



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

EMA/513271/2016

## European Medicines Agency decision

P/0210/2016

of 12 August 2016

on the acceptance of a modification of an agreed paediatric investigation plan for vemurafenib (Zelboraf), (EMEA-000978-PIP01-10-M01) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

### **Disclaimer**

This Decision does not constitute entitlement to the rewards and incentives referred to in Title V of Regulation (EC) No 1901/2006.

**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<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 European Medicines Agency's decision P/91/2011 issued on 8 April 2011,

Having regard to the application submitted by Roche Registration Limited on 31 March 2016 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral and proposing a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 24 June 2016, in accordance with Article 22 of Regulation (EC) No 1901/2006 and Article 13 of said Regulation,

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 on the acceptance of changes to the agreed paediatric investigation plan and to the deferral and on the granting of a waiver.
- (2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan, including changes to the deferral.
- (3) It is therefore appropriate to adopt a decision on the granting of a waiver.

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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.

Has adopted this decision:

**Article 1**

Changes to the agreed paediatric investigation plan for vemurafenib (Zelboraf), film coated tablet, oral use, including changes to the deferral, are hereby accepted in the scope set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices.

**Article 2**

A waiver for vemurafenib (Zelboraf), film coated tablet, oral use, the details of which are set out in the opinion of the Paediatric Committee the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

**Article 3**

This decision is addressed to Roche Registration Limited, 6 Falcon Way, Shire Park, AL7 1TW - Welwyn Garden City, United Kingdom.



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

EMA/PDCO/283372/2016

London, 24 June 2016

## Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan and on the granting of a product-specific waiver

EMA-000978-PIP01-10-M01

### Scope of the application

**Active substance(s):**

Vemurafenib

**Invented name:**

Zelboraf

**Condition(s):**

Treatment of melanoma

**Authorised indication(s):**

See Annex II

**Pharmaceutical form(s):**

Film coated tablet

**Route(s) of administration:**

Oral use

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

Roche Registration Limited

**Information about the authorised medicinal product:**

See Annex II



## **Basis for opinion**

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Roche Registration Limited submitted to the European Medicines Agency on 31 March 2016 an application for modification of the agreed paediatric investigation plan with a deferral as set out in the European Medicines Agency's decision P/91/2011 issued on 8 April 2011.

The application for modification proposed changes to the agreed paediatric investigation plan and to the deferral and proposed a waiver for all subsets of the paediatric population.

The procedure started on 26 April 2016.

## **Scope of the modification**

A waiver has been added for all age subsets.

## **Opinion**

The Paediatric Committee, having assessed the application in accordance with Article 22 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

- to agree to changes to the paediatric investigation plan and to the deferral;
- to grant a product-specific waiver for all subsets of the paediatric population concluded 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, as set out in Annex I of this opinion.

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

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

## **Annex I**

**The subset(s) of the paediatric population and condition(s) covered by the waiver and the measures and timelines of the agreed paediatric investigation plan (PIP)**

# 1. Waiver

## 1.1. Condition

Treatment of melanoma

The waiver applies to:

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

## **Annex II**

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



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

1. Treatment of melanoma

Authorised indication(s):

- Vemurafenib is indicated in monotherapy for the treatment of adult patients with BRAF V600 mutation-positive unresectable or metastatic melanoma.

**Authorised pharmaceutical form(s):**

Film-coated tablet

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

Oral use