MHRA
10 South Colonnade
Canary Wharf
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United Kingdom

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Decision Cover Letter

Decision of the licensing authority to:

accept change(s) to the agreed paediatric investigation plan (MHRA-100601-PIP01-22-M02)
MHRA-100601-PIP01-22-M03

Scope of the Application

Active Substance(s)

ELASOMERAN; IMELASOMERAN; DAVESOMERAN; ANDUSOMERAN

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 the Decision

Pursuant to the Human Medicines Regulations 2012, Moderna Biotech Spain, S.L. submitted to the licensing authority on 13/10/2023 14:02 BST an application for a Modification

The procedure started on 24/01/2024 08:05 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

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-100601-PIP01-22-M03

Of 28/02/2024 15:49 GMT

On the adopted decision for ELASOMERAN; IMELASOMERAN; DAVESOMERAN; ANDUSOMERAN (MHRA-100601-PIP01-22-M03) 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 ELASOMERAN; IMELASOMERAN; DAVESOMERAN; ANDUSOMERAN, Dispersion for injection , INTRAMUSCULAR USE .

This decision is addressed to Moderna Biotech Spain, S.L., Calle Del Principe De Vergara 132 Plt 12, Madrid, SPAIN, 28002

ANNEX I

1. Waiver

1.1 Condition:

Prevention of Coronavirus Disease 2019 (COVID-2019) The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 12 weeks of age Pharmaceutical form(s): Dispersion for injection Route(s) of administration: INTRAMUSCULAR USE Reason for granting waiver: on the grounds that the specific medicinal product is likely to be ineffective.

2. Paediatric Investigation Plan:

2.1 Condition(s):

Prevention of Coronavirus Disease 2019 (COVID-2019)

2.2 Indication(s) targeted by the PIP:

Prevention of Coronavirus Disease 2019 (COVID-2019)

2.3 Subset(s) of the paediatric population concerned by the paediatric development:

The paediatric population from 12 weeks to less than 18 years of age

2.4 Pharmaceutical Form(s):

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	4	Study 1 (P203) Randomised, observer-blind, placebo-controlled, study to evaluate safety, reactogenicity, and immunogenicity of elasomeran as primary series and as booster in adolescents from 12 to less than 18 years of age for the prevention of COVID-19. Study 2 (P204) Randomised, 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 Open label, uncontrolled, safety and immunogenicity study of elasomeran in immunocompromised children for prevention of COVID-19. Study 4 (P206) (Added during procedure MHRA-100601-PIP01-22-M01) 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 the prevention to COVID-19.
Extrapolation, Modeling & Simulation Studies	0	Not applicable.
Other Studies	0	Not applicable.
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:	31/03/2025
Deferral of one or more studies contained in the paediatric investigation plan:	Yes