MHRA
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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-100796-PIP01-22

Scope of the Application

Active Substance(s)

Single-stranded 5' capped mRNA encoding the Respiratory syncytial virus glycoprotein F stabilized in the prefusion conformation

Condition(s)

Prevention of lower respiratory tract illness (LRTI) caused by respiratory syncytial virus (RSV)

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 24/02/2023 09:07 GMT an application for a Paediatric Investigation Plan

The procedure started on 21/06/2023 09:55 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-100796-PIP01-22

Of 28/07/2023 12:05 BST

On the adopted decision for Single-stranded 5' capped mRNA encoding the Respiratory syncytial virus glycoprotein F stabilized in the prefusion conformation (MHRA-100796-PIP01-22) 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 Respiratory syncytial virus glycoprotein F stabilized in the prefusion conformation , Dispersion for injection , INTRAMUSCULAR USE .

This decision is addressed to Moderna Biotech Spain, S.L., Calle Del Principe De Vergara 132 Plt 12, Madrid, SPAIN, 28002

ANNEX I

1. Waiver

1.1 Condition:

Prevention of lower respiratory tract illness (LRTI) caused by respiratory syncytial virus (RSV) 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 lower respiratory tract illness (LRTI) caused by respiratory syncytial virus (RSV)

2.2 Indication(s) targeted by the PIP:

Prevention of lower respiratory tract illness (LRTI) caused by respiratory syncytial virus (RSV)

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	6	Study 1 (mRNA-1345-P101) Randomised, observer-blind, placebo-controlled, dose escalation study to evaluate the safety, reactogenicity, and immunogenicity of mRNA-1345, in respiratory syncytial virus (RSV) seropositive children from 12 month of age to less than 60 months of age. Study 2 (mRNA-1365-P101) Randomised, observer-blind, placebo controlled, age de-escalation study of the safety, tolerability, and immunogenicity of mRNA-1345 in children from 5 months of age to less than 24 months of age. Study 3 Randomised, observer-blind, placebo-controlled study of mRNA-1345 in children from 6 weeks of age to less than 7 months of age for regimen and dose selection, and safety, reactogenicity, and immunogenicity evaluation. Co-administration with routine childhood vaccines. Study 4 Randomised, observer-blind, placebo-controlled study of mRNA-1345 in children from 6 weeks of age to less than 7 months of age for safety and efficacy for

		the prevention of RSV-associated lower respiratory tract illness (LRTI). Co-administration with routine childhood vaccines. Study 5 Open-label study of safety, reactogenicity, and immunogenicity evaluation of mRNA-1345 in children from 7 months to less than 60 months of age. Study 6 Open-label, study of safety, reactogenicity, and immunogenicity evaluation of mRNA-1345 in children from 5 years to less than 18 years of age with underlying conditions (Cohort A) and in immunocompromised children (Cohort B).
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:	31/12/2035
Deferral of one or more studies contained in the paediatric investigation plan:	Yes