European Medicines Agency

Doc. Ref. EMA/37131/2010
P/13/2010

EUROPEAN MEDICINES AGENCY DECISION

of 22 January 2010

on the acceptance of a modification of an agreed Paediatric Investigation Plan for Human Papillomavirus type 6 L1 protein / Human Papillomavirus type 11 L1 protein / Human Papillomavirus type 16 L1 protein / Human Papillomavirus type 18 L1 protein (Gardasil) EMEA-000375-PIP01-08-M02 in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council as amended

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

DISCLAIMER: This Decision does not entitle to the rewards and incentives referred to in Title V of Regulation (EC) No 1901/2006, as amended.

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THE EUROPEAN MEDICINES AGENCY,

Having regard to the Treaty establishing the European Community,

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 as amended 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 decision P/110/2009 of the European Medicines Agency on 16 June 2009,

Having regard to the application submitted by Sanofi Pasteur MSD SNC on 23 December 2009 under Article 22 of Regulation (EC) No 1901/2006 as amended proposing changes to the agreed Paediatric Investigation Plan in the scope of a waiver and a request for a deferral,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 15 January 2010, in accordance with Article 22 of Regulation (EC) No 1901/2006 as amended, and in accordance with Article 21 of said Regulation,

Having regard to Article 25 of Regulation (EC) No 1901/2006 as amended,

WHEREAS:

(1) The Paediatric Committee of the European Medicines Agency has given an opinion on the acceptance of changes to an agreed Paediatric Investigation Plan in the scope of a waiver and on the granting of a deferral.

(2) It is therefore appropriate to adopt a Decision on the acceptance of changes in the scope of a waiver.

(3) It is therefore appropriate to adopt a Decision on the granting of 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

Changes in the scope of a waiver for Human Papillomavirus type 6 L1 protein / Human Papillomavirus type 11 L1 protein / Human Papillomavirus type 16 L1 protein / Human Papillomavirus type 18 L1 protein (Gardasil), suspension for injection, intramuscular 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, are hereby accepted.

Article 2

A deferral for Human Papillomavirus type 6 L1 protein / Human Papillomavirus type 11 L1 protein / Human Papillomavirus type 16 L1 protein / Human Papillomavirus type 18 L1 protein (Gardasil), suspension for injection, intramuscular use, the details of which are set out in the Opinion of the Paediatric Committee the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 3

This decision is addressed to Sanofi Pasteur MSD SNC, 8 rue Jonas Salk, 69007 Lyon, France.

Done at London, 22 January 2010

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)

European Medicines Agency
Pre-authorisation Evaluation of Medicines for Human Use

Doc. Ref. EMA/PDCO/38332/2010
EMEA-000375-PIP01-08-M02

OPINION OF THE PAEDIATRIC COMMITTEE ON THE ACCEPTANCE OF A MODIFICATION OF AN AGREED PAEDIATRIC INVESTIGATION PLAN

Scope of the application

Active substances:
Human Papillomavirus type 6 L1 protein / Human Papillomavirus type 11 L1 protein / Human Papillomavirus type 16 L1 protein / Human Papillomavirus type 18 L1 protein

Invented name:
Gardasil

Conditions:
Infection by Human Papillomavirus

Pharmaceutical forms:
Suspension for injection
Suspension for injection in pre-filled syringe

Route of administration:
Intramuscular use

Name/corporate name of the PIP applicant:
Sanofi Pasteur MSD SNC

Information about the authorised medicinal product
See Annex II

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Sanofi Pasteur MSD SNC submitted to the EMEA on 23 December 2009 an application for modification of the agreed paediatric investigation plan and a waiver as set out in the EMEA decision P/110/2009 of 16 June 2009. The application for modification proposed changes in the scope of waiver and a request for a deferral.

The procedure started on 23 December 2009.

Scope of the modification

The modification intends to clarify the specific paediatric subsets covered by the waiver and includes the addition of a deferral for the completion of the adolescent boy study.

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Opinion

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 the changes proposed by the applicant regarding the scope of the waiver,
- to grant a deferral for part of the paediatric population concluded in accordance with Article 21 of said Regulation.

The Norwegian and Icelandic Paediatric Committee members agree with the above-mentioned recommendation of the Paediatric Committee.

This opinion is forwarded to the applicant and the Executive Director of the Agency, together with its annexes.

London, 15 January 2010

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman

(Signature on file)

ANNEX I

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

A. CONDITION(S)

Infection by Human Papillomavirus

B. WAIVER

- **Condition**

Infection by Human Papillomavirus

The waiver applies to:

- the paediatric population (boys and girls) from birth to less than 9 years of age for the suspension for injection and the suspension for injection in pre-filled syringe for intramuscular use
- the girl subset from 9 to less than 18 years of age for the suspension for injection and the suspension for injection in pre-filled syringe for intramuscular use
- the boy subset from 9 to less than 16 years of age for the suspension for injection and the suspension for injection in pre-filled syringe for intramuscular use

on the grounds that clinical studies cannot be expected to be of significant therapeutic benefit.

C. PAEDIATRIC INVESTIGATION PLAN

- **Condition to be investigated**

Infection by Human Papillomavirus

- **Proposed PIP indication**

Prevention of premalignant genital lesions (cervical, vulvar, vaginal, anal, perineal, perianal, penile), cervical, anal, perineal, and perianal cancer, and external genital warts (condyloma acuminata) causally related to Human Papillomavirus (HPV) types 6, 11, 16 and 18 in males.

- **Subset(s) of the paediatric population concerned by the paediatric development**

Boys from 16 to less than 18 years.

- **Formulation(s)**

Suspension for injection
Suspension for injection in pre-filled syringe

- **Studies**

Area	Number of studies	Description
Quality	0	Not applicable.
Non-clinical	0	Not applicable.
Clinical	1	Randomised, double-blind, placebo-controlled, multicentre trial to evaluate safety, immunogenicity and efficacy of Gardasil in male children from 16 to less than 18 years (and in adult subjects).

Measures to address long term follow-up of potential safety issues in relation to paediatric use:	No

Date of completion of the paediatric investigation plan:	By May 2010
Deferral for some or all studies contained in the paediatric investigation plan:	Yes

ANNEX II

INFORMATION ABOUT THE AUTHORISED MEDICINAL PRODUCT

EU Number	Invented name	Strength	Pharmaceutical Form	Route of Administration	Packaging	Content	Package size
EU/1/06/357/001	Gardasil	--[1]	Suspension for injection	Intramuscular use	vial (glass)	0.5 ml	1 vial
EU/1/06/357/002	Gardasil	--[1]	Suspension for injection	Intramuscular use	vial (glass)	0.5 ml	10 vials
EU/1/06/357/003	Gardasil	--[1]	Suspension for injection	Intramuscular use	pre-filled syringe (glass)	0.5 ml	1 pre-filled syringe
EU/1/06/357/004	Gardasil	--[1]	Suspension for injection	Intramuscular use	pre-filled syringe (glass)	0.5 ml	10 pre-filled syringes
EU/1/06/357/005	Gardasil	--[1]	Suspension for injection	Intramuscular use	pre-filled syringe (glass)	0.5 ml	1 pre-filled syringe + 1 needle
EU/1/06/357/006	Gardasil	--[1]	Suspension for injection	Intramuscular use	pre-filled syringe (glass)	0.5 ml	10 pre-filled syringes + 10 needles
EU/1/06/357/007	Gardasil	--[1]	Suspension for injection	Intramuscular use	pre-filled syringe (glass)	0.5 ml	1 pre-filled syringe + 2 needles
EU/1/06/357/008	Gardasil	--[1]	Suspension for injection	Intramuscular use	pre-filled syringe (glass)	0.5 ml	10 pre-filled syringes + 20 needles
EU/1/06/357/009	Gardasil	--[1]	Suspension for injection	Intramuscular use	pre-filled syringe (glass)	0.5 ml	1 pre-filled syringe with needle guard
EU/1/06/357/010	Gardasil	--[1]	Suspension for injection	Intramuscular use	pre-filled syringe (glass)	0.5 ml	10 pre-filled syringes with needle guard
EU/1/06/357/011	Gardasil	--[1]	Suspension for injection	Intramuscular use	pre-filled syringe (glass)	0.5 ml	20 pre-filled syringes with needle guard
EU/1/06/357/012	Gardasil	--[1]	Suspension for injection	Intramuscular use	pre-filled syringe (glass)	0.5 ml	1 pre-filled syringe with needle guard + 1 needle
EU/1/06/357/013	Gardasil	--[1]	Suspension for injection	Intramuscular use	pre-filled syringe (glass)	0.5 ml	10 pre-filled syringes with needle guard + 10 needles
EU/1/06/357/014	Gardasil	--[1]	Suspension for injection	Intramuscular use	pre-filled syringe (glass)	0.5 ml	20 pre-filled syringes with needle guard + 20 needles
EU/1/06/357/015	Gardasil	--[1]	Suspension for injection	Intramuscular use	pre-filled syringe (glass)	0.5 ml	1 pre-filled syringe with needle guard + 2 needles
EU/1/06/357/016	Gardasil	--[1]	Suspension for injection	Intramuscular use	pre-filled syringe (glass)	0.5 ml	10 pre-filled syringes with needle guard + 20 needles
EU/1/06/357/017	Gardasil	--[1]	Suspension for injection	Intramuscular use	pre-filled syringe (glass)	0.5 ml	20 pre-filled syringes with needle guard + 40 needles
EU/1/06/357/018	Gardasil	--[1]	Suspension for injection	Intramuscular use	vial (glass)	0.5 ml	20 vials

EU/1/06/357/019	Gardasil	--[1]	Suspension for injection	Intramuscular use	pre-filled syringe (glass)	0.5 ml	20 pre-filled syringes
EU/1/06/357/020	Gardasil	--[1]	Suspension for injection	Intramuscular use	pre-filled syringe (glass)	0.5 ml	20 pre-filled syringes + 20 needles
EU/1/06/357/021	Gardasil	--[1]	Suspension for injection	Intramuscular use	pre-filled syringe (glass)	0.5 ml	20 pre-filled syringe + 40 needles