EMA/319202/2024

European Medicines Agency decision

P/0238/2024

of 18 July 2024

on the acceptance of a modification of an agreed paediatric investigation plan for regadenoson (Rapiscan), (EMEA-000410-PIP01-08-M07) 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[1],

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency[2],

Having regard to the European Medicines Agency's decision P/82/2009 issued on 24 April 2009, the decision P/0256/2013 issued on 29 October 2013, the decision P/0015/2018 issued on 30 January 2018, the decision P/0030/2019 issued on 29/01/2019 and the decision P/0029/2024 issued on 29 January 2024,

Having regard to the application submitted by GE Healthcare AS on 23 February 2024 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral and a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 31 May 2024, in accordance with Article 22 of Regulation (EC) No 1901/2006,

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 to the 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 and to the waiver.

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

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for regadenoson (Rapiscan), solution for injection, intravenous use, including changes to the deferral and to the waiver, 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

This decision is addressed to GE Healthcare AS, Nycoveien 1, NO-0485 – Oslo, Norway.

EMA/PDCO/89972/2024
Amsterdam, 31 May 2024

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan

EMEA-000410-PIP01-08-M07

Scope of the application

Active substance(s):

Regadenoson

Invented name and authorisation status:

See Annex II

Condition(s):

Diagnosis of myocardial perfusion disturbances

Pharmaceutical form(s):

Solution for injection

Route(s) of administration:

Intravenous use

Name/corporate name of the PIP applicant:

GE Healthcare AS

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, GE Healthcare AS submitted to the European Medicines Agency on 23 February 2024 an application for modification of the agreed paediatric investigation plan with a deferral and a waiver as set out in the European Medicines Agency's decision P/82/2009 issued on 24 April 2009, the decision P/0256/2013 issued on 29 October 2013, the decision P/0015/2018 issued on 30 January 2018, the decision P/0030/2019 issued on 29/01/2019 and the decision P/0029/2024 issued on 29 January 2024.

The application for modification proposed changes to the agreed paediatric investigation plan and to the deferral.

The procedure started on 2 April 2024.

Scope of the modification

Some measures and timelines of the Paediatric Investigation Plan have been modified. The scope of the waiver has been extended to include an additional population.

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 and to the deferral and to the waiver in the scope set out in the Annex I of this opinion;
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 (PIP)

1. Waiver

1.1. Condition:

Diagnosis of myocardial perfusion disturbances

The waiver applies to:

- from birth to less than 2 years 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 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 2 years to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Solution for injection

2.1.4. Measures

Area	Description
Quality	Not applicable.
Non-clinical	Not applicable.
Clinical	**Study 1** Open-label, single -dose, safety and pharmacokinetic study of intravenous regadenoson for diagnostic evaluation of myocardial perfusion disturbances in paediatric patients from 2 years to less than 18 years of age (Study GE-262-001)
Modelling and simulation	Not applicable
Other	**Study 2** Multi-centre, retrospective study to assess regadenoson safety, tolerability, and effectiveness in paediatric patients from 2 years to less than 18 years of age who underwent stress perfusion cardiac magnetic

	resonance test after administration of regadenoson as a single intravenous bolus dose (Study GE-262-004)

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 September 2027
Deferral for one or more measures contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Information provided by the applicant:

Condition(s) and authorised indication(s)

1. Diagnosis Myocardial Perfusion Disturbances

Authorised indication(s):

- Rapiscan is a selective coronary vasodilator for use as a pharmacological stress agent for myocardial perfusion imaging (MPI) in adult patients unable to undergo adequate exercise stress
  - Invented name(s): Rapiscan
  - Authorised pharmaceutical form(s): Solution for injection
  - Authorised route(s) of administration: intravenous use
  - Authorised via centralised procedure
- The measurement of fractional flow reserve (FFR) of a single coronary artery stenosis during invasive coronary angiography, when repeated FFR measurements are not anticipated
  - Invented name(s): Rapiscan
  - Authorised pharmaceutical form(s): solution for injection
  - Authorised route(s) of administration: intravenous use
  - Authorised via centralised procedure