

EMA/440418/2021

## European Medicines Agency decision

P/0384/2021

of 8 September 2021

on the granting of a product specific waiver for atezolizumab (Tecentriq), (EMA-001638-PIP02-21) 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 Roche Registration GmbH on 19 April 2021 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 23 July 2021 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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<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**

A waiver for atezolizumab (Tecentriq), solution for injection, subcutaneous 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 Roche Registration GmbH, Emil-Barell-Strasse 1, 79639 - Grenzach-Wyhlen, Germany.



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

EMA/PDCO/270467/2021  
Amsterdam, 23 July 2021

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

EMA-001638-PIP02-21

### Scope of the application

**Active substance(s):**

Atezolizumab

**Invented name:**

Tecentriq

**Condition(s):**

Treatment of all conditions included in the category of malignant neoplasms (except central nervous system tumours, hematopoietic and lymphoid tissue neoplasms and melanoma).

**Authorised indication(s):**

See Annex II

**Pharmaceutical form(s):**

Solution for injection

**Route(s) of administration:**

Subcutaneous use

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

Roche Registration GmbH

**Information about the authorised medicinal product:**

See Annex II



## Basis for opinion

Pursuant to Article 13 of Regulation (EC) No 1901/2006 as amended, Roche Registration GmbH submitted to the European Medicines Agency on 19 April 2021 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 25 May 2021.

## 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 all conditions included in the category of malignant neoplasms (except central nervous system tumors, hematopoietic and lymphoid tissue neoplasms and melanoma).

The waiver applies to:

- all subsets of the paediatric population from birth to less than 18 years of age;
- solution for injection, subcutaneous 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 all conditions included in the category of malignant neoplasms (except central nervous system tumours, hematopoietic and lymphoid tissue neoplasms and melanoma).

Authorised indication(s):

- Tecentriq as monotherapy is indicated for the treatment of adult patients with locally advanced or metastatic urothelial carcinoma (UC):
  - after prior platinum-containing chemotherapy, or
  - who are considered cisplatin ineligible, and whose tumours have a PD-L1 expression  $\geq 5\%$
- Tecentriq as monotherapy is indicated for the first-line treatment of adult patients with metastatic nonsmall cell lung cancer (NSCLC) whose tumours have a PD-L1 expression  $\geq 50\%$  tumour cells (TC) or  $\geq 10\%$  tumour-infiltrating immune cells (IC) and who do not have EGFR mutant or ALK-positive NSCLC.
- Tecentriq as monotherapy is indicated for the treatment of adult patients with locally advanced or metastatic NSCLC after prior chemotherapy. Patients with EGFR mutant or ALK-positive NSCLC should also have received targeted therapies before receiving Tecentriq.
- Tecentriq in combination with nab-paclitaxel is indicated for the treatment of adult patients with unresectable locally advanced or metastatic triple-negative breast cancer (TNBC) whose tumours have PD-L1 expression  $\geq 1\%$  and who have not received prior chemotherapy for metastatic disease.
- Tecentriq, in combination with carboplatin and etoposide, is indicated for the first-line treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC).
- Tecentriq, in combination with bevacizumab, is indicated for the treatment of adult patients with advanced or unresectable hepatocellular carcinoma (HCC) who have not received prior systemic therapy.

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

Concentrate for solution for infusion

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

Intravenous use