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

gov.uk/mhra

Decision Cover Letter

Decision of the licensing authority to:

agree a paediatric investigation plan and grant a deferral and grant a waiver

MHRA-102146-PIP01-25

Scope of the Application

Active Substance(s)

TROSPIUM CHLORIDE; xanomeline tartrate

Condition(s)

Treatment of schizophrenia

Pharmaceutical Form(s)

Capsule, hard

Route(s) of Administration

ORAL USE

Name / Corporate name of the PIP applicant

BRISTOL-MYERS SQUIBB PHARMA EEIG

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, BRISTOL-MYERS SQUIBB PHARMA EEIG submitted to the licensing authority on 01/10/2025 22:31 BST an application for a Paediatric Investigation Plan

The procedure started on 08/10/2025 13:17 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 agree a paediatric investigation plan and grant a deferral and grant a waiver

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-102146-PIP01-25

Of 03/12/2025 14:31 GMT

On the adopted decision for TROSPIUM CHLORIDE; xanomeline tartrate (MHRA-102146-PIP01-25) 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 a paediatric investigation plan

This decision applies to a Paediatric Investigation Plan for TROSPIUM CHLORIDE; xanomeline tartrate, Capsule, hard , ORAL USE .

This decision is addressed to BRISTOL-MYERS SQUIBB PHARMA EEIG , Plaza 254, Blanchardstown Corporate Park 2 , Dublin 15, IRELAND, D15 T867

ANNEX I

1. Waiver

1.1 Condition:

Treatment of schizophrenia The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 13 years of age Pharmaceutical form(s): Capsule, hard 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):

Treatment of schizophrenia

2.2 Indication(s) targeted by the PIP:

Treatment of schizophrenia

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

The paediatric population from 13 years to less than 18 years of age

2.4 Pharmaceutical Form(s):

Capsule, hard

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	0	Not applicable.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	2	Study 1 (CN012-0020) Double-blind, randomised, placebo-controlled trial to evaluate the efficacy and safety of KarXT compared to placebo in adolescents from 13 years to less than 18 years with schizophrenia. Study 2 (CN012-0021) Open-label study to evaluate the long-term safety and tolerability of flexible-dose KarXT in adolescents from 13 years to less than 18 years with schizophrenia, who completed the double-blind treatment period of PIP Study 1.
Extrapolation, Modeling & Simulation Studies	0	Not applicable.
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:	31/12/2030
Deferral of one or more studies contained in the paediatric investigation plan:	Yes