

EMA/465427/2018

European Medicines Agency decision

P/0222/2018

of 17 July 2018

on the acceptance of a modification of an agreed paediatric investigation plan for recombinant varicella zoster virus (VZV) glycoprotein E (Shingrix), (EMA-001426-PIP01-13-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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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/0168/2013 issued on 29 July 2013 and the decision P/0228/2017 issued on 9 August 2017,

Having regard to the application submitted by GlaxoSmithKline Biologicals SA on 2 March 2018 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 1 June 2018, 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 recombinant varicella zoster virus (VZV) glycoprotein E (Shingrix), powder and suspension for suspension for injection, intramuscular 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 GlaxoSmithKline Biologicals SA, Rue de l'Institut 89, 1330 – Rixensart Belgium.



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/PDCO/170712/2018

London, 1 June 2018

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan EMA-001426-PIP01-13-M02

Scope of the application

Active substance(s):

Recombinant varicella zoster virus (VZV) glycoprotein E

Invented name:

Shingrix

Condition(s):

Prevention of varicella zoster virus (VZV) reactivation

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Powder and suspension for suspension for injection

Route(s) of administration:

Intramuscular use

Name / corporate name of the PIP applicant:

GlaxoSmithKline Biologicals SA

Information about the authorised medicinal product:

See Annex II



Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, GlaxoSmithKline Biologicals SA submitted to the European Medicines Agency on 12 March 2018 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/0168/2013 issued on 29 July 2013 and the decision P/0228/2017 issued on 9 August 2017.

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

The procedure started on 3 April 2018.

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 and to the deferral 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 annexes and appendix.

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 (PIP)

1. Waiver

1.1. Condition: prevention of varicella zoster virus reactivation

The waiver applies to:

- newborns and infants from birth to less than one year of age;
- powder and suspension for suspension for injection, intramuscular use;
- on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subset(s).

2. Paediatric Investigation Plan

2.1. Condition: prevention of varicella zoster virus reactivation

2.1.1. Indication(s) targeted by the PIP

Prevention of herpes zoster in immunocompromised subjects

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

From 1 to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Powder and suspension for suspension for injection

2.1.4. Measures

Area	Number of studies	Description
Quality-related studies	1	Study 3 Development of an AS01 _E -adjuvanted vaccine formulation
Non-clinical studies	0	Not applicable
Clinical studies	2	Study 1 Open-label, randomised study to assess the safety, reactogenicity and immunogenicity of the paediatric formulation of HZ/su for the prevention of zoster in immunocompromised children 1 to less than 18 years of age Study 2 Open-label, non-randomised clinical study to assess safety, immunogenicity and reactogenicity of the paediatric formulation of HZ/su for the

		prevention of zoster in immunocompromised children 1 to less than 18 years of age
Extrapolation, modelling and simulation studies	0	Not applicable
Other studies	0	Not applicable
Other measures	0	Not applicable

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety/efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By August 2030
Deferral for one or more studies contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Prevention of varicella zoster virus (VZV) reactivation

Authorised indication(s):

- Shingrix is indicated for prevention of herpes zoster (HZ) and post-herpetic neuralgia (PHN), in adults 50 years of age or older (see section 5.1).

The use of Shingrix should be in accordance with official recommendations.

Authorised pharmaceutical form(s):

Powder and suspension for suspension for injection

Authorised route(s) of administration:

Intramuscular use