Sorafenib Accord

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 /	C.I.11 Introduction of, or change(s) to, the	29/09/2025	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).

EMA/VR/0000287524	obligations and conditions of a marketing authorisation, including the risk management plan - C.I.11.z Other RMP changes (e.g. agreed wording + template change) - Accepted C.I.11.z (Type IB) - To update Part I with details concerning indication and dosage, and Part II (SVIII) by removing important identified and potential risks, in alignment with the redefined criteria set forth in GVP Module V, Rev. 2. Parts III and VII (Annex 4) are revised through the removal of targeted follow-up questionnaires. Part VI and VII (Annex 8) has also been updated to reflect changes made across the RMP. These changes follow the same changes previously assessed for the reference product Nexavar.				
Variation type IA_IN / EMA/VR/0000291696	B.III.1.a European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - B.III.1.a.1 New certificate from an already approved manufacturer - Accepted	12/08/2025	N/A		
Variation type IA_IN / EMA/VR/0000279488	This was an application for a group of variations. 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	27/06/2025		Annex II and PL	

	site - Accepted B.II.b.2.c Replacement or addition of a manufacturer responsible for importation and/or batch release - B.II.b.2.c.2 Including batch control/testing - Accepted				
Variation type IB / EMA/VR/0000256236	C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.z Other variation - Accepted C.I.z - To update sections 4.1, 4.2, 4.4, 4.6, and 5.1 of the SmPC, and section 1 of the package leaflet to carve-in the information on differentiated thyroid carcinoma, in line with the reference product Nexavar, following the end of orphan market exclusivity for "Treatment of follicular thyroid cancer" and "Treatment of papillary thyroid cancer" on 27 May 2024. In addition, the MAH has taken the opportunity to introduce minor editorial changes to section 4.8 of the SmPC and section 3 of the package leaflet, in line with the reference product. Lastly, the MAH has taken the opportunity to remove the UK (Northern Ireland) from the list of local representatives at the end of the package leaflet.	16/04/2025	15/05/2025	SmPC and PL	