EMA/296650/2024

# European Medicines Agency decision

P/0255/2024

of 19 July 2024

on the acceptance of a modification of an agreed paediatric investigation plan for severe acute respiratory syndrome coronavirus 2 recombinant spike protein nanoparticle vaccine/ matrix-M1 adjuvant (Nuvaxovid), (EMEA-002941-PIP01-20-M05) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

**Disclaimer**

This decision does not constitute entitlement to the rewards and incentives referred to in Title V of Regulation (EC) No 1901/2006.

**Only the English text is authentic.**

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The European Medicines Agency,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No. 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004[1],

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency[2],

Having regard to the European Medicines Agency's decision P/0126/2021 issued on 15 March 2021, the decision P/0483/2021 issued on 3 December 2021, the decision P/0250/2022 issued on 8 July 2022 and the decision P/0423/2023 issued on 27 October 2023,

Having regard to the application submitted by Novavax CZ, a.s. on 22 February 2024 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 31 May 2024, in accordance with Article 22 of Regulation (EC) No 1901/2006,

Having regard to Article 25 of Regulation (EC) No 1901/2006,

Whereas:

(1) The Paediatric Committee of the European Medicines Agency has given an opinion on the acceptance of changes to the agreed paediatric investigation plan.

(2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan.

[1] OJ L 378, 27.12.2006, p.1, as amended.
[2] OJ L 136, 30.4.2004, p. 1, as amended.

Has adopted this decision:

***Article 1***

Changes to the agreed paediatric investigation plan for severe acute respiratory syndrome coronavirus 2 recombinant spike protein nanoparticle vaccine/ matrix-M1 adjuvant (Nuvaxovid), suspension for injection, intramuscular use, are hereby accepted in the scope set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices.

***Article 2***

This decision is addressed to Novavax CZ, a.s., 138 Bohumil, 281 63 – Jevany, Czech Republic.

EMA/PDCO/91743/2024
Amsterdam, 31 May 2024

# Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan

EMEA-002941-PIP01-20-M05

## Scope of the application

**Active substance(s):**

Severe acute respiratory syndrome coronavirus 2 recombinant spike protein nanoparticle vaccine/ matrix-M1 adjuvant

**Invented name and authorisation status:**

See Annex II

**Condition(s):**

Prevention of coronavirus disease 2019 (COVID-19)

**Pharmaceutical form(s):**

Suspension for injection

**Route(s) of administration:**

Intramuscular use

**Name/corporate name of the PIP applicant:**

Novavax CZ, a.s.

## Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Novavax CZ, a.s. submitted to the European Medicines Agency on 22 February 2024 an application for modification of the agreed paediatric investigation plan with a deferral as set out in the European Medicines Agency's decision P/0126/2021 issued on 15 March 2021, the decision P/0483/2021 issued on 3 December 2021, the decision P/0250/2022 issued on 8 July 2022 and the decision P/0423/2023 issued on 27 October 2023.

The application for modification proposed changes to the agreed paediatric investigation plan.

The procedure started on 2 April 2024.

## Scope of the modification

Some measures of the Paediatric Investigation Plan have been modified.

## Opinion

1. The Paediatric Committee, having assessed the application in accordance with Article 22 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:
    - to agree to changes to the paediatric investigation plan in the scope set out in the Annex I of this opinion.
2. The measures and timelines of the paediatric investigation plan are set out in the Annex I.

This opinion is forwarded to the applicant and the Executive Director of the European Medicines Agency, together with its annexes and appendix.

# Annex I

# The subset(s) of the paediatric population and condition(s) covered by the waiver and the measures and timelines of the agreed paediatric investigation plan (PIP)

# 1. Waiver

Not applicable

# 2. Paediatric investigation plan

## *2.1. Condition:*

Prevention of coronavirus disease 2019 (COVID-19)

### 2.1.1. Indication(s) targeted by the PIP

Prevention of coronavirus disease 2019 (COVID-19)

### 2.1.2. Subset(s) of the paediatric population concerned by the paediatric development

From birth to less than 18 years of age

### 2.1.3. Pharmaceutical form(s)

Suspension for injection

### 2.1.4. Measures

| Area | Description |
|---|---|
| Quality-related studies | Not applicable |
| Non-clinical studies | Not applicable |
| Clinical studies | **Study 1**<br>*This study was deleted with procedure EMEA-002941-PIP01-20-M01*<br>**Study 2 (2019nCoV-301)**<br>Randomised, observer-blinded, controlled study to evaluate efficacy, safety and immunogenicity of severe acute respiratory syndrome coronavirus 2 recombinant spike protein nanoparticle vaccine (SARS-CoV-2 rS) / matrix-M1 adjuvant in paediatric participants from 6 years to less than 18 years of age (and adults)<br>Paediatric participants will be enrolled in Part 2 (Paediatric expansion) of the study (safety and immunogenicity only)<br>**Study 3 (2019nCoV-503)**<br>Randomised, observer-blinded, placebo-controlled study to evaluate the safety and immunogenicity of severe acute respiratory syndrome coronavirus 2 recombinant spike protein nanoparticle vaccine (SARS-CoV-2 rS) / matrix-M1 adjuvant in paediatric participants from 6 months to less than 12 years of age. |

| | |
|---|---|
| | **Study 4 (2019nCoV-504)**<br><br>Randomised, observer-blinded, controlled study to evaluate the safety and immunogenicity of severe acute respiratory syndrome coronavirus 2 recombinant spike protein nanoparticle vaccine (SARS-CoV-2 rS) / matrix-M1 adjuvant in immunocompromised paediatric participants from birth to less than 18 years of age.<br><br>**Study 5 (2019nCoV-506)**<br><br>*This study was added during procedure EMEA-002941-PIP01-20-M02.*<br><br>Randomized, 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 born to unvaccinated mothers. |
| Extrapolation, modelling and simulation studies | Not applicable |
| Other studies | Not applicable |
| Other measures | Not applicable |

# 3. Follow-up, completion and deferral of PIP

| | |
|---|---|
| Concerns on potential long term safety/efficacy issues in relation to paediatric use: | No |
| Date of completion of the paediatric investigation plan: | By December 2026 |
| Deferral for one or more measures contained in the paediatric investigation plan: | Yes |

# Annex II

# Information about the authorised medicinal product

## *Information provided by the applicant:*

## Condition(s) and authorised indication(s)

1. Prevention of coronavirus disease 2019 (COVID-19)

Authorised indication(s):

- Active immunisation to prevent COVID-19 caused by SARS-CoV-2 individuals 12 years of age and older.
  - Invented name(s): Nuvaxovid
  - Authorised pharmaceutical form(s): Dispersion for injection (injection)
  - Authorised route(s) of administration: Intramuscular route
  - Authorised via centralised procedure.