the shelf life of the finished product - Q.II.f.1.b.1 As packaged for sale (supported by real time data, fully in line with the stability protocol) - Accepted Q.II.f.1 Change in the shelf life or storage - Q.II.f.1.e Change to an approved stability protocol of the finished product - Accepted	31/03/2026	04/06/2026	SmPC	
Variation type II / EMA/VR/0000309506	Outcome: B.I.a.1 Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer	22/01/2026			

	(including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - B.I.a.1.j Changes to quality control testing arrangements for a biological active substance: replacement or addition of a site where batch control/testing including a biological / immunological / immunochemical method takes place - Accepted				
PSUR / EMA/PSUR/0000288247	EURD: PSUSA/00010931/202504 Active substance: dostarlimab Outcome: Variation In view of available data on Stevens-Johnson syndrome from spontaneous reports and in view of a plausible mechanism of action, the PRAC Rapporteur considers that a causal relationship between dostarlimab and Stevens-Johnson syndrome (SJS) is at least a reasonable possibility. The PRAC Rapporteur concluded that the product information of products containing dostarlimab should be amended accordingly.	11/12/2025	10/02/2026	SmPC and PL	Variation
Variation type IA / EMA/VR/0000313767	Outcome: This was an application for a group of variations. B.I.a.4 Change to in-process tests or limits applied during the manufacture of the active	05/12/2025			

	substance - B.I.a.4.a Tightening of in-process limits - Accepted A.5 Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - A.5.b The activities for which the manufacturer/importer is responsible do not include batch release - Accepted				
Variation type IB / EMA/VR/0000305087	Outcome: B.I ACTIVE SUBSTANCE - B.I.z Other variation - Accepted	10/11/2025			
Variation type IB / EMA/VR/0000301588	Outcome: B.I.b.1 Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - B.I.b.1.b Tightening of specification limits - Accepted	23/10/2025			
Marketing Authorisation Transfer - H / EMA/T/0000292052	Outcome: transfer of marketing authorisation from GlaxoSmithKline (Ireland) Limited to GlaxoSmithKline Trading Services Limited	01/09/2025	15/09/2025	SmPC, Labelling and PL	
Variation type IA_IN / EMA/VR/0000287894	Outcome: B.II.b.2.c Replacement or addition of a	11/08/2025			

	manufacturer responsible for importation and/or batch release - B.II.b.2.c.1 Not including batch control/testing - Accepted				
Variation type IB / EMA/VR/0000264716	Outcome: B.I.a.1 Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - B.I.a.1.k New storage site of Master Cell Bank and/or Working Cell Banks - Accepted	16/06/2025			
Variation type IB / EMA/VR/0000263951	Outcome: B.I.a.2 Changes in the manufacturing process of the active substance - B.I.a.2.a Minor change in the manufacturing process of the active substance - Accepted	06/06/2025			
Variation type II / EMA/VR/0000256521	Outcome: This was an application for a group of variations. A. ADMINISTRATIVE CHANGES - A.7 Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for	05/06/2025	15/09/2025	Annex II and PL	The Annex II has been updated to add the new manufacturer responsible for batch release: GlaxoSmithKline Manufacturing S.p.A Strada Provinciale Asolana, 90, 43056 San Polo di Torrile Parma, Italy

	batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* - Accepted B.II.b.2.c Replacement or addition of a manufacturer responsible for importation and/or batch release - B.II.b.2.c.3 Including batch control/testing for a biological/immunological product and any of the test methods performed at that site is a biological / immunological / immunochemical method - Accepted				
Variation type IB / EMA/VR/0000255440	Outcome: B.I.a.2 Changes in the manufacturing process of the active substance - B.I.a.2.a Minor change in the manufacturing process of the active substance - Accepted	30/04/2025			
Variation type IB / EMA/VR/0000248620	Outcome: This was an application for a group of variations. B.II. FINISHED PRODUCT - B.II.z Other variation - Accepted B.II. FINISHED PRODUCT - B.II.z Other variation - Accepted B.II. FINISHED PRODUCT - B.II.z Other variation - Accepted	20/02/2025			
