EMA/456116/2013

European Medicines Agency decision

P/0196/2013

of 2 September 2013

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 / Human Papillomavirus Type 31 L1 protein / Human Papillomavirus Type 33 L1 protein / Human Papillomavirus Type 45 L1 protein / Human Papillomavirus Type 52 L1 protein / Human Papillomavirus Type 58 L1 protein (EMEA-000654-PIP01-09-M02) 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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European Medicines Agency decision

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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 726/2004[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 European Medicines Agency's decision P/103/2010 issued on 11 June 2010,

Having regard to the application submitted by Sanofi Pasteur MSD SNC on 29 April 2013 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 19 July 2013, 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.

(2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan.

[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 Human Papillomavirus Type 6 L1 protein / Human Papillomavirus Type 11 L1 protein / Human Papillomavirus Type 16 L1 protein / Human Papillomavirus Type 18 L1 protein / Human Papillomavirus Type 31 L1 protein / Human Papillomavirus Type 33 L1 protein / Human Papillomavirus Type 45 L1 protein / Human Papillomavirus Type 52 L1 protein / Human Papillomavirus Type 58 L1 protein, suspension for injection, suspension for injection in pre-filled syringe, intramuscular use, 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 Sanofi Pasteur MSD SNC, 8, rue Jonas Salk, 69367 - Lyon cedex 07, France.

Done at London, 2 September 2013

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

EMA/PDCO/276301/2013

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

EMEA-000654-PIP01-09-M02

Scope of the application

Active substance(s):

Human Papillomavirus Type 6 L1 protein / Human Papillomavirus Type 11 L1 protein / Human Papillomavirus Type 16 L1 protein / Human Papillomavirus Type 18 L1 protein / Human Papillomavirus Type 31 L1 protein / Human Papillomavirus Type 33 L1 protein / Human Papillomavirus Type 45 L1 protein / Human Papillomavirus Type 52 L1 protein / Human Papillomavirus Type 58 L1 protein

Condition(s):

Prevention of infection by human papillomavirus

Pharmaceutical form(s):

Suspension for injection

Suspension for injection in pre-filled syringe

Route(s) of administration:

Intramuscular use

Name/corporate name of the PIP applicant:

Sanofi Pasteur MSD SNC

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Sanofi Pasteur MSD SNC submitted to the European Medicines Agency on 29 April 2013 an application for modification of the agreed paediatric investigation plan with a waiver and a deferral as set out in the European Medicines Agency's decision P/103/2010 issued on 11 June 2010.

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

The procedure started on 22 May 2013.

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Scope of the modification

Some measures and timelines of the 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 in the scope set out in the Annex I of this opinion.

   The Norwegian Paediatric Committee member agrees 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, 19 July 2013

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 infection by human papillomavirus

Prevention of premalignant genital lesions (cervical, vulvar, and vaginal), cervical cancers and external genital warts (condyloma acuminate) causally related to Human Papillomavirus (HPV) types 6, 11, 16, 18, 31, 33, 45, 52, and 58.

The waiver applies to:

- Girls and boys from birth to less than 9 years of age;
- for suspension for injection and suspension for injection in pre-filled syringe, intramuscular use;
- on the grounds that clinical studies cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the paediatric population.

And to:

- Boys from 16 to less than 18 years of age;
- for suspension for injection and suspension for injection in pre-filled syringe, intramuscular use;
- on the grounds that the medicinal product cannot be expected to be of significant therapeutic benefit over existing treatments.

2. Paediatric Investigation Plan

2.1. Condition: prevention of infection by human papillomavirus

2.1.1. Indication(s) targeted by the PIP

Prevention of premalignant genital lesions (cervical, vulvar, and vaginal), cervical cancers and external genital warts (condyloma acuminate) causally related to Human Papillomavirus (HPV) types 6, 11, 16, 18, 31, 33, 45, 52, and 58.

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

Preadolescent and adolescent girls from 9 to less than 18 years of age.

Preadolescent and adolescent boys from 9 to less than 16 years of age.

2.1.3. Pharmaceutical form(s)

Suspension for injection and suspension for injection in pre-filled syringe, intramuscular use.

2.1.4. Measures

Area	Number of measures	Description
Quality	0	Not applicable.
Non-clinical	0	Not applicable.
Clinical	3	**Measure 1 (study V503-001):** Efficacy, immunogenicity, and safety study of the 9-valent HPV vaccine in adolescent girls and young women 16 to less than 27 years of age. **Measure 2 (V503-002):** Immunogenicity and safety study of the 9-valent HPV vaccine and to compare the immunogenicity of the 9-valent vaccine in boys and girls 9 to less than 16 years of age and in females 16 to less than 27 years of age. **Measure 3 (V503-xxx):** Immunogenicity study of the 9-valent HPV vaccine and Gardasil/Silgard in preadolescent and adolescent girls 9 to less than 16 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 December 2013
Deferral for one or more studies contained in the paediatric investigation plan:	Yes