



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/641295/2012

European Medicines Agency decision

P/0234/2012

of 12 October 2012

on the acceptance of a modification of an agreed paediatric investigation plan for Influenza Virus Type A, H1N1 / Influenza Virus Type A, H3N2 / Influenza Virus Type B, Yamagata lineage / Influenza Virus Type B, Victoria lineage, (EMA-001051-PIP01-10-M03) 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.



European Medicines Agency decision

P/0234/2012

of 12 October 2012

on the acceptance of a modification of an agreed paediatric investigation plan for Influenza Virus Type A, H1N1 / Influenza Virus Type A, H3N2 / Influenza Virus Type B, Yamagata lineage / Influenza Virus Type B, Victoria lineage, (EMEA-001051-PIP01-10-M03) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

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/140/2011 issued on 6 June 2011 and the decision P/250/2011 issued on 25 October 2011,

Having regard to the application submitted by MedImmune Limited on 18 June 2012 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 7 September 2012, 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.
- (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.

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 Influenza Virus Type A, H1N1 / Influenza Virus Type A, H3N2 / Influenza Virus Type B, Yamagata lineage / Influenza Virus Type B, Victoria lineage, nasal spray, suspension, nasal use, including changes to the deferral, 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 MedImmune Limited, Granta Park, Great Abington, Cambs, CB21 6GH – Cambridge, United Kingdom.

Done at London, 12 October 2012

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

EMA/PDCO/543300/2012

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

EMA-001051-PIP01-10-M03

Scope of the application

Active substance(s):

Influenza Virus Type A, H1N1 / Influenza Virus Type A, H3N2 / Influenza Virus Type B, Yamagata lineage / Influenza Virus Type B, Victoria lineage

Condition(s):

Prevention of influenza infection

Pharmaceutical form(s):

Nasal spray, suspension

Route(s) of administration:

Nasal use

Name / corporate name of the PIP applicant:

MedImmune Limited

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, MedImmune Limited submitted to the European Medicines Agency on 18 June 2012 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/140/2011 issued on 06 June 2011 and the decision P/250/2011 issued on 25 October 2011.

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

The procedure started on 11 July 2012.

Scope of the modification

Some measures, timelines and the deferral of the original 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 and to the deferral 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, 7 September 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

1.1. Condition: prevention of influenza infection

The waiver applies to:

- the children from birth to less than 2 years of age;
- for nasal spray for nasal use;
- on the grounds that the specific medicinal product is likely to be unsafe.

2. Paediatric Investigation Plan

2.1. Condition: prevention of influenza infection

2.1.1. Indication(s) targeted by the PIP

Prevention of influenza infection.

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

From 2 to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Nasal spray for nasal use.

2.1.4. Studies

Area	Number of studies	Description
Quality	1	Study 1) Screening of permissive cell lines for use in neutralisation assay to investigate a serological correlate for immune protection following vaccination. Study 2) Validation and optimization of an assay to test neutralising antibodies also measuring anti-NA and retesting of paediatric sera collected in study MI-CP208 to investigate a serological correlate for immune protection following vaccination.
Non-clinical		Not applicable.
Clinical	1	Study 3) Randomised, double-blind, active controlled, multicenter study to assess the safety and immunogenicity of Q/LAIV in comparison with two formulations of FluMist in children from 2 to less than 18 years of age.

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 March 2013
Deferral for one or more studies contained in the paediatric investigation plan:	Yes

s