MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
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-100588-PIP01-22

Scope of the Application

Active Substance(s)

UB-612

Condition(s)

Prevention of Coronavirus Disease 2019 (COVID-19)

Pharmaceutical Form(s)

Suspension for injection

Route(s) of Administration

INTRAMUSCULAR USE

Name / Corporate name of the PIP applicant

Vaxxinity

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Vaxxinity submitted to the licensing authority on 30/06/2022 09:30 BST an application for a Paediatric Investigation Plan

The procedure started on 18/08/2022 08:20 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-100588-PIP01-22

Of 31/01/2023 17:15 GMT

On the adopted decision for UB-612 (MHRA-100588-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 UB-612, Suspension for injection , INTRAMUSCULAR USE .

This decision is addressed to Vaxxinity, 70 SIR JOHN ROGERSON'S QUAY, Dublin, IRELAND, D02 R296

ANNEX I

1. Waiver

1.1 Condition:

Prevention of Coronavirus Disease 2019 (COVID-19) The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 6 months of age Pharmaceutical form(s): Suspension for injection Route(s) of administration: INTRAMUSCULAR USE Reason for granting waiver: on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as the needs are already covered.

2. Paediatric Investigation Plan:

2.1 Condition(s):

Prevention of Coronavirus Disease 2019 (COVID-19)

2.2 Indication(s) targeted by the PIP:

Heterologous booster for prevention of COVID-19 in individuals 6 months of age and older

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

The paediatric population from 6 months to less than 18 years of age

2.4 Pharmaceutical Form(s):

Suspension 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 (UB-612-V-205) Randomised, placebo-controlled, observer-blind study to evaluate the immunogenicity, safety, and tolerability of a primary series of UB-612 vaccine in healthy adolescents (and adults). Study 2 (UB-612-305) Randomised active-controlled platform study to evaluate the immunogenicity, safety and tolerability of a single booster dose of UB-612 compared to a comparator COVID-19 vaccine in adolescents (and adult subjects) who completed their primary immunisation series with the same comparator vaccine at least 3 months prior to enrolment. Study 3 Open label, 2-part study to evaluate safety, tolerability, and immunogenicity of a heterologous booster dose of UB-612 adolescents from 12 years to less than 18 years of age who have completed their primary vaccination series with another COVID-19 vaccine. Study 4 Open label, single-arm, 2-part study to evaluate safety, tolerability, and immunogenicity of a heterologous booster dose of UB-612 Vaccine in children from 6 years to less than 12 years of age who have completed a

		received primary vaccination series with another COVID-19 vaccine. Study 5 Open label, single-arm 2-part study to evaluate safety, tolerability, and immunogenicity of a heterologous booster dose of UB-612 vaccine in children and infants from 6 months to less than 6 years of age who have completed their primary vaccination series with another COVID-19 vaccine. Study 6 Open label, single-arm study to evaluate safety, tolerability, and immunogenicity of a heterologous booster with UB-612 vaccine in immunocompromised children from 6 months to less than 18 years of age who completed their primary series with another COVID-19 vaccine.
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:	31/12/2026
Deferral of one or more studies contained in the paediatric investigation plan:	Yes