European Medicines Agency decision
P/0046/2021

of 27 January 2021


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 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 CambPharma Solution (CY) Ltd on 14 September 2020 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 11 December 2020 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.

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Has adopted this decision:

**Article 1**

A waiver for ublituximab, solution for injection, intravenous 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 CambPharma Solutions (CY) Ltd, Agiou Athanasiou 59 D. Vrachimis Building Agios Athanasios, 4102 – Limassol, Cyprus.
Opinion of the Paediatric Committee on the granting of a product-specific waiver
EMEA-002889-PIP01-20

Scope of the application

Active substance(s):
Ublituximab

Condition(s):
Treatment of mature B cell malignancies

Pharmaceutical form(s):
Solution for injection

Route(s) of administration:
Intravenous use

Name/corporate name of the PIP applicant:
CambPharma Solution (CY) Ltd

Basis for opinion


The procedure started on 13 October 2020.
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 mature B cell malignancies

The waiver applies to:

- all subsets of the paediatric population from birth to less than 18 years of age;
- solution for injection, intravenous use;
- on the grounds that clinical studies with the specific medicinal product cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the specified paediatric subset(s).