Spexotras

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 /		19/05/2026		SmPC 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).

EMA/VR/0000340747	Outcome: C.3 Change(s) in the summary of product characteristics, labelling or package leaflet intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Article 45 or 46 of Regulation (EC) No 1901/2006, or the outcome of a PRAC signal recommendation, or to adapt to a joint recommendation of EU competent authorities (e.g. a Core SmPC, or following the assessment of an Urgent Safety Restriction etc.) - C.3.b) Implementation of the agreed wording that requires additional minor assessment (e.g. translations are not yet agreed upon) - Accepted Type IB, C.3.b – to update section 4.8 of the SmPC and section 4 of the PL following adoption of PRAC recommendation from procedure PSUSA/00010262/202505 (dated 15-Jan-2026), to include the risk of potentiation of radiation toxicity in the product information for Spexotras 0.05 mg/ml powder for oral solution. In addition, the MAH proposes to align the PI with the EU Excipient Labelling Guideline, the three main components of strawberry flavour (acacia gum, triacetin and artificial flavour)				

	are now included in the Section 6.1 of the SmPC and PL. During the linguistic review of procedure Tafinlar-PSUR-0000296502, the Italian Health Authority (AIFA) requested several terminology amendments to the dabrafenib product information. For consistency, the same amendments have been applied to the trametinib product information.				
Variation type IA_IN / EMA/VR/0000308071	Outcome: C.I.3 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006 - C.I.3.z Implementation of wording agreed by the competent authority + QRD update - Accepted	03/11/2025		SmPC and PL	To update Section 4.8 of the SmPC and Section 4 of the PL to implement the signal recommendations on 'Tattoo associated skin reaction (EPITT no 20160)' adopted at the 4 September 2025 PRAC.
Variation type IA_IN / EMA/VR/0000293331	Outcome: A.5 Change in the name and/or address of a manufacturer/importer of the finished	28/08/2025		Annex II and PL	

	product (including batch release or quality control testing sites) - A.5.a The activities for which the manufacturer/importer is responsible include batch release - Accepted				
Variation type IB / EMA/VR/0000281571	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.d Other changes to a test procedure (including replacement or addition) - Accepted 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 B.II.d.1 Change in the specification parameters and/or limits of the finished product - B.II.d.1.z Other changes - 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	20/08/2025		SmPC, Annex II and PL	

	finished product - B.II.d.2.a Minor changes to an approved test procedure - Accepted				
Variation type IA / EMA/VR/0000247847	Outcome: This was an application for a group of variations. 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.c Addition of a new specification parameter to the specification with its corresponding test method - Accepted 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.d Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) - Accepted B.I.c.1 Change in immediate packaging of the active substance - B.I.c.1.a Qualitative and/or quantitative composition - Accepted A. ADMINISTRATIVE CHANGES - A.7 Deletion of manufacturing sites for an active	13/02/2025			

	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 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.b Downscaling down to 10-fold - Accepted				
PSUR / EMA/PSUR/0000296499	EURD: PSUSA/00010262/202505 Active substance: trametinib Outcome: Maintenance	15/01/2026			Maintenance