Amsterdam, 25 May 2023
EMA/CHMP/231523/2023
Committee for Medicinal Products for Human use (CHMP)
EMEA/H/C/002148/II/0088

Opinion of the committee for medicinal products for human use on a type II variation to the terms of the marketing authorisation

Medicinal product:	**International non-proprietary name/Common name:**	**Presentations:**
Eliquis	apixaban	See Annex A

Basis for opinion

Pursuant to Article 16 of Commission Regulation (EC) No 1234/2008, Bristol-Myers Squibb / Pfizer EEIG submitted to the European Medicines Agency on 11 November 2022 an application for a Type II variation for the above medicinal product

The procedure started on 28 November 2022.

The steps taken for the assessment of the above-mentioned medicinal product are detailed in the appended assessment report.

Opinion

1. The CHMP, having considered the application as set out in the appended variation assessment report, recommends by consensus the variation(s) to the terms of the marketing authorisation, concerning the following change(s):

Variation(s) requested		**Type**	**Annex(es) affected**
C.I.4	C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	II	I

Update of sections 4.2 and 5.1 of the SmPC in order to update efficacy and safety information in the paediatric population based on results of the paediatric studies performed in compliance

with the paediatric investigation plan (PIP), including studies CV185155 and CV185362. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI.

The CHMP members of Iceland and Norway agree with the above-mentioned recommendation of the CHMP on variation to the terms of the marketing authorisation.

2. The revised annex I is included in this opinion.

In accordance with Article 16(4) of Commission Regulation (EC) No. 1234/2008 the marketing authorisation holder has the right to request a re-examination of this opinion within 15 days of receipt of the opinion by giving written notice to the Agency. Detailed grounds for the re-examination request must be sent to the Agency within 60 days of receipt of the opinion.

This opinion is forwarded to the European Commission, to the Member States, to Iceland, Liechtenstein and Norway and to the marketing authorisation holder, together with its full set of annexes and appendix(ces).

The European Commission shall adopt a decision within 12 months in accordance with the procedure laid down in Article 23(1a)(b) of Commission Regulation (EC) No. 1234/2008.

Annex A

MA (EU) number	(Invented) name	Strength	Pharmaceutical Form	Route of Administration	Immediate Packaging	Pack size
EU/1/11/691/001	Eliquis	2.5 mg	Film-coated tablet	Oral use	blister (PVC/PVDC/alu)	10 tablets
EU/1/11/691/002	Eliquis	2.5 mg	Film-coated tablet	Oral use	blister (PVC/PVDC/alu)	20 tablets
EU/1/11/691/003	Eliquis	2.5 mg	Film-coated tablet	Oral use	blister (PVC/PVDC/alu)	60 tablets
EU/1/11/691/004	Eliquis	2.5 mg	Film-coated tablet	Oral use	blister (PVC/PVDC/alu)	60 x 1 tablets (unit dose)
EU/1/11/691/005	Eliquis	2.5 mg	Film-coated tablet	Oral use	blister (PVC/PVDC/alu)	100 x 1 tablets (unit dose)
EU/1/11/691/006	Eliquis	5 mg	Film-coated tablet	Oral use	blister (PVC/PVDC/alu)	14 tablets
EU/1/11/691/007	Eliquis	5 mg	Film-coated tablet	Oral use	blister (PVC/PVDC/alu)	20 tablets
EU/1/11/691/008	Eliquis	5 mg	Film-coated tablet	Oral use	blister (PVC/PVDC/alu)	56 tablets
EU/1/11/691/009	Eliquis	5 mg	Film-coated tablet	Oral use	blister (PVC/PVDC/alu)	60 tablets
EU/1/11/691/010	Eliquis	5 mg	Film-coated tablet	Oral use	blister (PVC/PVDC/alu)	100 x 1 tablets (unit dose)
EU/1/11/691/011	Eliquis	5 mg	Film-coated tablet	Oral use	blister (PVC/PVDC/alu)	168 tablets
EU/1/11/691/012	Eliquis	5 mg	Film-coated tablet	Oral use	blister (PVC/PVDC/alu)	200 tablets
EU/1/11/691/013	Eliquis	2.5 mg	Film-coated tablet	Oral use	blister (PVC/PVDC/alu)	168 tablets
EU/1/11/691/014	Eliquis	5 mg	Film-coated tablet	Oral use	blister (PVC/PVDC/alu)	28 tablets
EU/1/11/691/015	Eliquis	2.5 mg	Film-coated tablet	Oral use	blister (PVC/PVDC/alu)	200 tablets