

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

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## **Decision Cover Letter**

### **Decision of the licensing authority to:**

grant a product specific waiver

MHRA-101277-PIP01-23

### **Scope of the Application**

#### **Active Substance(s)**

LIVE ATTENUATED MEASLES VIRUS (SCHWARZ STRAIN); LIVE ATTEN'D MUMPS VIRUS (RIT 4385 DERIVED FROM JERYL LYNN); LIVE ATTENUATED RUBELLA (WISTAR RA 27/3 STRAIN); Varicella virus OKA strain (live, attenuated)

#### **Condition(s)**

Prevention of measles, mumps, rubella and varicella

#### **Pharmaceutical Form(s)**

Powder and solvent for solution for injection

#### **Route(s) of Administration**

PARENTERAL 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 06/12/2023 16:15 GMT an application for a Waiver

The procedure started on 12/02/2024 07:44 GMT

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 grant a product specific waiver

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-101277-PIP01-23

Of 22/03/2024 16:48 GMT

On the adopted decision for LIVE ATTENUATED MEASLES VIRUS (SCHWARZ STRAIN); LIVE ATTEN'D MUMPS VIRUS (RIT 4385 DERIVED FROM JERYL LYNN); LIVE ATTENUATED RUBELLA (WISTAR RA 27/3 STRAIN); Varicella virus Oka strain (live, attenuated) (MHRA-101277-PIP01-23) in accordance with the Human Medicines Regulations 2012.

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

Granting a waiver in all age groups for the listed condition(s)

This decision applies to a Waiver for LIVE ATTENUATED MEASLES VIRUS (SCHWARZ STRAIN); LIVE ATTEN'D MUMPS VIRUS (RIT 4385 DERIVED FROM JERYL LYNN); LIVE ATTENUATED RUBELLA (WISTAR RA 27/3 STRAIN); Varicella virus Oka strain (live, attenuated), Powder and solvent for solution for injection , PARENTERAL 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 measles, mumps, rubella and varicella The waiver applies / applied to: Paediatric Subset(s): All subsets of the paediatric population from birth to less than 18 years of age  
Pharmaceutical form(s): Powder and solvent for solution for injection Route(s) of administration: PARENTERAL USE Reason for granting waiver: on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as the needs are already covered

### 2. Paediatric Investigation Plan:

#### 2.1 Condition(s):

Not Applicable

**2.2 Indication(s) targeted by the PIP:**

Not Applicable

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

Not Applicable

**2.4 Pharmaceutical Form(s):**

Not Applicable

**2.5 Studies:**

<b>Study Type</b>	<b>Number of Studies</b>	<b>Study Description</b>
<b>Quality Measures</b>		
<b>Non-Clinical Studies</b>		
<b>Clinical Studies</b>		
<b>Extrapolation, Modeling &amp; Simulation Studies</b>		
<b>Other Studies</b>		
<b>Other Measures</b>		

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

<b>Concerns on potential long term safety and efficacy issues in relation to paediatric use:</b>	
<b>Date of completion of the paediatric investigation plan:</b>	
<b>Deferral of one or more studies contained in the paediatric investigation plan:</b>	

