Apixaban 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 /	Outcome:	24/07/2026		Annex II,	

[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/0000357501	C.9 Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - C.9.b) Implementation of changes which require additional minor assessment (e.g. change to the due date of obligations and conditions of a marketing authorisation and required pharmacovigilance activities in the risk management plan, including changes to the due date of study milestones, and template updates) - Accepted			Labelling and PL	
Variation type IB / EMA/VR/0000343438	Outcome: Q.I.b.2 Change to analytical procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Q.I.b.2.d) Other change to an analytical procedure (including replacement or addition) for the active substance - Accepted	20/07/2026			
Variation type IB / EMA/VR/0000324419	Outcome: C.9 Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - C.9.b) Implementation of changes which require additional minor assessment (e.g. change to the due date of	24/02/2026			To update the RMP of Apixaban Accord to align with the RMP of the reference product Eliquis.

	obligations and conditions of a marketing authorisation and required pharmacovigilance activities in the risk management plan, including changes to the due date of study milestones, and template updates) - Accepted C.9.b (Type IB) – To update the RMP of Apixaban Accord to align with the RMP of the reference product Eliquis.				
Variation type IB / EMA/VR/0000321408	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	11/02/2026			
Variation type IA / EMA/VR/0000319888	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)* - Refused	22/12/2025			

Variation type IA / EMA/VR/0000316001	Outcome: 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 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 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	15/12/2025			
Variation type IA / EMA/VR/0000313534	Outcome: B.II.b.5 Change to in-process tests or limits applied during the manufacture of the finished product - B.II.b.5.z Other changes - Accepted	04/12/2025			
Variation type IB / EMA/VR/0000269318	Outcome: C.I.11 Introduction of, or change(s) to, the obligations and conditions of a marketing	21/07/2025			

	authorisation, including the risk management plan - C.I.11.z Other RMP changes (e.g. agreed wording + template change) - Accepted C.I.11.z - to update Risk Management Plan of Apixaban Accord in line with the EPAR for Risk Management Plan of reference product Eliquis (V. 21.3) published on EMA website on 19-Aug-2024.				
Variation type IB / EMA/VR/0000275536	Outcome: This was an application for a group of variations. C.I.2 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - C.I.2.a Implementation of change(s) for which no new additional data is required to be submitted by the MAH - Accepted C.I.2 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - C.I.2.a Implementation of change(s) for which no new additional data is required to be submitted by the MAH - Accepted C.I.2 Change(s) in the Summary of Product	16/06/2025	18/07/2025	SmPC, Annex II, Labelling and PL	Extension of indication to include the treatment of venous thromboembolism (VTE) and prevention of recurrent VTE in paediatric patients from 28 days to less than 18 years of age for Eliquis (all strengths), As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8, 4.9, 5.1 and 5.2 of the SmPCs are updated. The Package Leaflet and Annex II are updated in accordance. The changes follow assessment of the same changes to the reference product Eliquis (EMEA/H/C/002148/X/0089). To update section 4.8 of the SmPC and section 4 of the PL with information on Anticoagulant-related nephropathy, following assessment of the same change to the reference product Eliquis (EMEA/H/C/PSUSA/00000226/202405). To include a single Patient Alert Card (PAC) combining already approved information for paediatric and adult patients in all boxes, and to update sections 4.2, 4.8(for 5 mg) and 5.2 of the SmPC and section 2 (for 5mg) of the PL to align with editorial changes made to the PI of the reference product. The

	Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - C.I.2.a Implementation of change(s) for which no new additional data is required to be submitted by the MAH - Accepted C.I.2.a - Extension of indication to include the treatment of venous thromboembolism (VTE) and prevention of recurrent VTE in paediatric patients from 28 days to less than 18 years of age for Eliquis (all strengths), based on a pre-specified interim analysis from Study CV185325; this is an open-label, multi-centre, randomized, active controlled trial to provide PK data and data on anti-Xa activity to support the extrapolation of efficacy to children, to evaluate safety and efficacy of apixaban in children who require anticoagulation for a venous thromboembolism; As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8, 4.9, 5.1 and 5.2 of the SmPCs are updated. The Package Leaflet and Annex II are updated in accordance. The changes follow assessment of the same changes to the reference product Eliquis (EMEA/H/C/002148/X/0089). C.I.2.a - To update section 4.8 of the SmPC and section 4 of the PL with information on Anticoagulant-related nephropathy, following assessment of the same change to the				changes follow assessment of the same changes to the reference product Eliquis (EMEA/H/C/002148/IB/0096)

	reference product Eliquis (EMEA/H/C/PSUSA/00000226/202405). C.I.2.a - To include a single Patient Alert Card (PAC) combining already approved information for paediatric and adult patients in all boxes, and to update sections 4.2, 4.8(for 5 mg) and 5.2 of the SmPC and section 2 (for 5mg) of the PL to align with editorial changes made to the PI of the reference product. The changes follow assessment of the same changes to the reference product Eliquis (EMEA/H/C/002148/IB/0096) Additionally, the MAH took the opportunity to update section 4.2, 4.9 and 5.1 of the SmPC and sections 3 and 4 of the PL with editorial changes to align with the PI of the reference product, and updated the contact information of the local representative for GR.				
Variation type IA / EMA/VR/0000248163	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.a Minor change in the manufacturing process - Accepted	03/02/2025			
Variation type IA_IN / EMA/VR/0000246186	Outcome: This was an application for a group of variations.	23/01/2025	18/07/2025	Annex II and PL	

	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 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				