MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

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Decision Cover Letter

Decision of the licensing authority to:

accept change(s) to the agreed paediatric investigation plan (MHRA-100197-PIP01-21-M01) and to the deferral

MHRA-100197-PIP01-21-M02

Scope of the Application

Active Substance(s)

Ebola Zaire Vaccine (rVSV#G-ZEBOV-GP, live)

Condition(s)

Prevention of Ebola disease

Pharmaceutical Form(s)

Suspension for injection

Route(s) of Administration

INTRAMUSCULAR USE

Name / Corporate name of the PIP applicant

Merck Sharp & Dohme (UK) Limited

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Merck Sharp & Dohme (UK) Limited submitted to the licensing authority on 17/02/2024 20:55 GMT an application for a Modification

The procedure started on 19/02/2024 18:57 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 accept change(s) to the agreed paediatric investigation plan and to the 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-100197-PIP01-21-M02

Of 27/02/2024 11:21 GMT

On the adopted decision for Ebola Zaire Vaccine (rVSV$_{\Delta}$G-ZEBOV-GP, live) (MHRA-100197-PIP01-21-M02) 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 modification of a paediatric investigation plan (including modification of a waiver or deferral included in that paediatric investigation plan).

This decision applies to a Modification for Ebola Zaire Vaccine (rVSV$_{\Delta}$G-ZEBOV-GP, live), Suspension for injection , INTRAMUSCULAR USE .

This decision is addressed to Merck Sharp & Dohme (UK) Limited, 120 Moorgate, London, UNITED KINGDOM, EC2M 6UR

ANNEX I

1. Waiver

1.1 Condition:

Prevention of Ebola disease. The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 1 year 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 clinical studies(s) are not feasible.

2. Paediatric Investigation Plan:

2.1 Condition(s):

Prevention of Ebola disease.

2.2 Indication(s) targeted by the PIP:

Prevention of Ebola disease.

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

The paediatric population from 1 year of age 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	2	Study 1 (V920-016) Partnership for Research on Ebola VACcination (PREVAC) Randomised, double-blind, placebo-controlled study to evaluate the immunogenicity and safety of 1 or 2 doses of rVSVAG-ZEBOV-GP in healthy children (and adults) from 1 year of age. Study 2 (V920-015) Safety and Immunogenicity HIV+ subject study Randomised, double-blind, placebo-controlled study to evaluate the safety and immunogenicity of 1 or 2 doses of V920 in HIV-infected adolescents (and adults) from 13 years 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:	Yes
Date of completion of the paediatric investigation plan:	31/07/2024
Deferral of one or more studies contained in the paediatric investigation plan:	Yes