MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

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Decision Cover Letter

Decision of the licensing authority to:

accept change(s) to the agreed paediatric investigation plan and to the deferral

MHRA-101004-PIP01-23-M01

Scope of the Application

Active Substance(s)

APIXABAN

Condition(s)

Treatment of venous thromboembolism

Pharmaceutical Form(s)

Film-coated tablet. Age-appropriate oral liquid dosage form Age-appropriate dosage form, other

Route(s) of Administration

ORAL USE

Name / Corporate name of the PIP applicant

Bristol-Myers Squibb / Pfizer EEIG

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Bristol-Myers Squibb / Pfizer EEIG submitted to the licensing authority on 05/05/2023 17:52 BST an application for a Modification

The procedure started on 26/09/2023 09:30 BST

1. The licensing authority, having assessed the application in accordance with the Human Medicines Regulations 2012, decides, as set out in the appended summary report:

to accept change(s) to the agreed paediatric investigation plan and to the deferral

2. The measures and timelines of the paediatric investigation plan are set out in the Annex I.

This decision is forwarded to the applicant, together with its annex and appendix.

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Final Decision Letter

MHRA-101004-PIP01-23-M01

Of 16/10/2023 07:08 BST

On the adopted decision for APIXABAN (MHRA-101004-PIP01-23-M01) in accordance with the Human Medicines Regulations 2012.

The licensing authority, in accordance with the Human Medicines Regulations 2012, has adopted this decision:

Agreement on modification of a paediatric investigation plan (including modification of a waiver or deferral included in that paediatric investigation plan)

This decision applies to a Modification for APIXABAN, Film-coated tablet Age-appropriate oral liquid dosage form Age-appropriate dosage form, other , ORAL USE .

This decision is addressed to Bristol-Myers Squibb / Pfizer EEIG, Plaza 254 - Blanchardstown Corporate Park 2, Dublin 15, IRELAND, D15 T867

ANNEX I

1. Waiver

1.1 Condition:

Not applicable

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of venous thromboembolism

2.2 Indication(s) targeted by the PIP:

Treatment of venous thromboembolism

2.3 Subset(s) of the paediatric population concerned by the paediatric development:

The paediatric population from birth to less than 18 years of age

2.4 Pharmaceutical Form(s):

Film-coated tablet for oral use Age-appropriate oral liquid dosage form Age-appropriate dosage form, other

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	0	Not applicable.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	1	Study 1 Open-label, multi-centre, randomised, 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 (full term neonates of at least 2.6 kg to less than 18 years of age) who require anticoagulation for a venous thromboembolism.
Extrapolation, Modeling & Simulation Studies	1	Study 2 (Added during procedure EMEA-000183-PIP02-12-M03) Modelling and simulation study to derive dosing of apixaban for use in neonates for treatment of venous thromboembolism.
Other Studies	0	Not applicable.
Other Measures	0	Not applicable.

3. Follow-up, completion and deferral of a PIP:

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	30/04/2025
Deferral of one or more studies contained in the paediatric investigation plan:	Yes