

EMA/792962/2017

European Medicines Agency decision

P/0015/2018

of 30 January 2018

on the acceptance of a modification of an agreed paediatric investigation plan for regadenoson (Rapiscan), (EMA-000410-PIP01-08-M02) 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 726/2004¹,

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 Agency²,

Having regard to the European Medicines Agency's decision P/82/2009 issued on 24 April 2009 and the decision P/0256/2013 issued on 29 October 2013,

Having regard to the application submitted by Rapiscan Pharma EU Solutions (RPS) EU Limited on 25 September 2017 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a waiver and proposing a deferral,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 15 December 2017, in accordance with Article 22 of Regulation (EC) No 1901/2006, and Article 21 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 on the granting of a deferral.
- (2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan.
- (3) It is therefore appropriate to adopt a decision on the granting of a deferral.

¹ OJ L 378, 27.12.2006, p.1.

² OJ L 136, 30.4.2004, p. 1.

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for regadenoson (Rapiscan), solution for injection, intravenous use, 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 deferral for regadenoson (Rapiscan), solution for injection, intravenous 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 Rapidscan Pharma Solutions EU Limited, Regent's Place - 338 Euston Road, NW1 3BT - London, United Kingdom.

EMA/PDCO/643049/2017 **Corr**

London, 15 December 2017

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan EMA-000410-PIP01-08-M02

Scope of the application

Active substance(s):

Regadenoson

Invented name:

Rapiscan

Condition(s):

Diagnosis of myocardial perfusion disturbances

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Solution for injection

Route(s) of administration:

Intravenous use

Name / corporate name of the PIP applicant:

Rapiscan Pharma EU Solutions (RPS) EU 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, Rapidscan Pharma EU Solutions (RPS) EU Limited submitted to the European Medicines Agency on 25 September 2017 an application for modification of the agreed paediatric investigation plan with a waiver as set out in the European Medicines Agency's decision P/82/2009 issued on 24 April 2009 and the decision P/0256/2013 issued on 29 October 2013.

The application for modification proposed a deferral.

The procedure started on 17 October 2017.

Scope of the modification

A deferral has been granted.

Opinion

1. 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 in the scope set out in the Annex I of this opinion;
 - to grant a deferral, the details of which are set out in the Annex I of this opinion.

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

2. The measures and timelines of the paediatric investigation plan and the subset(s) of the paediatric population and condition(s) covered by the waiver are set out in the 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

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

1. Waiver

1.1. Condition:

Diagnosis of myocardial perfusion disturbances

The waiver applies to:

- preterm and term newborn infants (from birth to less than 28 days of age);
- for solution for injection for intravenous use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as clinical studies(s) are not feasible.

2. Paediatric Investigation Plan

2.1. Condition:

Diagnosis of myocardial perfusion disturbances

2.1.1. Indication(s) targeted by the PIP

Diagnostic evaluation of myocardial perfusion disturbances

2.1.2. Subset(s) of the paediatric population concerned by the paediatric development

From one month to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Solution for injection

2.1.4. Measures

Area	Number of measures	Description
Quality	0	Not applicable.
Non-clinical	0	Not applicable.
Clinical	1	An Open-label, Single Ascending-dose, Pharmacokinetic, Pharmacodynamic and Safety Study of Regadenoson in Paediatric Patients with Cardiovascular Conditions and Diseases.

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By October 2018
Deferral for one or more measures contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Diagnosis of myocardial perfusion disturbances

Authorised indication(s):

- Rapiscan is a selective coronary vasodilator for use as a pharmacological stress agent for radionuclide myocardial perfusion imaging (MPI) in adult patients unable to undergo adequate exercise stress.

Authorised pharmaceutical form(s):

Solution for injection

Authorised route(s) of administration:

Parenteral use