MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

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Decision Cover Letter

Decision of the licensing authority to:

accept change(s) to the agreed paediatric investigation plan (EMEA-001426-PIP01-13-M02) and to the deferral

MHRA-101583-PIP01-24-M01

Scope of the Application

Active Substance(s)

Recombinant Varicella Zoster Virus Glycoprotein E

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 UK Limited

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, GlaxoSmithKline UK Limited submitted to the licensing authority on 20/08/2024 13:10 BST an application for a Modification

The procedure started on 25/10/2024 09:07 BST

1. The licensing authority, having assessed the application in accordance with the Human Medicines Regulations 2012, decides, as set out in the appended summary report:

to accept change(s) to the agreed paediatric investigation plan and to the deferral

2. The measures and timelines of the paediatric investigation plan are set out in the Annex I.

This decision is forwarded to the applicant, together with its annex and appendix.

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Final Decision Letter

MHRA-101583-PIP01-24-M01

Of 21/11/2024 16:24 GMT

On the adopted decision for Recombinant Varicella Zoster Virus Glycoprotein E (MHRA-101583-PIP01-24-M01) in accordance with the Human Medicines Regulations 2012.

The licensing authority, in accordance with the Human Medicines Regulations 2012, has adopted this decision:

Agreement on modification of a paediatric investigation plan (including modification of a waiver or deferral included in that paediatric investigation plan)

This decision applies to a Modification for Recombinant Varicella Zoster Virus Glycoprotein E, Powder and suspension for suspension for injection; Suspension for injection , INTRAMUSCULAR USE .

This decision is addressed to GlaxoSmithKline UK Limited, 980 Great West Road, Brentford, UNITED KINGDOM, TW8 9GS

ANNEX I

1. Waiver

1.1 Condition:

Prevention of varicella zoster virus (VZV) reactivation The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 1 year of age Pharmaceutical form(s): Powder and suspension for suspension for injection Suspension for injection Route(s) of administration: INTRAMUSCULAR USE Reason for granting waiver: 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(s):

Prevention of varicella zoster virus (VZV) reactivation

2.2 Indication(s) targeted by the PIP:

Prevention of herpes zoster in immunocompromised subjects

2.3 Subset(s) of the paediatric population concerned by the paediatric development:

The paediatric population from 1 year to less than 18 years of age

2.4 Pharmaceutical Form(s):

Powder and suspension for suspension for injection Suspension for injection

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	1	Study 3 Development of an AS01E-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 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, Modeling & Simulation Studies	0	Not applicable.
Other Studies	0	Not applicable.
Other Measures	0	Not applicable.

3. Follow-up, completion and deferral of a PIP:

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	30/09/2032
Deferral of one or more studies contained in the paediatric investigation plan:	Yes