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European Medicines Agency decision

P/0228/2018

of 29 July 2018

on the refusal of a product specific waiver for moxonidine (EMEA-002275-PIP01-17) 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 application submitted by Abbott Laboratories on 23 January 2018 under Article 13 of Regulation (EC) No 1901/2006,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 29 June 2018 in accordance with Article 13 of Regulation (EC) No 1901/2006,

Having regard to Article 25 of Regulation (EC) No 1901/2006,

Whereas:

(1) The Paediatric Committee has given an opinion on the refusal of a product specific waiver.

(2) It is therefore appropriate to adopt a decision refusing a waiver.

Has adopted this decision:

Article 1

A waiver for moxonidine, film coated tablet, oral 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 refused.

Article 2

This decision is addressed to Abbott Laboratories, Abbott House, Vanwall Business Park, SL6 4XE – Maidenhead, United Kingdom.

[1] OJ L 378, 27.12.2006, p.1.
[2] OJ L 136, 30.4.2004, p. 1.

EMA/PDCO/145614/2018
London, 1 June 2018

Opinion of the Paediatric Committee on the refusal of a product-specific waiver

EMEA-002275-PIP01-17

Scope of the application

Active substance(s):

Moxonidine

Condition(s):

Treatment of hypertension

Pharmaceutical form(s):

Film coated tablet

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Abbott Laboratories

Basis for opinion

Pursuant to Article 13 of Regulation (EC) No 1901/2006 as amended, Abbott Laboratories submitted to the European Medicines Agency on 23 January 2018 an application for a product-specific waiver on the grounds set out in Article 11 of said Regulation for the above mentioned medicinal product.

The procedure started on 3 April 2018.

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Opinion

1. The Paediatric Committee, having assessed the waiver application in accordance with Article 13 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

   - to refuse the granting of a product-specific waiver for all subsets of the paediatric population and the above mentioned condition(s) as it does not meet the grounds detailed in Article 11(1) of said Regulation.

   The Norwegian Paediatric Committee member agrees with the above-mentioned recommendation of the Paediatric Committee.

2. The scientific conclusions and the grounds for refusal are set out in the summary report appended to this opinion.

3. The grounds for refusal are summarised in Annex I.

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

Annex I

Grounds for the refusal of the waiver

1. Waiver

1.1. Condition:

Treatment of hypertension

The request for the waiver applied to:

- all subsets of the paediatric population from birth to less than 18 years of age;
- film coated tablet, oral use.

The waiver request does not provide evidence to support the following grounds set out in Article 11(1) of Regulation (EC) No 1901/2006 that:

- (a) the specific medicinal product is likely to be ineffective or unsafe in the paediatric population;
- (b) the disease or condition for which the specific medicinal product is intended occurs only in adult populations;
- (c) the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients.

Because:

- the specific medicinal product is not likely to be ineffective or unsafe;
- the disease or condition for which the specific medicinal product is intended, does occur in the paediatric population(s);
- measures would be justified by the expected therapeutic benefit and clinical trials may be feasible;
- the specific medicinal product may represent a significant therapeutic benefit as the needs are not met;
- clinical studies may fulfil a therapeutic need of the paediatric population.

The waiver request is therefore refused by the PDCO.