MHRA
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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-100797-PIP02-24

Scope of the Application

Active Substance(s)

mRNA encoding Influenza A, H1N1 strain, hemagglutinin glycoprotein, mRNA encoding Influenza A, H3N2 strain, hemagglutinin glycoprotein, mRNA encoding Influenza B/Victoria, hemagglutinin glycoprotein

Condition(s)

Prevention of influenza disease

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 04/06/2025 21:44 BST an application for a

The procedure started on 14/07/2025 13:02 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-100797-PIP02-24

Of 01/08/2025 13:23 BST

On the adopted decision for mRNA encoding Influenza A, H1N1 strain, hemagglutinin glycoprotein, mRNA encoding Influenza A, H3N2 strain, hemagglutinin glycoprotein, mRNA encoding Influenza B/Victoria, hemagglutinin glycoprotein (MHRA-100797-PIP02-24) 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 for mRNA encoding Influenza A, H1N1 strain, hemagglutinin glycoprotein, mRNA encoding Influenza A, H3N2 strain, hemagglutinin glycoprotein, mRNA encoding Influenza B/ Victoria, hemagglutinin glycoprotein, 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 influenza disease The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 6 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 influenza disease

2.2 Indication(s) targeted by the PIP:

Prevention of influenza disease

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

The paediatric population from 6 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	5	Study 1 Randomised, observer-blind, active-controlled, age de-escalation study to evaluate the safety, reactogenicity, and immunogenicity of mRNA-1010 in children and adolescents from 6 months to less than 18 years of age. Study 2 Randomised, observer-blind, active-controlled, study to evaluate the safety, reactogenicity, and immunogenicity of mRNA-1010 compared to a licensed influenza vaccine in children from 9 years to less than 18 years of age. Study 3 Randomised, observer-blind, non-influenza active-controlled study to evaluate safety, efficacy, and immunogenicity of mRNA-1010 vaccine in children from 6 months to less than 36 months of age. Study 4 Randomised, observer-blind, active-controlled study to evaluate the safety and immunogenicity of mRNA-1010 vaccine in children from 3 years to less than 9 years of age. Study 5 Two-part placebo-controlled study to evaluate the safety and immunogenicity of

		mRNA-1010 vaccine in infants from 6 weeks 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:	30/09/2032
Deferral of one or more studies contained in the paediatric investigation plan:	Yes