



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

EMA/534276/2018

## European Medicines Agency decision

P/0267/2018

of 13 August 2018

on the granting of a product specific waiver for elotuzumab (Empliciti), (EMA-002377-PIP01-18) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

**Only the English text is authentic.**



# European Medicines Agency decision

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on the granting of a product specific waiver for elotuzumab (Empliciti), (EMA-002377-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 726/2004<sup>1</sup>,

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<sup>2</sup>,

Having regard to the application submitted by Bristol-Myers Squibb Pharma EEIG on 23 April 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 27 July 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 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 elotuzumab (Empliciti), powder for concentrate for solution for infusion, 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 Bristol-Myers Squibb Pharma EEIG, Uxbridge Business Park, Sanderson Road, UB8 1DH - Uxbridge, United Kingdom.

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<sup>1</sup> OJ L 378, 27.12.2006, p.1.

<sup>2</sup> OJ L 136, 30.4.2004, p. 1.



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EMA/PDCO/345836/2018

London, 27 July 2018

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

EMA-002377-PIP01-18

### Scope of the application

**Active substance(s):**

Elotuzumab

**Invented name:**

Empliciti

**Condition(s):**

Treatment of multiple myeloma

**Authorised indication(s):**

See Annex II

**Pharmaceutical form(s):**

Powder for concentrate for solution for infusion

**Route(s) of administration:**

Intravenous use

**Name/corporate name of the PIP applicant:**

Bristol-Myers Squibb Pharma EEIG

**Information about the authorised medicinal product:**

See Annex II

### Basis for opinion

Pursuant to Article 13 of Regulation (EC) No 1901/2006 as amended, Bristol-Myers Squibb Pharma EEIG submitted to the European Medicines Agency on 23 April 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 29 May 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 annexes and appendix.

## **Annex I**

### **Grounds for the granting of the waiver**

# 1. Waiver

## 1.1. Condition

Treatment of multiple myeloma

The waiver applies to:

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

## **Annex II**

### **Information about the authorised medicinal product**

**Condition(s) and authorised indication(s):**

1. Treatment of multiple myeloma

Authorised indication(s):

- Empliciti is indicated in combination with lenalidomide and dexamethasone for the treatment of multiple myeloma in adult patients who have received at least one prior therapy.

**Authorised pharmaceutical form(s):**

Powder for concentrate for solution for infusion

**Authorised route(s) of administration:**

Intravenous use