EMA/152609/2021

European Medicines Agency decision
P/0126/2021

of 15 March 2021


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.
European Medicines Agency decision
P/0126/2021

of 15 March 2021


The European Medicines Agency,

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


Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency2,

Having regard to the application submitted by Novavax, Inc. on 11 December 2021 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said regulation and a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 26 February 2021, in accordance with Article 17 of Regulation (EC) No 1901/2006 and Article 21 of said Regulation,

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 agreement of a paediatric investigation plan and on the granting of a deferral.

(2) It is therefore appropriate to adopt a decision agreeing a paediatric investigation plan.

(3) It is therefore appropriate to adopt a decision granting a deferral.

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Has adopted this decision:

**Article 1**

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

**Article 2**

A deferral for severe acute respiratory syndrome coronavirus 2 recombinant spike protein nanoparticle vaccine (SARS-CoV-2 rS) / matrix-M1 adjuvant, suspension for injection, intramuscular use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

**Article 3**

This decision is addressed to Novavax, Inc., 21 Firstfield Road, 20878 -Gaithersburg, USA.
Opinion of the Paediatric Committee on the agreement of a Paediatric Investigation Plan and a deferral
EMEA-002941-PIP01-20

Scope of the application

Active substance(s):  
Severe acute respiratory syndrome coronavirus 2 recombinant spike protein nanoparticle vaccine (SARS-CoV-2 rS) / matrix-M1 adjuvant

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, Inc.

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Novavax, Inc. submitted for agreement to the European Medicines Agency on 11 December 2020 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation.

The procedure started on 4 January 2021.

Supplementary information was provided by the applicant on the 11 February 2021. The applicant proposed modifications to the paediatric investigation plan and withdrew its request for a waiver.
Opinion

1. The Paediatric Committee, having assessed the proposed paediatric investigation plan in accordance with Article 17 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

   • to agree the paediatric investigation plan in accordance with Article 17(1) of said Regulation;
   • to grant a deferral in accordance with Article 21 of said Regulation.

   The Norwegian Paediatric Committee member agrees with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the agreed 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 annex 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

<table>
<thead>
<tr>
<th>Area</th>
<th>Number of measures</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quality-related studies</td>
<td>0</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Non-clinical studies</td>
<td>0</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>
| Clinical studies      | 4                   | **Study 1 (2019nCoV-502)**

Randomised, observer-blinded, active-controlled study to evaluate safety and immunogenicity of a severe acute respiratory syndrome coronavirus 2 recombinant spike protein nanoparticle vaccine (SARS-CoV-2 rS) / matrix-M1 adjuvant in adolescents from 12 to less than 18 years of age (and adults)

**Study 2 (2019nCoV-301)**

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 to less than 18 years of age (and adults)

Paediatric participants will be enrolled in Part 2 (Paediatric expansion) of the study (safety and immunogenicity only)

**Study 3 (2019nCoV-503)**
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 paediatric participants from birth to less than 6 years of age

**Study 4 (2019nCoV-504)**

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

| Extrapolation, modelling and simulation studies | 0 | Not applicable |
| Other studies | 0 | Not applicable |
| Other measures | 0 | 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 March 2025 |
| Deferral for one or more measures contained in the paediatric investigation plan: | Yes |