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 (MHRA-101407-PIP01-24) and to the deferral

MHRA-101407-PIP01-24-M01

Scope of the Application

Active Substance(s)

chikungunya virus virus-like particle

Condition(s)

Prevention of chikungunya virus disease

Pharmaceutical Form(s)

Suspension for injection

Route(s) of Administration

INTRAMUSCULAR USE

Name / Corporate name of the PIP applicant

Bavarian Nordic A/S

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Bavarian Nordic A/S submitted to the licensing authority on 02/12/2024 13:27 GMT an application for a Modification

The procedure started on 13/01/2025 14:22 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 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-101407-PIP01-24-M01

Of 30/04/2025 08:37 BST

On the adopted decision for chikungunya virus virus-like particle (MHRA-101407-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 chikungunya virus virus-like particle, Suspension for injection , INTRAMUSCULAR USE .

This decision is addressed to Bavarian Nordic A/S, Philip Heymans Alle 3, Hellerup, DENMARK, 2900

ANNEX I

1. Waiver

1.1 Condition:

Not applicable

2. Paediatric Investigation Plan:

2.1 Condition(s):

Prevention of chikungunya virus disease

2.2 Indication(s) targeted by the PIP:

Prevention of chikungunya virus disease

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

All subsets of the paediatric population from birth to less than 18 years of age

2.4 Pharmaceutical Form(s):

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	5	Study 1 (EBSI-CV-317-004) Randomised, placebo-controlled, double-blind safety and immunogenicity study of Chikungunya Virus Virus-Like Particle Vaccine/ aluminium hydroxide (CHIKV VLP) in adolescents from 12 years to less than 18 years of age (and adults). Study 2 (EBSI-CV-317-006) Randomised, double-blind, controlled, safety and immunologic superiority study of CHIKV VLP vaccine in children from 2 years to less than 12 years of age. Study 3 (EBSI-CV-317-009) Randomised, double blind, controlled, safety and immunogenicity study of CHIKV VLP vaccine in children from birth to less than 2 years of age. Study 4 (EBSI-CV-317-008) Randomised, double-blind, long-term immunogenicity study in adolescents from 12 years to less than 18 years of age (and adults) who were previously administered CHIKV VLP vaccine in study EBSI-CV-317-004 (PIP Study 1). Study 5 (EBSI-CV-317-007) Double blind, randomised, placebo-controlled, event-driven efficacy study to evaluate the efficacy, safety, and immunogenicity of an Adjuvanted Chikungunya Virus Virus-like Particle Vaccine (CHIKV

		VLP) vaccine for the prevention of Chikungunya Disease in adolescents from 12 years to less than 18 years of age (and adults). Vaccination will be performed only during a Chikungunya virus (CHIKV) outbreak.
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:	30/06/2032
Deferral of one or more studies contained in the paediatric investigation plan:	Yes