

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-102302-PIP01-26

Scope of the Application

Active Substance(s)

mRNA encoding Influenza A, subtype H5N1, strain A/chicken/Ghana/2021, haemagglutinin

Condition(s)

Prevention of pandemic influenza

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 16/01/2026 12:19 GMT an application for a Paediatric Investigation Plan

The procedure started on 20/01/2026 17:11 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 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-102302-PIP01-26

Of 23/03/2026 08:38 GMT

On the adopted decision for mRNA encoding Influenza A, subtype H5N1, strain A/chicken/Ghana/2021, haemagglutinin (MHRA-102302-PIP01-26) 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 encoding Influenza A, subtype H5N1, strain A/chicken/Ghana/2021, haemagglutinin , 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:

Not applicable.

2. Paediatric Investigation Plan:

2.1 Condition(s):

Prevention of pandemic influenza

2.2 Indication(s) targeted by the PIP:

Prevention of pandemic influenza

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):

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	2	Study 1 (mRNA-1018-P201) Randomised, placebo-controlled, observer-blind, 2 part, dose-finding, dose-confirmation study to evaluate the safety, reactogenicity, and immunogenicity of mRNA-1018 in healthy children from 6 months to less than 18 years of age. Study 2 (mRNA-1018-P202) Randomised, placebo-controlled study to evaluate the safety and immunogenicity of mRNA-1018 in healthy children 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:	01/01/2040
Deferral of one or more studies contained in the paediatric investigation plan:	Yes

