EMA/717956/2010

European Medicines Agency decision

P/14/2011

of 3 January 2011

on the review of a granted waiver for influenza virus type A, H3N2, influenza virus type A, H1N1, influenza virus type B (Fluenz) (EMEA-000249-PIP01-10) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

Only the English text is authentic.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8670
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

European Medicines Agency decision

P/14/2011

of 3 January 2011

on the review of a granted waiver for influenza virus type A, H3N2, influenza virus type A, H1N1, influenza virus type B (Fluenz) (EMEA-000249-PIP01-10) 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 726/2004[1],

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 Agency[2],

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 17 October 2008,

Having regard to the decision of the European Medicines Agency P/101/2008, adopted on 3 November 2008,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued of its own motion on 12 November 2010 in accordance with Article 14(2) 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 of its own motion on the review of the granted waiver.

(2) It is therefore appropriate to adopt a decision reviewing the granted 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 review of the granted waiver for influenza virus type A, H3N2, influenza virus type A, H1N1, influenza virus type B (Fluenz), nasal spray suspension, intranasal, 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

This decision is addressed to MedImmune, LLC, One MedImmune Way, 20878 Gaithersburg, Maryland, United-States.

Done at London, 3 January 2011

For the European Medicines Agency
Andreas Pott
Acting Executive Director

(Signature on file)

EMA/PDCO/717950/2010

Opinion of the Paediatric Committee on the review of a granted product specific waiver

EMEA- 000249-PIP01-10

Scope of the waiver

Active substance(s):

Influenza virus type A, H3N2, influenza virus type A, H1N1, influenza virus type B

Invented name:

Fluenz

Condition(s):

Prevention of influenza infection

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Nasal spray suspension

Route(s) of administration:

Intranasal

Name/corporate name of the waiver addressee:

MedImmune, LLC

Information about the authorised medicinal product:

See Annex II

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7523 7040
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

Scope of the review

Condition: Prevention of influenza infection

Scope of the changes: The subsets covered by the waiver in the condition “Prevention of influenza infection” have been modified

Basis for opinion

On 17 October 2008, an opinion on the granting of a product specific waiver was adopted by the Paediatric Committee, followed by the European Medicines Agency’s decision P/101/2008 issued on 3 November 2008.

According to Article 14(2) of Regulation (EC) No 1901/2006 as amended, the Paediatric Committee may, at any time, adopt an opinion advocating the review of a granted waiver.

The procedure started on 13 October 2010.

Opinion

1. The Paediatric Committee, having assessed the granted product specific waiver, recommends as set out in the appended summary report:

   - to review the granted product-specific waiver for one or more subsets of the paediatric population on its own motion in accordance with Article 14(2) of said Regulation;
   - the reviewed waiver is based on: 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 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 addressee of the waiver and the Executive Director of the European Medicines Agency, together with its annex and appendix.

London, 12 November 2010

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

1. Waiver

1.1. Condition

Prevention of influenza infection

The waiver applies to:

- Infants less than 2 years of age,
- for nasal spray suspension, intranasal use,
- on the grounds that the specific medicinal product is likely to be unsafe.

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Prevention of influenza infection

   Authorised indications:

   Prophylaxis of influenza in individuals 24 months to less than 18 years of age.

EU Number	Invented name	Strength	Pharmaceutical form	Route of administration	Packaging	Content (concentration)	Package size
EMEA/H/C/001101/0000/001	FLUENZ	- 1 -	Nasal spray, suspension	Nasal use	sprayer (glass/PE)	0.2 ml	1 sprayer
EMEA/H/C/001101/0000/002	FLUENZ	- 1 -	Nasal spray, suspension	Nasal use	sprayer (glass/PE)	0.2 ml	10 sprayers