

EMA/121698/2019

European Medicines Agency decision P/0078/2019

of 22 March 2019

on the granting of a product specific waiver for genetically modified *Mycobacterium bovis* BCG (EMEA-002461-PIP01-18) 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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on the granting of a product specific waiver for genetically modified *Mycobacterium bovis* BCG (EMA-002461-PIP01-18) 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 application submitted by medac Gesellschaft für klinische Spezialpräparate mbH on 26 October 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 1 February 2019 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 granting of a product specific waiver.
- (2) It is therefore appropriate to adopt a decision granting a waiver.

Has adopted this decision:

Article 1

A waiver for genetically modified *Mycobacterium bovis* Bacille Calmette-Guérin (Δ ureC::hly; genetic background Danish strain, subtype Prague, powder for intravesical suspension, intravesical 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.

Article 2

This decision is addressed to medac Gesellschaft für klinische Spezialpräparate mbH, Theaterstrasse 6, 22880 – Wedel, Germany.

¹ OJ L 378, 27.12.2006, p.1.

² OJ L 136, 30.4.2004, p. 1.

EMA/PDCO/801027/2018
London, 1 February 2019

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

EMA-002461-PIP01-18

Scope of the application

Active substance(s):

Genetically modified Mycobacterium bovis BCG

Condition(s):

Treatment of ureter and bladder carcinoma

Pharmaceutical form(s):

Powder for intravesical suspension

Route(s) of administration:

Intravesical use

Name/corporate name of the PIP applicant:

medac Gesellschaft für klinische Spezialpräparate mbH

Basis for opinion

Pursuant to Article 13 of Regulation (EC) No 1901/2006 as amended, medac Gesellschaft für klinische Spezialpräparate mbH submitted to the European Medicines Agency on 26 October 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 4 December 2018.

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 grant a product-specific waiver for all subsets of the paediatric population and the above mentioned condition(s) 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 grounds for the granting of the waiver are set out in 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

Grounds for the granting of the waiver

1. Waiver

1.1. Condition:

Treatment of ureter and bladder carcinoma

The waiver applies to:

- all subsets of the paediatric population from birth to less than 18 years of age;
- powder for intravesical suspension, intravesical use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as clinical studies(s) are not feasible.