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Decision Cover Letter

Decision of the licensing authority to:

accept change(s) to the agreed paediatric investigation plan (MHRA-100392-PIP01-21-M06) and to the deferral

MHRA-100392-PIP01-21-M07

Scope of the Application

Active Substance(s)

Highly purified single-stranded, 5’-capped mRNA encoding full-length SARS-CoV-2 spike protein (BNT162b2) FAMTOZINAMERAN/RILTOZINAMERAN/ TOZINAMERAN

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 the Decision

Pursuant to the Human Medicines Regulations 2012, BioNTech Manufacturing GmbH submitted to the licensing authority on 22/10/2025 12:40 BST an application for a Modification

The procedure started on 02/12/2025 12:54 GMT

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 and to the deferral

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-100392-PIP01-21-M07

Of 03/03/2026 08:34 GMT

On the adopted decision for Highly purified single-stranded, 5'-capped mRNA encoding full-length SARS-CoV-2 spike protein (BNT162b2); Tozinameran; Famtozinameran; Riltozinameran; Raxtozinameran; Bretovameran Cemivameran; COVID-19 mRNA Vaccine (MHRA-100392-PIP01-21-M07) 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 Highly purified single-stranded, 5'-capped mRNA encoding full-length SARS-CoV-2 spike protein (BNT162b2); Tozinameran; Famtozinameran; Riltozinameran; Raxtozinameran; Bretovameran Cemivameran; COVID-19 mRNA Vaccine , Concentrate for dispersion for injection Dispersion for injection , Intravenous use .

This decision is addressed to BioNTech Manufacturing GmbH, An der Goldgrube 12, Mainz, GERMANY, 55131

ANNEX I

1. Waiver

1.1 Condition:

Prevention of Coronavirus disease 2019 (COVID-19) The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 6 weeks of age Pharmaceutical form(s): Concentrate for dispersion for injection Dispersion for injection Route(s) of administration: INTRAMUSCULAR USE Reason for granting waiver: 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(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):

Concentrate for dispersion for injection 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	5	Study 1 (C4591001) Observer blind, dose-finding study of safety, tolerability and immunogenicity of SARS-CoV-2 RNA vaccine candidates (part 1: adults only) 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 MHRA-100392-PIP01-21-M03. Interventional, randomised, active controlled study to evaluate the safety, tolerability and immunogenicity of BNT162b RNA-based vaccine candidates in COVID-19 vaccine-experienced healthy individuals in adolescents from 12 years to less than 18 years of age (and adults) for the prevention of COVID-19.
Extrapolation, Modeling & Simulation Studies	0	Not applicable.
Other Studies	1	Study 6 (C4591048) Added during procedure MHRA-100392-PIP01-21-M03. Observer-blind, randomised, 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 or cemivameran in children 6 months to less than 2 years and single-dose of raxtozinameran in children from 2 years to less than 5 years of age (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 than 12 years who are COVID-19 vaccine-naïve (Substudy E: SSE).
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:	31/08/2027
Deferral of one or more studies contained in the paediatric investigation plan:	Yes