

**MHRA**  
10 South Colonnade  
Canary Wharf  
London  
E14 4PU  
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-M03)  
MHRA-100601-PIP01-22-M04

### **Scope of the Application**

#### **Active Substance(s)**

Elasomeran, davesomeran, andusomeran, mRNA-1273.167; IMELASOMERAN

#### **Condition(s)**

Prevention of Coronavirus Disease 2019 (COVID-2019)

#### **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 19/03/2025 12:30 GMT an application for a Modification

The procedure started on 10/04/2025 16:40 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 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-M04

Of 16/06/2025 17:34 BST

On the adopted decision for Elasomeran, davesomeran, andusomeran, mRNA-1273.167;  
IMELASOMERAN (MHRA-100601-PIP01-22-M04) 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, davesomeran, andusomeran, mRNA-1273.167;  
IMELASOMERAN, Dispersion for injection , INTRAMUSCULAR USE .

This decision is addressed to Moderna Biotech Spain S.L., C/ Julián Camarillo n ° 31, Madrid, SPAIN,  
28037

## 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	3	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 (Deleted during procedure MHRA-100601-PIP01-22-M04) 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.

<b>Extrapolation, Modeling &amp; Simulation Studies</b>	0	Not applicable.
<b>Other Studies</b>	0	Not applicable.
<b>Other Measures</b>	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>	30/03/2025
<b>Deferral of one or more studies contained in the paediatric investigation plan:</b>	Yes