EMA/30340/2011

European Medicines Agency decision

P/26/2011

of 27 January 2011

on the agreement of a paediatric investigation plan and on the granting of a waiver for meropenem (EMEA-000898-PIP01-10) 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 waiver for meropenem (EMEA-000898-PIP01-10) 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 NeoMero Consortium on 3 May 2010 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 10 December 2010, in accordance with Article 18 of Regulation (EC) No 1901/2006, 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 agreement of a paediatric investigation plan and on the granting of a waiver.

(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 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 meropenem, powder for solution for injection or infusion, 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 waiver for meropenem, powder for solution for injection or infusion, 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 NeoMero Consortium, Fondazione PENTA Onlus, Dipartimento di Pediatria, via Giustiniani 3, 35128 Padova, Italy.

Done at London, 27 January 2011

For the European Medicines Agency
Andreas Pott
Acting Executive Director
(Signature on file)

EMA/PDCO/715636/2010

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

EMEA-000898-PIP01-10

Scope of the application

Active substance(s):

Meropenem

Condition(s):

Treatment of bacterial sepsis

Treatment of bacterial meningitis

Pharmaceutical form(s):

Powder for solution for injection or infusion

Route(s) of administration:

Intravenous use

Name/corporate name of the PIP applicant:

NeoMero Consortium

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, NeoMero Consortium submitted for agreement to the European Medicines Agency on 3 May 2010 an application for a paediatric investigation plan for the above mentioned medicinal product and a waiver under Article 13 of said Regulation.

The procedure started on 10 June 2010.

Supplementary information was provided by the applicant on 4 October 2010.

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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 waiver for one or more subsets of the paediatric population in accordance with Article 13 of said Regulation and concluded 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 Icelandic and the Norwegian Paediatric Committee members agree 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 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, 10 December 2010

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

1.1. Condition:Treatment of bacterial sepsis

The waiver applies to:

- All subsets of the paediatric population from 3 months to less than 18 years of age
- for powder for solution for injection or infusion, intravenous use
- on the grounds that clinical studies cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the paediatric population.

1.2. Condition: Treatment of bacterial meningitis

The waiver applies to:

- All subsets of the paediatric population from 3 months to less than 18 years of age
- for powder for solution for injection or infusion, intravenous use
- on the grounds that clinical studies cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the paediatric population.

2. Paediatric Investigation Plan

2.1. Condition: Treatment of bacterial sepsis

2.1.1. Indication(s) targeted by the PIP

Treatment of bacterial sepsis in neonates and infants below 3 months of age

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

From birth to less than 3 months of age.

2.1.3. Pharmaceutical form(s)

Powder for solution for injection or infusion

2.1.4. Studies

Area	Number of studies	Description
Quality	0	Not applicable.
Non-clinical	0	Not applicable.
Clinical	1	Study 1: Open label, randomised, multicentre, active comparator-controlled, efficacy and safety study in neonates and infants with bacterial sepsis

2.2. Condition: Treatment of bacterial meningitis

2.2.1. Indication(s) targeted by the PIP

Treatment of bacterial meningitis in neonates and infants below 3 months of age

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

From birth to less than 3 months of age.

2.2.3. Pharmaceutical form(s)

Powder for solution for injection or infusion

2.2.4. Studies

Area	Number of studies	Description
Quality	0	Not applicable.
Non-clinical	0	Not applicable.
Clinical	1	Study 2: Multicentre, single arm, open label PK and safety study in neonates and infants with bacterial meningitis

3. Follow-up, completion and deferral of PIP

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