



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/413702/2020

European Medicines Agency decision P/0312/2020

of 14 August 2020

on the refusal of a modification of an agreed paediatric investigation plan for derivative of 4H-pyrazolo[3,4-d]pyrimidin-4-one (BI409306) (EMA-001742-PIP01-14-M01) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

Only the English text is authentic.



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The European Medicines Agency,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No. 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004¹,

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency²,

Having regard to the European Medicines Agency's decision P/0236/2016 issued on 9 September 2016,

Having regard to the application submitted by Boehringer Ingelheim International GmbH on 23 March 2020 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral and a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 26 June 2020, in accordance with Article 22 of Regulation (EC) No 1901/2006,

Having regard to Article 25 of Regulation (EC) No 1901/2006,

Whereas:

- (1) The Paediatric Committee of the European Medicines Agency has given an opinion on the refusal of changes to the agreed paediatric investigation plan.
- (2) It is therefore appropriate to adopt a decision on the refusal of changes to the agreed paediatric investigation plan.

¹ OJ L 378, 27.12.2006, p.1.

² OJ L 136, 30.4.2004, p. 1.

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for derivative of 4H-pyrazolo[3,4-d]pyrimidin-4-one (BI409306) , film-coated tablet, oral use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, are hereby refused.

Article 2

This decision is addressed to Boehringer Ingelheim International GmbH, Bingerstrasse 173, 55216 - Ingelheim am Rhein, Germany.

EMA/PDCO/191685/2020
Amsterdam, 26 June 2020

Opinion of the Paediatric Committee on the refusal of a modification of an agreed Paediatric Investigation Plan

EMA-001742-PIP01-14-M01

Scope of the application

Active substance(s):

Derivative of 4H-pyrazolo[3,4-d]pyrimidin-4-one (BI409306)

Condition(s):

Treatment of schizophrenia

Pharmaceutical form(s):

Film-coated tablet

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Boehringer Ingelheim International GmbH

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Boehringer Ingelheim International GmbH submitted to the European Medicines Agency on 23 March 2020 an application for modification of the agreed paediatric investigation plan with a deferral and a waiver as set out in the European Medicines Agency's decision P/0236/2016 issued on 9 September 2016.

The application for modification proposed changes to the agreed paediatric investigation plan.

The procedure started on 30 April 2020.

Opinion

1. The Paediatric Committee, having assessed the application in accordance with Article 22 of Regulation (EC) No 1901/2006 as amended, recommends, as set out in the appended summary report:

- to refuse the changes proposed by the applicant regarding the paediatric investigation plan.

The Norwegian Paediatric Committee member agrees with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the agreed paediatric investigation plan and the subset(s) of the paediatric population and condition(s) covered by the waiver remain unchanged and are set out in the Annex I.
3. The scientific conclusions and the grounds for refusal are set out in the summary report appended to this opinion.

This opinion is forwarded to the applicant and the Executive Director of the European Medicines Agency, together with its annex and appendix.

Annex I

The subset(s) of the paediatric population and condition(s) covered by the waiver and the measures and timelines of the agreed paediatric investigation plan (PIP)

1. Waiver

1.1. Condition:

Treatment of schizophrenia

The waiver applies to:

- the paediatric population from birth to less than 13 years of age;
- for film-coated tablet, oral use;
- on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subset.

2. Paediatric investigation plan

2.1. Condition:

Treatment of schizophrenia

2.1.1. Indication(s) targeted by the PIP

Treatment of paediatric patients with cognitive impairment associated with schizophrenia

2.1.2. Subset(s) of the paediatric population concerned by the paediatric development

From 13 to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Film-coated tablet

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	0	Not applicable
Non-clinical studies	0	Not applicable
Clinical studies	2	Study 1: Randomised, double-blind, placebo-controlled study to evaluate the efficacy, safety, and pharmacokinetic of orally administered BI 409306 in adolescents with schizophrenia (1289.30)

		Study 2: Open-label, single arm study to evaluate the activity and safety of orally administered BI 409306 in adolescents with schizophrenia (1289.X)
Extrapolation, modelling and simulation studies	0	Not applicable
Other studies	0	Not applicable
Other measures	0	Not applicable

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety/efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By August 2022
Deferral for one or more measures contained in the paediatric investigation plan:	Yes