Pradaxa

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 HUMAN AND VETERINARY MEDICINAL	24/11/2025		SmPC, Annex	To (1) update the Labelling by removing the grey

[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/0000310386	PRODUCTS - C.I.z Other variation - Accepted C.I.z (Type IB) – To (1) update the Labelling by removing the grey shaded information 'PC', and (2) to update Section 3 of the SmPC in the languages used for multilingual blisters (DE, FR, NL, DA, NO, IS, ET, LV, LT, CS, SK, FI, SV, SL, HR, RO and BG) by adding the EDQM's patient-friendly term of the dosage form 'capsule'. The changes implement Product Information requirements approved with procedures EMEA/H/C/000829/N/0148 and EMEA/H/C/000829/N/0152 affecting the blisters of the Pradaxa 75mg, 110mg and 150mg hard capsules (EU/1/08/442/001-003, 005-007, 009-012, 014-019). In addition, the MAH took the opportunity to implement editorial changes to update the contact details for the local representative for NO in the PL, and correct typographical errors in Annex II.			II, Labelling and PL	shaded information 'PC', and (2) to update Section 3 of the SmPC in the languages used for multilingual blisters (DE, FR, NL, DA, NO, IS, ET, LV, LT, CS, SK, FI, SV, SL, HR, RO and BG) by adding the EDQM's patient-friendly term of the dosage form 'capsule'. The changes implement Product Information requirements approved with procedures EMEA/H/C/000829/N/0148 and EMEA/H/C/000829/N/0152 affecting the blisters of the Pradaxa 75mg, 110mg and 150mg hard capsules (EU/1/08/442/001-003, 005-007, 009-012, 014-019).
Variation type II / EMA/VR/0000256456	C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.13 Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority - Accepted Submission of the final report from the non-interventional paediatric PASS 1160.307, listed as a category 3 study in the RMP. This	04/09/2025	N/A		Please refer to Scientific Discussion EMA/VR/0000256456

	is an observational study to evaluate the safety of dabigatran etexilate for the treatment of venous thromboembolism (VTE) and prevention of recurrent VTE in paediatric patients from birth to less than 2 years of age in routine clinical practice setting. The RMP version 41.3 has also been submitted.				