EMA/494333/2012

European Medicines Agency decision

P/0222/2012

of 1 October 2012

on the agreement of a paediatric investigation plan and on the granting of a deferral for ioforminol, (EMEA-001197-PIP01-11) 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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on the agreement of a paediatric investigation plan and on the granting of a deferral for ioforminol, (EMEA-001197-PIP01-11) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

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 GE Healthcare on 8 August 2011 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 17 August 2012, in accordance with Article 18 of Regulation (EC) No 1901/2006, and Article 21 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 agreement of a paediatric investigation plan and on the granting of a deferral.

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

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

[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 ioforminol, solution for injection, intravenous 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 agreed.

Article 2

A deferral for ioforminol, solution for injection, intravenous 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 granted.

Article 3

This decision is addressed to GE Healthcare, Nycoveien 1-2, 0401 – Oslo, Norway.

Done at London, 1 October 2012

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

EMA/494333/2012

Opinion of the Paediatric Committee on the agreement of a Paediatric Investigation Plan and a deferral

EMEA-001197-PIP01-11

Scope of the application

Active substance(s):

Ioforminol

Condition(s):

Visualisation of anatomical structures of the body during computed tomography for diagnostic purposes

Pharmaceutical form(s):

Solution for injection

Route(s) of administration:

Intravenous use

Name/corporate name of the PIP applicant:

GE Healthcare

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, GE Healthcare submitted for agreement to the European Medicines Agency on 8 August 2011 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation.

The procedure started on 14 September 2011.

Supplementary information was provided by the applicant on 25 May 2012. The applicant proposed modifications to the paediatric investigation plan.

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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 agree the paediatric investigation plan in accordance with Article 18 of said Regulation,
   - to grant a deferral in accordance with Article 21 of said Regulation.

   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 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 subset(s) of the paediatric population and condition(s) covered by the waiver and the measures and timelines of the agreed Paediatric Investigation Plan

1. Waiver

Not applicable.

2. Paediatric Investigation Plan

2.1. Condition: Visualisation of anatomical structures of the body during computed tomography for diagnostic purposes

2.1.1. Indication(s) targeted by the PIP

Ioforminol is indicated for the diagnostic evaluation of contrast-enhanced neoplastic and non-neoplastic lesions

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

From birth to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Solution for injection for intravenous use.

2.1.4. Studies

Area	Number of studies	Description
Quality	1	Study 1: Development of a lower strength solution for injection
Non-clinical	0	Not applicable.
Clinical	2	Study 2: Open-label, assessor-blinded, randomised, multi-centre, dose escalating, active controlled study to evaluate safety, pharmacodynamics and tolerability of ioforminol compared to iodixanol in children from 1 to less than 18 years of age. Study 3: Open-label, assessor-blinded, image-randomised, multi-centre, active controlled study to evaluate safety, pharmacokinetics, pharmacodynamics and tolerability of ioforminol compared to iodixanol in children from birth to less than 1 year of age.

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By September 2019
Deferral for one or more studies contained in the paediatric investigation plan:	Yes