



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/384223/2011

European Medicines Agency decision P/140/2011

of 6 June 2011

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver 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) 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 MedImmune Limited on 3 September 2010 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 20 May 2011, 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 influenza virus type A, H1N1 / influenza virus type A, H3N2 / influenza virus type B, yamagata lineage / influenza virus type B, victoria lineage, nasal spray, nasal 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 influenza virus type A, H1N1 / influenza virus type A, H3N2 / influenza virus type B, yamagata lineage / influenza virus type B, victoria lineage, nasal spray, nasal 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 influenza virus type A, H1N1 / influenza virus type A, H3N2 / influenza virus type B, yamagata lineage / influenza virus type B, victoria lineage, nasal spray, nasal 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 MedImmune Limited, Milstein Building, Granta Park, Great Abington, Cambs, CB21 6GH Cambridge, United Kingdom.

Done at London, 6 June 2011

For the European Medicines Agency
Andreas Pott
Acting Executive Director
(Signature on file)



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/PDCO/183753/2011

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

EMA-001051-PIP01-10

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

Route(s) of administration:

Nasal use

Name/corporate name of the PIP applicant:

MedImmune Limited

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, MedImmune Limited submitted for agreement to the European Medicines Agency on 3 September 2010 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 13 October 2010.

Supplementary information was provided by the applicant on 4 March 2011. The applicant proposed modifications to the paediatric investigation plan.

A meeting with the Paediatric Committee took place on 18 May 2011



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)(a) of said Regulation, on the grounds that the specific medicinal product is likely to be ineffective or unsafe in part or all of the paediatric population.

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(es) and appendix.

London, 20 May 2011

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

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

2.1.1. Indication(s) targeted by the PIP

Prevention of Influenza

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 neutralization assay. Also measuring anti-NA to investigate a serological correlate for immune protection following vaccination. Study 2) Validation 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

Measures to address long term follow-up of potential safety and efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By December 2012
Deferral for one or more studies contained in the paediatric investigation plan:	Yes