MHRA
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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-101422-PIP02-24

Scope of the Application

Active Substance(s)

single-stranded 5' capped mRNA encoding the HAs of the influenza virus strains A and B and the N terminal domain (NTD) and receptor binding domain (RBD) of the SARS-CoV-2 spike glycoprotein.

Condition(s)

Prevention of influenza and coronavirus disease 2019 (COVID-19)

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 20/09/2024 18:20 BST an application for a Paediatric Investigation Plan

The procedure started on 01/10/2024 15:50 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-101422-PIP02-24

Of 08/10/2024 17:47 BST

On the adopted decision for single-stranded 5' capped mRNA encoding the HAs of the influenza virus strains A and B and the N terminal domain (NTD) and receptor binding domain (RBD) of the SARS-CoV-2 spike glycoprotein.; (mRNA-1083) (MHRA-101422-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 Paediatric Investigation Plan for single-stranded 5' capped mRNA encoding the HAs of the influenza virus strains A and B and the N terminal domain (NTD) and receptor binding domain (RBD) of the SARS-CoV-2 spike glycoprotein.; (mRNA-1083), Dispersion for injection , INTRAMUSCULAR USE .

This decision is addressed to Moderna Biotech Spain, S.L, C/ Julián Camarillo nº 31, Madrid, SPAIN, 28037

ANNEX I

1. Waiver

1.1 Condition:

Prevention of influenza and coronavirus disease 2019 (COVID-19) 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 and coronavirus disease 2019 (COVID-19)

2.2 Indication(s) targeted by the PIP:

Prevention of influenza and coronavirus disease 2019 (COVID-19)

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	3	Study 1 Randomised, double-blind, active-controlled age de-escalation study to evaluate the safety, reactogenicity, and immunogenicity of mRNA-1083 in healthy children and adolescents aged 6 months to less than 18 years of age. Study 2 Randomised, double-blind, active-controlled, study to evaluate the immunogenicity, safety, and reactogenicity of mRNA-1083 vaccine compared to licensed vaccines against influenza and COVID-19 co-administered to children aged 6 months to less than 18 years of age. Study 3 Open-label (phase I) and active controlled (phase II) study to evaluate the safety and immunogenicity of mRNA-1083 vaccine compared to licensed vaccines against influenza and COVID-19 co-administered to healthy children aged 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:	31/07/2035
Deferral of one or more studies contained in the paediatric investigation plan:	Yes