EMA/619839/2015

European Medicines Agency decision

P/0231/2015

of 27 October 2015

on the acceptance of a modification of an agreed paediatric investigation plan for chloroprocaine (hydrochloride), (EMEA-000639-PIP02-09-M02) 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 European Medicines Agency's decision P/149/2010 issued on 30 July, and the decision P/0221/2012 issued on 1 October 2012,

Having regard to the application submitted by Sintetica Italia Srl on 19 June 2015 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 11 September 2015, in accordance with Article 22 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 acceptance of changes to the agreed paediatric investigation plan and to the deferral and to the waiver.

(2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan, including changes to the deferral and the 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

Changes to the agreed paediatric investigation plan for chloroprocaine (hydrochloride), solution for injection, intrathecal use, including changes to the deferral, and the waiver, are hereby accepted in the scope set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices.

Article 2

This decision is addressed to Sintetica Italia Srl, Piazza della Repubblica 25, 20124 – Milan Italy.

Done at London, 27 October 2015

For the European Medicines Agency
Zaïde Frias
Head of Division
Human Medicines Research and Development Support
(Signature on file)

EMA/PDCO/462843/2015
London, 11 September 2015

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan and on the granting of a product-specific waiver

EMEA-000639-PIP02-09-M02

Scope of the application

Active substance(s):

Chloroprocaine (hydrochloride)

Condition(s):

Intrathecal anaesthesia

Pharmaceutical form(s):

Solution for injection

Route(s) of administration:

Intrathecal use

Name/corporate name of the PIP applicant:

Sintetica Italia Srl

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Sintetica Italia Srl submitted to the European Medicines Agency on 19 June 2015 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/149/2010 issued on 30 July 2010, the decision P/0221/2012 issued on 1 October 2012.

The application for modification proposed changes to the agreed paediatric investigation plan and to the deferral and changes to the waiver to cover the remaining subsets of the paediatric population.

The procedure started on 14 July 2015.

Scope of the modification

All measures of the Paediatric Investigation Plan have been removed and the scope of the waiver has been extended to cover all subsets of the paediatric population.

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 agree to changes to the paediatric investigation plan and to the deferral and to amend the scope of the waiver in accordance with Article 11(1)(c) of said Regulation, on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients.

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

2. The grounds for the granting of the waiver are set out in Annex I.

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

Annex I

Grounds for the granting of the waiver

1. Waiver

1.1. Condition: Intrathecal anaesthesia

The waiver applies to:

- The paediatric population from birth to less than 12 years of age;
- for solution for injection for intrathecal use;
- on the grounds that the specific medicinal product is likely to be ineffective.

The waiver applies to:

- The paediatric population from 12 to less than 18 years of age;
- for solution for injection for intrathecal use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as clinical studies(s) are not feasible.