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:

agree a paediatric investigation plan and grant a deferral and grant a waiver

MHRA-101882-PIP01-25

Scope of the Application

Active Substance(s)

Pentavalent mRNA vaccine encoding for NoV VP1

Condition(s)

Prevention of norovirus acute gastroenteritis

Pharmaceutical Form(s)

Dispersion for injection

Route(s) of Administration

INTRAMUSCULAR USE

Name / Corporate name of the PIP applicant

Moderna Biotech Spain SL

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Moderna Biotech Spain SL submitted to the licensing authority on 16/04/2025 13:52 BST an application for a Paediatric Investigation Plan

The procedure started on 06/05/2025 13:39 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 and grant a 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.

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Final Decision Letter

MHRA-101882-PIP01-25

Of 18/02/2026 19:55 GMT

On the adopted decision for Pentavalent mRNA vaccine encoding for NoV VP1 (MHRA-101882-PIP01-25) 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 Pentavalent mRNA vaccine encoding for NoV VP1, Dispersion for injection , INTRAMUSCULAR USE .

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

ANNEX I

1. Waiver

1.1 Condition:

Prevention of norovirus acute gastroenteritis The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 2 months of age Pharmaceutical form(s): Dispersion for injection Route(s) of administration: INTRAMUSCULAR USE Reason for granting waiver: on the grounds that clinical studies with the specific medicinal product cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the specified paediatric subset(s).

2. Paediatric Investigation Plan:

2.1 Condition(s):

Prevention of norovirus acute gastroenteritis

2.2 Indication(s) targeted by the PIP:

Active immunisation for the prevention of moderate to severe acute gastroenteritis (AGE) due to norovirus genotypes covered by the vaccine

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

The paediatric population from 2 months 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	5	Study 1 (mRNA-1405-P201) Randomised, observer-blind, placebo-controlled, dose escalation study to evaluate the safety, reactogenicity and immunogenicity of mRNA-1405 in healthy children from 2 months to less than 5 years of age. Study 2 (mRNA-1405-P302) Randomised, observer-blind, placebo-controlled study to evaluate the safety and efficacy of mRNA-1405 in healthy children from 2 months to less than 6 months of age. Study 3 Randomised, observer-blind, placebo-controlled study to evaluate the safety, reactogenicity and immunogenicity of mRNA-1405 in healthy children from 6 months to less than 5 years of age. Study 4 Randomised, observer-blind, placebo-controlled study to evaluate safety, reactogenicity and immunogenicity of mRNA-1405 in children from 5 years to less than 18 years of age. Study 5 Open-label study to evaluate the safety, reactogenicity and immunogenicity of mRNA-1405 in immunocompromised children and those at increased risk of severe

		norovirus acute gastroenteritis from 2 months to less than 18 years 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:	30/11/2036
Deferral of one or more studies contained in the paediatric investigation plan:	Yes