



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/458510/2012

European Medicines Agency decision P/0140/2012

of 20 July 2012

on the agreement of a paediatric investigation plan and on the granting of a deferral for potassium (chloride) / magnesium (sulphate heptahydrate) / procaine (hydrochloride) / xylitol (EMEA-001171-PIP01-11) 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 application submitted by Swiss Cardio Technologies AG on 5 August 2011 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 8 June 2012, in accordance with Article 18 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 agreement of a paediatric investigation plan and on the granting of a deferral.
- (2) It is therefore appropriate to adopt a decision agreeing a paediatric investigation plan.
- (3) It is therefore appropriate to adopt a decision granting 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

A paediatric investigation plan for potassium (chloride) / magnesium (sulphate heptahydrate) / procaine (hydrochloride) / xylitol, solution for injection, intracoronary use, 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 agreed.

Article 2

A deferral for potassium (chloride) / magnesium (sulphate heptahydrate) / procaine (hydrochloride) / xylitol, solution for injection, intracoronary use, 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 3

This decision is addressed to Swiss Cardio Technologies AG, Thunstr. 42, 3005 – Bern, Switzerland.

Done at London, 20 July 2012

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



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/PDCO/221070/2012

Opinion of the Paediatric Committee on the agreement of a Paediatric Investigation Plan and a deferral

EMA-001171-PIP01-11

Scope of the application

Active substance(s):

Potassium (chloride) / magnesium (sulphate heptahydrate) / procaine (hydrochloride) / xylitol

Condition(s):

Cardioplegia

Pharmaceutical form(s):

Solution for injection

Route(s) of administration:

Intracoronary use

Name/corporate name of the PIP applicant:

Swiss Cardio Technologies AG

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Swiss Cardio Technologies AG submitted for agreement to the European Medicines Agency on 5 August 2011 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation.

The procedure started on 14 September 2011.

Supplementary information was provided by the applicant on 26 March 2012. The applicant proposed modifications to the paediatric investigation plan.



Opinion

1. The Paediatric Committee, having assessed the proposed paediatric investigation plan in accordance with Article 17 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

- to agree the paediatric investigation plan in accordance with Article 18 of said Regulation,
- to grant a deferral in accordance with Article 21 of said Regulation.

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 agreed paediatric investigation plan 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(es) and appendix.

London, 8 June 2012

On behalf of the Paediatric Committee
Dr Daniel Brasseur, 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

Not applicable.

2. Paediatric Investigation Plan

2.1. Condition: Cardioplegia

2.1.1. Indication(s) targeted by the PIP

Cardioplegia

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

From birth to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Solution for injection

2.1.4. Studies

Area	Number of studies	Description
Quality	0	Not applicable.
Non-clinical	0	Not applicable.
Clinical	2	Study 1: Multicentre, multinational, patient blind, randomized, active controlled, non-inferiority study to explore the effects of potassium (chloride) / magnesium (sulphate heptahydrate) / procaine (hydrochloride) / xylitol on the protection of cardiac cells during the "ischaemic" period in order to allow a rapid and complete reversibility of the cardiac arrest when used during a cardiac surgical intervention under the assistance of a heart-lung machine in paediatric patients (SCT-Cpx-002) Study 2: Model-based bridging of clinical data to children and adolescents from 30 months to less than 18 years of age

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety or efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By March 2017
Deferral for one or more studies contained in the paediatric investigation plan:	Yes