MHRA
10 South Colonnade
Canary Wharf
London
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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-100149-PIP01-21-M01)

MHRA-100149-PIP01-21-M02

Scope of the Application

Active Substance(s)

NVX-COV2373

Condition(s)

Prevention of Coronavirus Disease 2019 (COVID-19)

Pharmaceutical Form(s)

Dispersion for injection

Route(s) of Administration

INTRAMUSCULAR USE

Name / Corporate name of the PIP applicant

Novavax CZ, a.s.

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Novavax CZ, a.s. submitted to the licensing authority on 24/02/2023 12:41 GMT an application for a Modification

The procedure started on 05/04/2023 15:21 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

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-100149-PIP01-21-M02

Of 21/07/2023 09:43 BST

On the adopted decision for NVX-COV2373 (MHRA-100149-PIP01-21-M02) 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 NVX-COV2373, Dispersion for injection , INTRAMUSCULAR USE .

This decision is addressed to Novavax CZ, a.s., Bohumil 138, Jevany, CZECH REPUBLIC, 281 63

ANNEX I

1. Waiver

1.1 Condition:

Not applicable

2. Paediatric Investigation Plan:

2.1 Condition(s):

Prevention of Coronavirus Disease 2019 (COVID-19)

2.2 Indication(s) targeted by the PIP:

Prevention of Coronavirus Disease 2019 (COVID-19)

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

The paediatric population from birth to less than 18 years of age

2.4 Pharmaceutical Form(s):

Dispersion 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	4	Study 1 (2019nCoV-301 – Part 2, Paediatric Expansion) Randomised, observer-blinded, placebo-controlled study to evaluate efficacy, safety and immunogenicity of a SARS-CoV-2 rS / Matrix-M1 adjuvant in paediatric participants from 12 years to less than 18 years of age (and adults). Study 2 (2019nCoV-503) Randomised, observer-blinded, placebo-controlled study to evaluate the safety and immunogenicity of SARS-CoV-2 rS / Matrix-M1 adjuvant in paediatric participants from 6 months to less than 12 years of age. Study 3 (2019nCoV-504) Randomised, observer-blinded, controlled study to evaluate the safety and immunogenicity of a SARS-CoV-2 Recombinant Spike Protein Nanoparticle Vaccine (SARS-CoV-2 rS) with Matrix-M1 Adjuvant in immunocompromised paediatric participants from birth to less than 18 years of age. Study 4 (2019nCOV-506) Study added during procedure MHRA-100149-PIP01-21-M01 Randomised, observer-blinded, placebo-controlled study to evaluate the safety and immunogenicity of SARS-CoV-2 rS / Matrix-M1 adjuvant in paediatric participants from birth to less than 6 months 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:	31/12/2026
Deferral of one or more studies contained in the paediatric investigation plan:	Yes