MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

gov.uk/mhra

Decision Cover Letter

Decision of the licensing authority to:

accept change(s) to the agreed paediatric investigation plan and to the deferral.

MHRA-101324-PIP01-23-M01

Scope of the Application

Active Substance(s)

REGADENOSON

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 the Decision

Pursuant to the Human Medicines Regulations 2012, GE Healthcare AS submitted to the licensing authority on 22/01/2024 12:21 GMT an application for a Modification

The procedure started on 15/08/2024 16:15 BST

1. The licensing authority, having assessed the application in accordance with the Human Medicines Regulations 2012, decides, as set out in the appended summary report:

to accept change(s) to the agreed paediatric investigation plan and to the deferral.

2. The measures and timelines of the paediatric investigation plan are set out in the Annex I.

This decision is forwarded to the applicant, together with its annex and appendix.

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Final Decision Letter

MHRA-101324-PIP01-23-M01

Of 20/08/2024 09:50 BST

On the adopted decision for REGADENOSON (MHRA-101324-PIP01-23-M01) in accordance with the Human Medicines Regulations 2012.

The licensing authority, in accordance with the Human Medicines Regulations 2012, has adopted this decision:

Agreement on modification of a paediatric investigation plan (including modification of a waiver or deferral included in that paediatric investigation plan).

This decision applies to a Modification for REGADENOSON, Solution for injection , INTRAVENOUS USE .

This decision is addressed to GE Healthcare AS, Nycoveien 1, Oslo, NORWAY, NO-0485

ANNEX I

1. Waiver

1.1 Condition:

Diagnosis of myocardial perfusion disturbances. The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 28 days of age. Pharmaceutical form(s): Solution for injection. Route(s) of administration: INTRAVENOUS USE Reason for granting waiver: 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(s):

Diagnosis of myocardial perfusion disturbances.

2.2 Indication(s) targeted by the PIP:

Diagnostic evaluation of myocardial perfusion disturbances.

2.3 Subset(s) of the paediatric population concerned by the paediatric development:

The paediatric population from one month to less than 18 years of age.

2.4 Pharmaceutical Form(s):

Solution for injection.

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	0	Not applicable.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	1	Study 1 (GE-262-001) Open-label, single -dose, safety and pharmacokinetic study of intravenous regadenoson for diagnostic evaluation of myocardial perfusion disturbances in paediatric patients from 2 to less than 18 years of age.
Extrapolation, Modeling & Simulation Studies	0	Not applicable.
Other Studies	1	Study 2 (GE-262-004) Multi-centre, retrospective study to assess regadenoson safety, tolerability, and effectiveness in paediatric patients from 1 month 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.
Other Measures	0	Not applicable.

3. Follow-up, completion and deferral of a PIP:

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	31/12/2026
Deferral of one or more studies contained in the paediatric investigation plan:	Yes