EMA/113893/2013

European Medicines Agency decision

P/0079/2013

of 27 March 2013

on the agreement of a paediatric investigation plan and on the granting of a waiver for vancomycin (EMEA-001311-PIP01-12) 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.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7523 7040
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

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on the agreement of a paediatric investigation plan and on the granting of a waiver for vancomycin (EMEA-001311-PIP01-12) 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 Fondazione PENTA Onlus on 2 July 2012 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 8 February 2013, 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 vancomycin, powder for concentrate for solution for 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 vancomycin, powder for concentrate for solution for 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.

This decision is addressed to Fondazione PENTA Onlus, Dipartimento di Pediatria, via Giustiniani 3, 35128 – Padova, Italy.

Done at London, 27 March 2013

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

EMA/PDCO/752431/2012

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

EMEA-001311-PIP01-12

Scope of the application

Active substance(s):

Vancomycin

Condition(s):

Treatment of bacterial sepsis

Pharmaceutical form(s):

Powder for concentrate for solution for infusion

Route(s) of administration:

Intravenous use

Name/corporate name of the PIP applicant:

Fondazione PENTA Onlus

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Fondazione PENTA Onlus submitted for agreement to the European Medicines Agency on 2 July 2012 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 9 August 2012.

Supplementary information was provided by the applicant on 16 November 2012. The applicant proposed modifications to the paediatric investigation plan.

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E-mail info@ema.europa.eu **Website** www.ema.europa.eu

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 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 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 and appendix.

London, 8 February 2013

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:

- the paediatric population from 3 months to less than 18 years of age;
- for Powder for concentrate for solution for infusion for Intravenous use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as the needs are already covered.

2. Paediatric Investigation Plan

2.1. Condition: treatment of bacterial sepsis

2.1.1. Indication(s) targeted by the PIP

Treatment of late onset bacterial sepsis caused by Vancomycin susceptible bacteria in neonates and infants aged under 3 months.

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 concentrate for solution for infusion

2.1.4. Measures

Area	Number of measures	Description
Quality	1	1. Development of a 125mg powder for concentrate for solution for infusion for pre-term and neonates.
Non-clinical	1	2. Determination *of* Pharmacokinetic-Pharmacodynamic *(*PK-PD) relationships from the hollow fibre infection model (HFIM) and a rabbit model infected with Coagulase negative Staphylococci (CoNS).
Clinical	2	3. Population PK meta-analysis based on all available published studies and data collected during clinical practice in centers participating in the Neovanc project to determine the optimised dosage regimen of vancomycin to be used in children less than 3 months of age. 4. Randomised controlled PK/PD study to compare the proportion of subjects reaching PD target and to evaluate safety and efficacy in children aged less than 3 months with late-onset neonatal sepsis.

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 December 2018
Deferral for one or more measures contained in the paediatric investigation plan:	No