



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

EMA/762548/2018

## European Medicines Agency decision P/0361/2018

of 7 December 2018

on the granting of a product specific waiver for crizotinib (Xalkori), (EMEA-001493-PIP02-18) 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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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 Pfizer Limited on 19 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 19 October 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 crizotinib (Xalkori), capsule, hard, 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 granted.

## **Article 2**

This decision is addressed to Pfizer Limited, Ramsgate Road, CT13 9NJ - Sandwich, 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/534236/2018  
London, 19 October 2018

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

EMA-001493-PIP02-18

### Scope of the application

**Active substance(s):**

Crizotinib

**Invented name:**

Xalkori

**Condition(s):**

Treatment of lung malignant neoplasms

**Authorised indication(s):**

See Annex II

**Pharmaceutical form(s):**

Capsule, hard

**Route(s) of administration:**

Oral use

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

Pfizer Limited

**Information about the authorised medicinal product:**

See Annex II



## Basis for opinion

Pursuant to Article 13 of Regulation (EC) No 1901/2006 as amended, Pfizer Limited submitted to the European Medicines Agency on 13 July 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 21 August 2018.

Supplementary information was provided by the applicant on 27 September 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)(b) of said Regulation, on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified subset(s) of the paediatric population.

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 lung malignant neoplasms

The waiver applies to:

- the paediatric population from birth to less than 18 years of age;
- capsule, hard, oral use;
- on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subsets.

## **Annex II**

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

## **Condition and authorised indications:**

1. Treatment of lung malignant neoplasms

Authorised indication(s):

Crizotinib as monotherapy is indicated for:

- the first-line treatment of adults with anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer (NSCLC);
- the treatment of adults with previously treated ALK-positive advanced NSCLC;
- the treatment of adults with ROS1-positive advanced NSCLC.

## **Authorised pharmaceutical form(s):**

Capsule, hard

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

Oral use