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

gov.uk/mhra

Decision Cover Letter

Decision of the licensing authority to:

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

MHRA-100439-PIP01-22-M01

Scope of the Application

Active Substance(s)

Asundexian

Condition(s)

Prevention of arterial thromboembolism

Pharmaceutical Form(s)

Film-coated tablet; Age-appropriate oral dosage form

Route(s) of Administration

ORAL USE

Name / Corporate name of the PIP applicant

Bayer plc

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Bayer plc submitted to the licensing authority on 27/03/2025 10:43 GMT an application for a Modification

The procedure started on 06/05/2025 08:46 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-100439-PIP01-22-M01

Of 24/07/2025 14:33 BST

On the adopted decision for Asundexian (MHRA-100439-PIP01-22-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 Asundexian, Film-coated tablet; Age-appropriate oral dosage form , ORAL USE .

This decision is addressed to Bayer plc, 400 South Oak Way, Reading, UNITED KINGDOM, RG2 6AD

ANNEX I

1. Waiver

1.1 Condition:

Prevention of arterial thromboembolism The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 6 months of age Pharmaceutical form(s): Film-coated tablet Age-appropriate oral dosage form Route(s) of administration: ORAL USE Reason for granting waiver: on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subset(s).

2. Paediatric Investigation Plan:

2.1 Condition(s):

Prevention of arterial thromboembolism

2.2 Indication(s) targeted by the PIP:

Secondary prevention of arterial ischaemic stroke

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

The paediatric population from 6 months to less than 18 years of age

2.4 Pharmaceutical Form(s):

Film-coated tablet Age-appropriate oral dosage form

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	1	Study 1 Development of an age-appropriate oral dosage form.
Non-Clinical Studies	3	Study 2 Dose range-finding juvenile toxicity study. Study 3 Definitive juvenile toxicity study. Study 4 In vitro spiking coagulation study.
Clinical Studies	1	Study 5 (Study AB, 22059) Open label two arm trial to evaluate pharmacokinetics, safety and activity of asundexian alone or as add-on to an anti-platelet medicine on children from 6 months to less than 18 years of age with arterial ischaemic stroke.
Extrapolation, Modeling & Simulation Studies	2	Study 6 Modelling and simulation study to support the initial dose selection of asundexian in children from 6 months to less than 18 years of age with arterial ischaemic stroke. Study 7 Modelling and simulation study to describe the PK and adjust the dose of asundexian in children from 6 months to less than 18 years of age with arterial ischaemic stroke.
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:	No
Date of completion of the paediatric investigation plan:	31/12/2033

Deferral of one or more studies contained in the paediatric investigation plan:	Yes