EMA/267331/2018

European Medicines Agency decision

P/0148/2018

of 18 May 2018

on the review of a granted waiver for delafloxacin (EMEA-001080-PIP01-10) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

Only the English text is authentic.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Contact EMA www.ema.europa.eu/contact

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on the review of a granted waiver for delafloxacin (EMEA-001080-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 opinion of the Paediatric Committee of the European Medicines Agency, issued on 18 March 2011,

Having regard to the decision of the European Medicines Agency P/98/2011 issued on 8 April 2011,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued of its own motion on 27 April 2018 in accordance with Article 14(2) 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 of its own motion on the review of the granted waiver.

(2) It is therefore appropriate to adopt a decision reviewing the granted waiver.

Has adopted this decision:

Article 1

A review of the granted waiver for delafloxacin, powder for solution for infusion, hard capsules, tablet, intravenous use, 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 agreed.

Article 2

This decision is addressed to A.Menarini - IndustrieFarmaceutiche Riunite - s.r.l., Via Sette Santi 3, 50131 – Florence, Italy.

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

EMA/PDCO/174354/2018
London, 27 April 2018

Opinion of the Paediatric Committee on the review of a granted product specific waiver

EMEA-001080-PIP01-10

Scope of the reviewed (part of the) waiver

Active substance(s):

Delafloxacin

Condition(s):

Treatment of local infections of skin and subcutaneous tissues

Pharmaceutical form(s):

Powder for solution for infusion

Hard capsule

Tablet

Route(s) of administration:

Intravenous use

Oral use

Name/corporate name of the waiver addressee:

A.Menarini - Industrie Farmaceutiche Riunite - s.r.l.

Scope of the review

Scope of the changes: a new pharmaceutical form (tablet) has been added.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

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Basis for opinion

On 18 March 2011, an opinion on the granting of a product specific waiver was adopted by the Paediatric Committee, followed by the European Medicines Agency's decision P/98/2011 issued on 8 April 2011.

According to Article 14(2) of Regulation (EC) No 1901/2006, the Paediatric Committee may, at any time, adopt an opinion advocating the review of a granted waiver.

The procedure started on 26 March 2018.

Opinion

1. The Paediatric Committee, having assessed the granted product specific waiver, recommends as set out in the appended summary report :

    - to review the granted product-specific waiver for all subsets of the paediatric population in the above specified condition(s) on its own motion in accordance with Article 14(2) of said Regulation;

    - the reviewed waiver is based on 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 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 addressee of the waiver 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

1. Waiver

1.1. Condition

Treatment of local infections of skin and subcutaneous tissues

The waiver applies to:

- all subsets of the paediatric population from birth to less than 18 years of age;
- for powder for solution for infusion, intravenous use, and hard capsule, oral use, and tablet, oral 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.