



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/45733/2014

European Medicines Agency decision

P/0051/2014

of 7 March 2014

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for citric acid (as citric acid anhydrous) / sodium chloride / simeticone / macrogol 4000 / sodium citrate / sodium sulfate (as sodium sulfate anhydrous) / potassium chloride (EMA-001356-PIP02-12) 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 ALFA WASSERMANN S.p.A. on 5 November 2012 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 17 January 2014, in accordance with Article 18 of Regulation (EC) No 1901/2006, and Article 21 of said Regulation and Article 13 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 and on the granting of a waiver.
- (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.
- (4) It is therefore appropriate to adopt a decision granting a waiver.

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 citric acid (as citric acid anhydrous) / sodium chloride / simeticone / macrogol 4000 / sodium citrate / sodium sulfate (as sodium sulfate anhydrous) / potassium chloride, powder for oral solution, oral 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 citric acid (as citric acid anhydrous) / sodium chloride / simeticone / macrogol 4000 / sodium citrate / sodium sulfate (as sodium sulfate anhydrous) / potassium chloride, powder for oral solution, oral 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

A waiver for citric acid (as citric acid anhydrous) / sodium chloride / simeticone / macrogol 4000 / sodium citrate / sodium sulfate (as sodium sulfate anhydrous) / potassium chloride, powder for oral solution, oral 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 4

This decision is addressed to ALFA WASSERMANN S.p.A., Via Ragazzi del '99 n. 5, 40133 – Bologna, Italy.

Done at London, 7 March 2014

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

EMA/PDCO/642117/2013

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

EMA-001356-PIP02-12

Scope of the application

Active substance(s):

Citric acid (as citric acid anhydrous) / sodium chloride / simeticone / macrogol 4000 / sodium citrate / sodium sulfate (as sodium sulfate anhydrous) / potassium chloride

Condition(s):

Diagnosis of large intestine disorders

Pharmaceutical form(s):

Powder for oral solution

Route(s) of administration:

Oral use

Name / corporate name of the PIP applicant:

ALFA WASSERMANN S.p.A.

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, ALFA WASSERMANN S.p.A. submitted for agreement to the European Medicines Agency on 5 November 2012 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation.

The procedure started on 12 December 2012.

Supplementary information was provided by the applicant on 16 October 2013. 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;
- to grant a waiver for one or more subsets of the paediatric population in accordance with Article 13 of said Regulation and concluded in accordance with Article 11(1)(c) of said Regulation, on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients.

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 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: diagnosis of large intestine disorders

The waiver applies to:

- the paediatric population from birth to less than 2 years;
- for powder for oral solution, oral 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: diagnosis of large intestine disorders

2.1.1. Indication(s) targeted by the PIP

Bowel preparation before a diagnostic procedure concerning the colon

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)

Powder for oral solution.

2.1.4. Measures

Area	Number of measures	Description
Quality	0	Not applicable.
Non-clinical	0	Not applicable.
Clinical	3	Measure 1: Study PMF104 PD1 / 13 Randomised, single-blind, active controlled, multi-centre trial to evaluate efficacy, safety, tolerability, acceptability and palatability of citric acid (as citric acid anhydrous) / sodium chloride / simeticone / macrogol 4000 / sodium citrate / sodium sulfate (as sodium sulfate anhydrous) / potassium chloride (PMF104) compared to a solution containing macrogol 3350 or macrogol 4000 (58-59.5 g per litre); anhydrous sodium sulfate (5.67-5.7 g per litre); sodium bicarbonate (1.67-1.7 g per litre); sodium chloride (1.45-1.47 g per litre); potassium chloride (0.73-0.75 g per litre) in children from 2 to less than 6 years of age requiring a diagnostic procedure concerning the

Area	Number of measures	Description
		colon. Measure 2: Study PMF104 PD2 / 13 Randomised, single-blind, active controlled, multi-centre trial to evaluate efficacy, safety, tolerability, acceptability and palatability of PMF104 compared to a solution containing macrogol 3350 or macrogol 4000 (58-59.5 g per litre); anhydrous sodium sulfate (5.67-5.7 g per litre); sodium bicarbonate (1.67-1.7 g per litre); sodium chloride (1.45-1.47 g per litre); potassium chloride (0.73-0.75 g per litre) in children from 6 to less than 12 years of age requiring a diagnostic procedure concerning the colon. Measure 3: Study PMF104 PD3 / 13 Randomised, single-blind, active controlled, multi-centre trial to evaluate efficacy, safety, tolerability, acceptability and palatability of PMF104 compared to a solution containing macrogol 3350 or macrogol 4000 (58-59.5 g per litre); anhydrous sodium sulfate (5.67-5.7 g per litre); sodium bicarbonate (1.67-1.7 g per litre); sodium chloride (1.45-1.47 g per litre); potassium chloride (0.73-0.75 g per litre) in children from 12 to less than 18 years of age requiring a diagnostic procedure concerning the colon.

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 June 2017
Deferral for one or more measures contained in the paediatric investigation plan:	Yes