MHRA
10 South Colonnade
Canary Wharf
London
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United Kingdom

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Decision Cover Letter

Decision of the licensing authority to:

agree a paediatric investigation plan and grant a deferral

MHRA-100913-PIP01-23

Scope of the Application

Active Substance(s)

mRNA that encodes for the NTD and RBD epitopes of the spike glycoprotein of SARS-CoV-2 (mRNA-1283)

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

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 23/03/2023 16:02 GMT an application for a Paediatric Investigation Plan

The procedure started on 10/07/2023 07:44 BST

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 agree a paediatric investigation plan and grant a 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-100913-PIP01-23

Of 13/02/2024 15:53 GMT

On the adopted decision for mRNA that encodes for the NTD and RBD epitopes of the spike glycoprotein of SARS-CoV-2 (mRNA-1283) (MHRA-100913-PIP01-23) 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 a paediatric investigation plan

This decision applies to a Paediatric Investigation Plan for mRNA that encodes for the NTD and RBD epitopes of the spike glycoprotein of SARS-CoV-2 (mRNA-1283), Suspension 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:

Not applicable

2. Paediatric Investigation Plan:

2.1 Condition(s):

Prevention of Coronavirus Disease 2019 (COVID-19)

2.2 Indication(s) targeted by the PIP:

Active immunisation to prevent COVID-19 caused by SARS-CoV-2

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

All subsets of the paediatric population from birth to less than 18 years of age

2.4 Pharmaceutical Form(s):

Suspension 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	3	Study 1 (mRNA-1283-P301) Randomised, observer-blind, active-controlled study to investigate the safety, immunogenicity, and efficacy of mRNA-1283.222 administered as a booster dose compared with mRNA-1273.222 in participants aged 12 years and older for the prevention of COVID-19. Study 2 (mRNA-1283-P302) Dose-ranging study (part 1) and randomised, observer-blind, active-controlled safety and immunogenicity study (part 2) in participants aged 6 months to less than 12 years of age with and without prior history of vaccination. Part 2A will enrol participants aged from 6 months to less than 5 years of age who have been previously vaccinated and participants from 5 to less than 12 years of age regardless of prior vaccination to receive a single dose vaccination. Part 2B will enrol participants from 6 months to less than 5 years of age who have not been previously vaccinated to receive a two-dose vaccination regimen. Study 3 (mRNA-1283-Pxxx) Dose-finding (cohort 1) and randomised, active- controlled, observer- blind, study (cohort 2) to evaluate the safety, reactogenicity,

		and immunogenicity of mRNA 1283 SARS-CoV-2 vaccine administered as 2 doses 6-8 weeks apart in infants from birth to less than 6 months of age.
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:	30/06/2034
Deferral of one or more studies contained in the paediatric investigation plan:	Yes