EMA/413604/2024

European Medicines Agency decision

P/0328/2024

of 13 September 2024

on the acceptance of a modification of an agreed paediatric investigation plan for recombinant varicella zoster virus (VZV) glycoprotein E (Shingrix), (EMEA-001426-PIP01-13-M03) 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 726/2004[1],

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency[2],

Having regard to the European Medicines Agency's decision P/0168/2013 issued on 29 July 2013, the decision P/0228/2017 issued on 9 August 2017 and the decision P/0222/2018 issued on 17 July 2018,

Having regard to the application submitted by GlaxoSmithKline Biologicals SA on 24 April 2024 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 26 July 2024, 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, as amended.
[2] OJ L 136, 30.4.2004, p. 1, as amended.

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, 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, 89 Rue De L'institut, 1330 - Rixensart Belgium.

EMA/PDCO/223502/2024
Amsterdam, 26 July 2024

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

EMEA-001426-PIP01-13-M03

Scope of the application

Active substance(s):

Recombinant varicella zoster virus (VZV) glycoprotein E

Invented name and authorisation status:

See Annex II

Condition(s):

Prevention of varicella zoster virus (VZV) reactivation

Pharmaceutical form(s):

Powder and suspension for suspension for injection

Suspension for injection

Route(s) of administration:

Intramuscular use

Name/corporate name of the PIP applicant:

GlaxoSmithKline Biologicals SA

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 24 April 2024 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, the decision P/0228/2017 issued on 9 August 2017 and the decision P/0222/2018 issued on 17 July 2018.

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

The procedure started on 27 May 2024.

Scope of the modification

Some measures and timelines of the Paediatric Investigation Plan have been modified.

A new pharmaceutical form was added.

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 Paediatric Committee member of Norway 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, 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 year to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Powder and suspension for suspension for injection

Suspension for injection

2.1.4. Measures

Area	Description
Quality-related studies	**Study 3** Development of an $AS01_E$-adjuvanted vaccine formulation
Non-clinical studies	Not applicable
Clinical studies	**Study 1** Open-label, randomised study to assess the safety, reactogenicity and immunogenicity of the paediatric formulation of Herpes Zoster candidate vaccine (HZ/su) for the prevention of zoster in immunocompromised children 1 year 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 year to less than 18 years of age

Extrapolation, modelling and simulation studies	Not applicable
Other studies	Not applicable
Other measures	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 September 2032
Deferral for one or more studies contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Information provided by the applicant:

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;
- adults 18 years of age or older at increased risk of HZ.

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

  - Invented name(s): Shingrix
  - Authorised pharmaceutical form(s): Powder and suspension for suspension for injection
  - Authorised route(s) of administration: Intramuscular use
  - Authorised via centralised procedure.