EMA/317695/2021

European Medicines Agency decision

P/0258/2021

of 9 July 2021

on the granting of a product specific waiver for [18F]CTT1057 (EMEA-002975-PIP01-21) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

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[1],

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[2],

Having regard to the application submitted by Advanced Accelerator Applications SA on 15 February 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 21 May 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.

[1] OJ L 378, 27.12.2006, p.1.
[2] OJ L 136, 30.4.2004, p. 1.

Has adopted this decision:

Article 1

A waiver for [18F]CTT1057, all pharmaceutical forms, all routes of administration, 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 Advanced Accelerator Applications SA, 20 rue Rudolf Diesel, 01630 - Saint-Genis-Pouilly, France.

EMA/PDCO/132369/2021
Amsterdam, 21 May 2021

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

EMEA-002975-PIP01-21

Scope of the application

Active substance(s):

[18F]CTT1057

Condition(s):

Visualisation of prostate-specific membrane antigen in adenocarcinoma of the prostate

Pharmaceutical forms:

All pharmaceutical forms

Routes of administration:

All routes of administration

Name/corporate name of the PIP applicant:

Advanced Accelerator Applications SA

Basis for opinion

Pursuant to Article 13 of Regulation (EC) No 1901/2006 as amended, Advanced Accelerator Applications SA submitted to the European Medicines Agency on 15 February 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 23 March 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)(b) of said Regulation, on the grounds that the disease or condition for which the specific medicinal product is intended occurs only in adult populations.

   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:

Visualisation of prostate-specific membrane antigen in adenocarcinoma of the prostate

The waiver applies to:

- all subsets of the paediatric population from birth to less than 18 years of age;
- all pharmaceutical forms, all routes of administration;
- on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subset(s).