



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/58300/2014

European Medicines Agency decision

P/0048/2014

of 8 March 2014

on the acceptance of a modification of an agreed paediatric investigation plan for rubidium (82Rb) chloride (EMEA-000882-PIP03-11-M01) 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/0059/2012 issued on 26 March 2012,

Having regard to the application submitted by Jubilant DraxImage Inc on 21 October 2013 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 17 January 2014, 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.
- (2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan.

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 rubidium (⁸²Rb) chloride, radionuclide generator, 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

This decision is addressed to Jubilant DraxImage Inc., 16751 Trans Canada Hwy, H9H 4J4 - Kirkland, QC, Canada.

Done at London, 8 March 2014

For the European Medicines Agency
Guido Rasi
Executive Director
(Signature on file)

EMA/PDCO/663735/2013

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

EMA-000882-PIP03-11-M01

Scope of the application

Active substance(s):

Rubidium (⁸²Rb) chloride

Condition(s):

Visualisation of myocardial perfusion for diagnostic purposes

Pharmaceutical form(s):

Radionuclide generator

Route(s) of administration:

Intravenous use

Name / corporate name of the PIP applicant:

Jubilant DraxImage Inc.

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Jubilant DraxImage Inc. submitted to the European Medicines Agency on 21 October 2013 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/0059/2012 issued on 26 March 2012.

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

The procedure started on 19 November 2013.

Scope of the modification

Some measures of the Paediatric Investigation Plan have been modified.

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.

The Icelandic and the Norwegian Paediatric Committee members agree 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 annex and appendix.

London, 17 January 2014

On behalf of the Paediatric Committee
Dr Dirk Mentzer, Chairman
(Signature on file)

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: Visualisation of myocardial perfusion for diagnostic purposes

The waiver applies to:

- Preterm and term neonates (from birth to less than 28 days of age);
- for radionuclide generator for intravenous use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

2. Paediatric Investigation Plan

2.1. Condition: visualisation of myocardial perfusion for diagnostic purposes

2.1.1. Indication(s) targeted by the PIP

Assessment of myocardial perfusion abnormalities.

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

From 1 month to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Radionuclide generator.

2.1.4. Studies

Area	Number of studies	Description
Quality	0	Not applicable.
Non-clinical	0	Not applicable.
Clinical	1	Study 1: Open-label, single centre, uncontrolled dosimetry, safety and tolerability trial of Rubidium (Rb82) chloride administered intravenously as contrast media for Positron Emission Tomography (PET) in paediatric patients from 1 month to less than 18 years of age at high risk of myocardial ischemia.

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By October 2016
Deferral for one or more studies contained in the paediatric investigation plan:	Yes