EMA/735836/2017

European Medicines Agency decision

P/0303/2017

of 8 November 2017

on the refusal of a paediatric investigation plan and on the refusal of a deferral and on the refusal of a waiver for 1H-Isoindol-1-one,2-[[1-[2-(4-fluorophenyl)-2-oxoethyl]-4-piperidinyl]methyl]-2,3-dihydro-, hydrochloride, hydrate (1:1:2) (MIN-101) (EMEA-002222-PIP01-17) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

Disclaimer

This decision does not constitute entitlement to the rewards and incentives referred to in Title V of Regulation (EC) No 1901/2006.

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 726/2004[1],

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 Agency[2],

Having regard to the application submitted by Minerva Neurosciences, Inc. on 10 July 2017 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 15 September 2017, in accordance with Article 17 of Regulation (EC) No 1901/2006 and Article 21 of said Regulation and Article 13 of said Regulation,

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 a paediatric investigation plan and on the refusal of a deferral and on the refusal of a waiver.

(2) It is therefore appropriate to adopt a decision refusing a paediatric investigation plan.

(3) It is therefore appropriate to adopt a decision refusing a deferral.

(4) It is therefore appropriate to adopt a decision refusing a waiver.

[1] OJ L 378, 27.12.2006, p.1.
[2] OJ L 136, 30.4.2004, p. 1.

Has adopted this decision:

Article 1

A paediatric investigation plan for 1H-Isoindol-1-one,2-[[1-[2-(4-fluorophenyl)-2-oxoethyl]-4-piperidinyl]methyl]-2,3-dihydro-, hydrochloride, hydrate (1:1:2) (MIN-101), gastro-resistant 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, is hereby refused.

Article 2

A deferral for 1H-Isoindol-1-one,2-[[1-[2-(4-fluorophenyl)-2-oxoethyl]-4-piperidinyl]methyl]-2,3-dihydro-, hydrochloride, hydrate (1:1:2) (MIN-101), gastro-resistant 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, is hereby refused.

Article 3

A waiver for 1H-Isoindol-1-one,2-[[1-[2-(4-fluorophenyl)-2-oxoethyl]-4-piperidinyl]methyl]-2,3-dihydro-, hydrochloride, hydrate (1:1:2) (MIN-101), gastro-resistant 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, is hereby refused.

Article 4

This decision is addressed to Minerva Neurosciences, Inc., 1601 Trapelo Road, Suite 284, Massachusetts, 02451 – Waltham, United States.

EMA/PDCO/615992/2017
London, 15 September 2017

Opinion of the Paediatric Committee on the refusal of a Paediatric Investigation plan and a deferral and a waiver

EMEA-002222-PIP01-17

Scope of the application

Active substance(s):

1H-Isoindol-1-one,2-[[1-[2-(4-fluorophenyl)-2-oxoethyl]-4-piperidinyl]methyl]-2,3-dihydro-, hydrochloride, hydrate (1:1:2) (MIN-101)

Condition(s):

Treatment of schizophrenia

Pharmaceutical form(s):

Gastro-resistant tablet

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Minerva Neurosciences, Inc.

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Minerva Neurosciences, Inc. submitted for agreement to the European Medicines Agency on 10 July 2017 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation.

The procedure started on 15 August 2017.

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Opinion

1. The Paediatric Committee, having assessed the proposed paediatric investigation plan in accordance with Article 17 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

   - to refuse the paediatric investigation plan in accordance with Article 17(1) of said Regulation, as the measures and the timelines are not appropriate to ensure the generation of the necessary data determining the conditions in which the medicinal product may be used to treat the paediatric population or some subsets, nor to adapt a paediatric formulation, or do not bring expected significant therapeutic benefit;
   - to refuse a deferral in accordance with Article 21 of said Regulation;
   - to refuse the granting of a waiver in accordance with Article 13 of said Regulation for the above mentioned condition(s) as all the subsets of the paediatric population are not covered.

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

2. 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 appendix.