



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/3765/2016 corr

European Medicines Agency decision

P/0026/2016

of 29 January 2016

on the acceptance of a modification of an agreed paediatric investigation plan for vancomycin (EMEA-001311-PIP01-12-01-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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on the acceptance of a modification of an agreed paediatric investigation plan for vancomycin (EMA-001311-PIP01-12-01-M01) 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 726/2004¹,

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 Agency²,

Having regard to the European Medicines Agency's decision P/0079/2013 issued on 27 March 2013,

Having regard to the application submitted by Fondazione PENTA Onlus on 21 September 2015 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 11 December 2015, 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 vancomycin, powder for concentrate for solution for infusion, intravenous 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 Fondazione PENTA Onlus, Corso Stati Uniti 4 c/o Torre di Ricerca Pediatrica, 35127 – Padova, Italy.

Done at London, 29 January 2016

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



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/PDCO/639970/2015 corr
London, 11 December 2015

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan EMA-001311-PIP01-12-01-M01

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 22 of Regulation (EC) No 1901/2006 as amended, Fondazione PENTA Onlus submitted to the European Medicines Agency on 21 September 2015 an application for modification of the agreed paediatric investigation plan with a waiver as set out in the European Medicines Agency's decision P/0079/2013 issued on 27 March 2013.

The application for modification proposed changes to the agreed paediatric investigation plan.

The procedure started on 13 October 2015.

Scope of the modification

Some measures and timelines of the Paediatric Investigation Plan have been modified.



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 and appendix.

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 (PIP)

1. Waiver

1.1. Condition: treatment of bacterial sepsis

The waiver applies to:

- the paediatric population from 90 days 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 90 days.

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

From birth to less than 90 days 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-related studies	1	Study 1 Development of a 125mg powder for concentrate for solution for infusion for pre-term and neonates.
Non-clinical studies	1	Study 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).(NeoVanc-1)
Clinical studies	1	Study 4 Deleted. Study 5 Multi-centre, randomised, open label study to compare the efficacy, safety and pharmacokinetics (PK) of an

Area	Number of measures	Description
		optimised dosing regimen compared to a standard dosing regimen of vancomycin in patients less than 90 days of age with late onset bacterial sepsis known or suspected to be caused by Gram-positive microorganisms. (NeoVanc)
Modelling and Simulation studies	1	Study 3 Population PK meta-analysis of individual data. (NeoVanc-2)

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	March 2018
Deferral for one or more measures contained in the paediatric investigation plan:	No