EMADOC-1700519818-1834650

European Medicines Agency decision

EMA/PE/0000221583

of 8 January 2025

on the acceptance of a modification of an agreed paediatric investigation plan for famtozinameran, riltozinameran, tozinameran (Comirnaty) 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/0480/2020 issued on 27 November 2020, the decision P/0179/2021 issued on 23 April 2021, the decision P/0396/2021 issued on 25 August 2021, the decision P/0547/2021 issued on 31 December 2021, the decision P/0378/2022 issued on 9 September 2022, the decision P/0466/2022 issued on 7 November 2022, the decision P/0393/2023 issued on 28 September 2023 and the decision P/0105/2024 issued on 12 April 2024,

Having regard to the application submitted by BioNTech Manufacturing GmbH on 4 September 2024 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral and proposing a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 13 December 2024, in accordance with Article 22 of Regulation (EC) No 1901/2006 and Article 13 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 acceptance of changes to the agreed paediatric investigation plan and to the deferral and on the granting of a waiver.

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

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

[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 famtozinameran, riltozinameran, tozinameran (Comirnaty), including changes to the deferral, 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

A waiver for famtozinameran, riltozinameran, tozinameran (Comirnaty), the details of which are set out in the opinion of the Paediatric Committee the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 3

This decision is addressed to BioNTech Manufacturing GmbH, 12 An Der Goldgrube, 55131 – Mainz, Rhineland-Palatinate, Germany.

EMADOC-1700519818-1703227
Amsterdam, 13 December 2024

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

EMA/PE/0000221583

Scope of the application

Active substance(s):

Famtozinameran / riltozinameran / tozinameran

Invented name and authorisation status:

See Annex II

Condition(s):

Prevention of coronavirus disease 2019 (COVID-19)

Pharmaceutical form(s):

Concentrate for dispersion for injection

Dispersion for injection

Route(s) of administration:

Intramuscular use

Name/corporate name of the PIP applicant:

BioNTech Manufacturing GmbH

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, BioNTech Manufacturing GmbH submitted to the European Medicines Agency on 4 September 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/0480/2020 issued on 27 November 2020, the decision P/0179/2021 issued on 23 April 2021, the decision P/0396/2021 issued on 25 August 2021, the decision P/0547/2021 issued on 31 December 2021, the decision P/0378/2022 issued on 9 September 2022, the decision P/0466/2022 issued on 7 November 2022, the decision P/0393/2023 issued on 28 September 2023 and the decision P/0105/2024 issued on 12 April 2024.

The application for modification proposed changes to the agreed paediatric investigation plan and to the deferral and proposed a waiver.

The procedure started on 14 October 2024.

Scope of the modification

Some measures and timelines of the Paediatric Investigation Plan have been modified. A waiver for a new paediatric subset has been added.

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 and to the deferral in the scope set out in the Annex I of this opinion;
   - to grant a waiver for one or more subsets of the paediatric population concluded in accordance with Article 11(1)(c) of Regulation (EC) No 1901/2006 as amended, on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients.

   The Paediatric Committee members of Liechtenstein and Norway agree 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 request for the waiver applied to:

- the paediatric population from birth to less than 6 weeks of age;
- concentrate for dispersion for injection, dispersion for injection; intramuscular use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

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 6 weeks to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Concentrate for dispersion for injection

Dispersion for injection

2.1.4. Measures

Area	Description
Quality-related studies	Not applicable
Non-clinical studies	Not applicable
Clinical studies	**Study 1 (C4591001)** Double blind, dose-finding study of safety, tolerability and immunogenicity of 2 different SARS-CoV-2 vaccine candidates (adults only) (part 1) and placebo-controlled efficacy, safety and immunogenicity study of highly purified single-stranded, 5'-capped mRNA encoding full-length SARS-CoV-2 spike protein (BNT162b2) in adolescents from 12 years to less than 18 years of age (and adults) (part 2) for prevention of COVID-19

	Study 2 (C4591007) Open-label, observer-blind, dose-finding safety, tolerability and immunogenicity study of tozinameran in paediatric subjects from 6 months to less than 16 years of age for prevention of COVID-19 **Study 3 (C4591067)** Open label, controlled, dose-finding, safety and immunogenicity study of tozinameran in children from 6 weeks to less than 6 months of age for prevention of COVID-19 **Study 4 (C4591024)** Open label, uncontrolled, safety and immunogenicity study of tozinameran in immunocompromised children from 2 years of age to less than 18 years of age for prevention of COVID-19 **Study 5 (C4591044)** *Added during procedure EMEA-002861-PIP02-20-M05.* Open label, safety, tolerability and immunogenicity study of a booster dose of tozinameran/famtozinameran in adolescents from 12 years to less than 18 years of age (and adults) for the prevention of COVID-19 **Study 6 (C4591048)** *Added during procedure EMEA-002861-PIP02-20-M05.* Observer-blind, randomized, controlled, safety, tolerability and immunogenicity study (substudy A: SSA) of 3-dose tozinameran/famtozinameran and fourth dose of raxtozinameran in COVID-19 vaccine–naïve children from 6 months to less than 4 years and 3 months of age (Part 1) and a 2-dose series of raxtozinameran in children 6 months to <2 years and single-dose in children aged 2 to <5 years (Part 2) Open label, safety, tolerability and immunogenicity study of a booster dose of tozinameran/famtozinameran in children from 6 months to less than 12 years age (Substudies B, C, and D); Open label, safety, tolerability, and immunogenicity study of raxtozinameran in children from 5 years of age to less 12 years who are COVID-19 vaccine–naïve (Substudy E: SSE).
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 August 2027
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):

- Comirnaty (30 µg/dose) is indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2, in individuals 12 years of age and older.
  - Invented name(s): Comirnaty, Comirnaty Original/Omicron BA.4-5, Comirnaty Omicron XBB.1.5, Comirnaty JN.1, Comirnaty KP.2
  - Authorised pharmaceutical form(s): Dispersion for injection
  - Authorised route(s) of administration: Intramuscular route
  - Authorised via centralised procedure
- Comirnaty (10 µg/dose) is indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2, in children aged 5 to 11 years of age.
  - Invented name(s): Comirnaty Original/Omicron BA.4-5, Comirnaty Omicron XBB.1.5, Comirnaty JN.1
  - Authorised pharmaceutical form(s): Concentrate for dispersion for injection, Dispersion for injection
  - Authorised route(s) of administration: Intramuscular route
  - Authorised via centralised procedure
- Comirnaty (10 µg/dose) is indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2, in children aged 5 to 11 years.
  - Invented name(s): Comirnaty
  - Authorised pharmaceutical form(s): Concentrate for dispersion for injection
  - Authorised route(s) of administration: Intramuscular route
  - Authorised via centralised procedure
- Comirnaty (10 µg/dose) is indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2, in children aged 5 to 11 years of age.
  - Invented name(s): Comirnaty KP.2
  - Authorised pharmaceutical form(s): Dispersion for injection
  - Authorised route(s) of administration: Intramuscular route
  - Authorised via centralised procedure
- Comirnaty (3 µg/dose) is indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2, in infants and children aged 6 months to 4 years.
  - Invented name(s): Comirnaty, Comirnaty Original/Omicron BA.4-5, Comirnaty Omicron XBB.1.5, Comirnaty JN.1, Comirnaty KP.2

- Authorised pharmaceutical form(s): Concentrate for dispersion for injection
- Authorised route(s) of administration: Intramuscular route
- Authorised via centralised procedure