EMA/460041/2017

European Medicines Agency decision

P/0231/2017

of 11 August 2017

on the refusal of a modification of an agreed paediatric investigation plan for chlorhexidine gluconate / isopropyl alcohol (EMEA-000989-PIP01-10-M02) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

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/163/2011 issued on 4 July 2011,

Having regard to the application submitted by 3M Health Care Limited on 31 March 2017 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 23 June 2017, in accordance with Article 22 of Regulation (EC) No 1901/2006, and of its own motion in accordance with Article 12 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 refusal of changes to the agreed paediatric investigation plan and to the deferral.

(2) It is therefore appropriate to adopt a decision on the refusal of changes to the agreed paediatric investigation plan, including changes to the deferral.

(3) It is therefore appropriate to adopt a decision on the granting of 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

Changes to the agreed paediatric investigation plan for chlorhexidine gluconate / isopropyl alcohol, solution, cutaneous use, including changes to the deferral, 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, are hereby refused.

Article 2

A waiver for chlorhexidine gluconate / isopropyl alcohol, solution, cutaneous use, the details of which are set out in the opinion of the Paediatric Committee the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 3

This decision is addressed to 3M Health Care Limited, 1 Morley Street, LE11 1EP - Loughborough, United Kingdom.

EMA/PDCO/226623/2017 Corr
London, 23 June 2017

Opinion of the Paediatric Committee on the refusal of a modification of an agreed Paediatric Investigation Plan and on the granting of a product-specific waiver

EMEA-000989-PIP01-10-M02

Scope of the application

Active substance(s):

Chlorhexidine gluconate / isopropyl alcohol

Condition(s):

Prevention of infection prior to invasive procedures

Pharmaceutical form(s):

Solution

Route(s) of administration:

Cutaneous use

Name/corporate name of the PIP applicant:

3M Health Care Limited

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, 3M Health Care Limited submitted to the European Medicines Agency on 31 March 2017 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/163/2011 issued on 4 July 2011.

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

The procedure started on 25 April 2017.

Opinion

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 refuse the changes proposed by the applicant regarding the paediatric investigation plan and to the deferral;
- and in accordance with Article 12 of Regulation (EC) No 1901/2006 as amended, recommends to grant a product-specific waiver on its own motion for all subsets of the paediatric population 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.

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

Annex I

Grounds for the granting of the waiver

1. Waiver

1.1. Condition

Prevention of infection prior to invasive procedures

The waiver applies to:

- all subsets of the paediatric population from birth to less than 18 years of age;
- for solution, for cutaneous use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.