EMADOC-1700519818-1993726

European Medicines Agency decision

EMA/PE/0000228531

of 20 March 2025

on the acceptance of a modification of an agreed paediatric investigation plan for davesomeran, elasomeran, imelasomeran, andusomeran, SARS-CoV-2 JN.1 mRNA (Spikevax bivalent Original/Omicron BA.1, Spikevax bivalent Original/Omicron BA.4-5, Spikevax) 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/0481/2020 issued on 30 November 2020, the decision P/0444/2021 issued on 22 November 2021, the decision P/0256/2022 issued on 30 June 2022, the decision P/0152/2023 issued on 24 April 2023 and the decision P/0373/2023 issued on 8 September 2023,

Having regard to the application submitted by Moderna Biotech Spain S.L. on 07 November 2024 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral and a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 28 February 2025, 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 davesomeran, elasomeran, imelasomeran, andusomeran, SARS-CoV-2 JN.1 mRNA (Spikevax bivalent Original/Omicron BA.1, Spikevax bivalent Original/Omicron BA.4-5, Spikevax), 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 Moderna Biotech Spain S.L., Calle Julian Camarillo No 31, 28037 – Madrid, Spain.

EMADOC-1700519818-1809486
Amsterdam, 28 February 2025

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

EMA/PE/0000228531

Scope of the application

Active substance(s):

Elasomeran

Elasomeran / imelasomeran

Elasomeran / davesomeran

Andusomeran

SARS-CoV-2 JN.1 mRNA

Invented name and authorisation status:

See Annex II

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:

Moderna Biotech Spain S.L.

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Moderna Biotech Spain S.L. submitted to the European Medicines Agency on 7 November 2024 an application for modification of the agreed paediatric investigation plan with a deferral and a waiver as set out in the European Medicines Agency's decision P/0481/2020 issued on 30 November 2020, the decision P/0444/2021

issued on 22 November 2021, the decision P/0256/2022 issued on 30 June 2022, the decision P/0152/2023 issued on 24 April 2023 and the decision P/0373/2023 issued on 8 September 2023.

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

The procedure started on 2 January 2025.

Scope of the modification

Some measures and timelines 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;

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

2. The measures and timelines of the paediatric investigation plan and the subset(s) of the paediatric population and condition(s) covered by the waiver 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

1.1. Condition:

Prevention of Coronavirus disease 2019 (COVID-19)

The waiver applies to:

- the paediatric population from birth to less than 12 weeks of age;
- dispersion for injection; intramuscular route;
- on the grounds that the specific medicinal product is likely to be ineffective.

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 12 weeks to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Dispersion for injection

2.1.4. Measures

Area	Description
Quality-related studies	Not applicable
Non-clinical studies	Not applicable
Clinical studies	**Study 1 (P203)** Randomised, observer-blind, placebo-controlled, study to evaluate safety, reactogenicity, and immunogenicity of elasomeran as primary series and of elasomeran and elasomeral/imelasomeran as booster in adolescents from 12 to less than 18 years of age for prevention of COVID-19. **Study 2 (P204)** Randomized, observer-blind, placebo-controlled study to evaluate dose finding (part 1), and safety, reactogenicity, and immunogenicity (part 2) of

	elasomeran in children from 6 months to less than 12 years of age, and of elasomeran or elasomeran/imelasomeran as booster. **Study 3** *This study was removed with procedure EMA/PE/0000228531* **Study 4 (P206)** Added during procedure EMEA-002893-PIP01-20-M02 Randomised, observer-blind, placebo-controlled, study to evaluate the safety, reactogenicity, and immunogenicity of 2 dose levels of elasomeran/imelasomeran administered as 2 doses 6-8 weeks apart in infants from 12 weeks to 6 months of age for prevention of COVID-19.
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 March 2025
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 COVID-19

Authorised indication(s):

- Spikevax is indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2 in individuals 6 months of age and older
  - Invented name(s): Spikevax
  - Authorised pharmaceutical form(s): Dispersion for injection
  - Authorised route(s) of administration: Intramuscular use
  - Authorised via centralised procedure