

**MHRA**  
10 South Colonnade  
Canary Wharf  
London  
E14 4PU  
United Kingdom

[gov.uk/mhra](http://gov.uk/mhra)

## **Decision Cover Letter**

### **Decision of the licensing authority to:**

accept change(s) to the agreed paediatric investigation plan and to the waiver

MHRA-100913-PIP01-23-M02

### **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 10/10/2025 12:04 BST an application for a Modification

The procedure started on 04/11/2025 15:27 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 waiver

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.

**MHRA**  
10 South Colonnade  
Canary Wharf  
London  
E14 4PU  
United Kingdom

[gov.uk/mhra](http://gov.uk/mhra)

## Final Decision Letter

MHRA-100913-PIP01-23-M02

Of 03/03/2026 10:10 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-M02) 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 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., c/Julian Camarillo no 31, Madrid , SPAIN, 28037

## 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 6 months to less than 12 years of age Pharmaceutical form(s): Suspension 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:

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 6 months of age and from 12 years 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	2	Study 1 (mRNA-1283-P301) Randomised, observer-blind, active-controlled study to investigate the safety, immunogenicity, and relative vaccine efficacy of mRNA-1283 compared with mRNA-1273 in participants aged 12 years and older for the prevention of COVID-19. Study 2 (mRNA-1283-P302) Deleted during procedure MHRA-100913-PIP01-23-M02. 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:

<b>Concerns on potential long term safety and efficacy issues in relation to paediatric use:</b>	No
<b>Date of completion of the paediatric investigation plan:</b>	30/06/2034
<b>Deferral of one or more studies contained in the paediatric investigation plan:</b>	Yes