EMA/568824/2012

European Medicines Agency decision

P/0221/2012

of 1 October 2012

on the acceptance of a modification of an agreed paediatric investigation plan for chloroprocaine (hydrochloride) (EMEA-000639-PIP02-09-M01) 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 2010,

Having regard to the application submitted by Sintetica Italia S.r.l. on 24 May 2012 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 17 August 2012, 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 acceptance of changes to the agreed paediatric investigation plan.

(2) It is therefore appropriate to adopt a decision on the acceptance 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 chloroprocaine (hydrochloride), solution for injection, intrathecal use, 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 S.r.l., Piazza della Repubblica, 25, 20124 – Milan, Italy.

Done at London, 1 October 2012

For the European Medicines Agency
Guido Rasi
Executive Director
(Signature on file)

EMA/PDCO/382333/2012

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

EMEA-000639-PIP02-09-M01

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 S.r.l.

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Sintetica Italia S.r.l. submitted to the European Medicines Agency on 24 May 2012 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 application for modification proposed changes to the agreed paediatric investigation plan.

The procedure started on 19 June 2012.

Scope of the modification

Some measures of the agreed PIP have been modified.

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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 in the scope set out in the Annex I of this opinion.

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

2. The measures and timelines of the paediatric investigation plan and the subset(s) of the paediatric population and condition(s) covered by the waiver are set out in the Annex I.

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

London, 17 August 2012

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman
(Signature on file)

Annex I

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

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.

2. Paediatric Investigation Plan

2.1. Condition to be investigated: Intrathecal anaesthesia

2.1.1. Indication targeted by the PIP

Spinal anaesthesia.

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

From 12 to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Solution for injection for intrathecal use.

2.1.4. Studies

Area	**Number of studies**	**Description**
Quality	0	Not applicable.
Non-clinical	0	Not applicable.
Clinical	1	A blind observer, randomised, multicentre, dose-finding trial to evaluate efficacy of chloroprocaine in children from 12 to less than 18 years undergoing lower limb surgical procedures of short duration.

3. Follow-up, completion and deferral of PIP

Measures to address long term follow-up of potential safety issues or efficacy in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By October 2015
Deferral for one or more studies contained in the paediatric investigation plan:	Yes