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

**gov.uk/mhra**

# Decision Cover Letter

## Decision of the licensing authority to:

agree a paediatric investigation plan and grant a waiver

MHRA-101641-PIP01-24

# Scope of the Application

## Active Substance(s)

Japanese encephalitis virus, strain SA14-14-2, Live

## Condition(s)

Prevention of Japanese encephalitis

## Pharmaceutical Form(s)

Powder and solvent for suspension for injection

## Route(s) of Administration

SUBCUTANEOUS USE

## Name / Corporate name of the PIP applicant

SUBSTIPHARM BIOLOGICS

## Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, SUBSTIPHARM BIOLOGICS submitted to the licensing authority on 21/11/2024 15:10 GMT an application for a Paediatric Investigation Plan

The procedure started on 02/12/2024 07:41 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 agree a paediatric investigation plan and grant a 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-101641-PIP01-24

Of 25/07/2025 14:33 BST

On the adopted decision for Japanese encephalitis virus, strain SA14-14-2, Live (MHRA-101641-PIP01-24) 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 a paediatric investigation plan

This decision applies to a Paediatric Investigation Plan for Japanese encephalitis virus, strain SA14-14-2, Live , Powder and solvent for suspension for injection , SUBCUTANEOUS USE .

This decision is addressed to SUBSTIPHARM BIOLOGICS, 4 esplanade de Pont Rouge, GRAND LANCY, SWITZERLAND, 1212

## ANNEX I

### 1. Waiver

### 1.1 Condition:

| |
|---|
| Prevention of Japanese encephalitis The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 9 months of age Pharmaceutical form(s): Powder and solvent for suspension for injection Route(s) of administration: SUBCUTANEOUS USE Reason for granting waiver: on the grounds that the specific medicinal product is likely to be unsafe. |

### 2. Paediatric Investigation Plan:

### 2.1 Condition(s):

| |
|---|
| Prevention of Japanese encephalitis |

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

Active immunisation against Japanese encephalitis in children from 9 months to less than 18 years of age

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

The paediatric population from 9 months to less than 18 years of age

### 2.4 Pharmaceutical Form(s):

Powder and solvent for suspension for injection

### 2.5 Studies:

| Study Type | Number of Studies | Study Description |
|---|---|---|
| **Quality Measures** | 0 | Not applicable. |
| **Non-Clinical Studies** | 0 | Not applicable. |
| **Clinical Studies** | 6 | Study 1 (JEC01) Randomised, open label, active controlled, cross-over study to evaluate the safety and immunogenicity of Japanese encephalitis vaccine in children from 12 month to less than 5 years of age. Study 2 (JEC02) Randomised, observer-blind, active-controlled trial to evaluate safety, immunogenicity and lot-to-lot consistency of three consecutive lots of Japanese encephalitis vaccine (JE-CV) in children from 12 months to less than 18 month of age. Study 3 (JEC04) Open label, randomised, trial to evaluate the immunogenicity and safety of Japanese encephalitis chimeric virus vaccine (JE-CV) administered with measles, mumps, and rubella (MMR) vaccine in children from 12 months to less than 18 months of age. Study 4 (JEC05) Long term follow up study to evaluate the persistence of immunity in children who received their JE-CV primary vaccination at 12 to less than 18 months of age in Study JEC02 (PIP Study 2). Study 5 (JEC07) Randomised, observer-blind trial to evaluate the immunogenicity and safety of a single dose of Japanese encephalitis |

| | | |
|---|---|---|
| | | (JE) chimeric virus vaccine (JE-CV) compared with a single dose of Japanese encephalitis live vaccine (SA14-14-2) in children from 9 months to less than 18 months of age. Study 6 (JEC12) Randomised, observer-blinded, trial to evaluate the immunogenicity and safety of a single dose of a Live attenuated Japanese encephalitis chimeric virus vaccine in comparison with a single dose of Japanese encephalitis live attenuated vaccine (SA14 14 2 vaccine) in healthy children from 12 months to less than 24 months of age. |
| **Extrapolation, Modeling & Simulation Studies** | 0 | Not applicable. |
| **Other Studies** | 2 | Study 7 (JEC13) Open-label, single-arm trial to evaluate the immunogenicity and safety of a single primary dose of live attenuated Japanese encephalitis chimeric virus vaccine in children from 9 months to less than 18 years of age (and adults). Study 8 (JEC15) Open-label, controlled, multicentre trial to evaluate the duration of immune response and safety of Japanese encephalitis chimeric virus vaccine (JE-CV) in children from 36 months to 42 months of age, previously immunised with a single dose of JE-CV. |
| **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:** | 31/10/2015 |
| **Deferral of one or more studies contained in the paediatric investigation plan:** | No |