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:

accept change(s) to the agreed paediatric investigation plan (MHRA-100600-PIP01-22-M01) and to the deferral

MHRA-101097-PIP01-23-M01

Scope of the Application

Active Substance(s)

Modified Vaccinia Ankara - Bavarian Nordic virus (smallpox)

Condition(s)

Prevention of smallpox, mpox and related orthopoxvirus infection and disease

Pharmaceutical Form(s)

Suspension for injection

Route(s) of Administration

SUBCUTANEOUS USE

Name / Corporate name of the PIP applicant

Bavarian Nordic A/S

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Bavarian Nordic A/S submitted to the licensing authority on 10/10/2023 08:29 BST an application for a Modification

The procedure started on 23/01/2024 11:56 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-101097-PIP01-23-M01

Of 16/04/2024 07:50 BST

On the adopted decision for Modified Vaccinia Ankara - Bavarian Nordic virus (smallpox) (MHRA-101097-PIP01-23-M01) 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 Modified Vaccinia Ankara - Bavarian Nordic virus (smallpox) , Suspension for injection , SUBCUTANEOUS USE .

This decision is addressed to Bavarian Nordic A/S, Philip-Heymans-Allee.3, Hellerup, DENMARK, 2900

ANNEX I

1. Waiver

1.1 Condition:

Not applicable

2. Paediatric Investigation Plan:

2.1 Condition(s):

Prevention of smallpox, mpox and related orthopoxvirus infection and disease

2.2 Indication(s) targeted by the PIP:

Active immunisation against smallpox, mpox and related orthopoxvirus infection and disease

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

The paediatric population from birth 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	5	Study 1 Extrapolation from Modified Vaccinia Ankara - Bavarian Nordic virus (MVA-BN)-smallpox vaccine adult studies to children and adolescents aged 12 years to less than 18 years of age. Study 2 Extrapolation from clinical recombinant MVA-BN-based measles vaccine and extrapolation from pre-clinical (juvenile rats immunised with MVA-BN-based measles vaccine) to infants 28 days to less than 6 months of age and to children 6 months to less than 11 years of age. Study 3 Extrapolation from clinical recombinant MVA-BN-based measles vaccine and extrapolation from pre-clinical (newborn mice immunised with MVA-BN-smallpox vaccine) to pre-term and term infants from birth to less than 28 days of age. Study 4 Deleted during procedure MHRA-101097-PIP01-23-M01. Study 5 (Added during procedure MHRA-101097-PIP01-23-M01) Open label, comparative, multicentre immunogenicity and safety study of MVA-BN-smallpox vaccine in children from 12 years to less than 18 years of age compared to young adults for the prevention of smallpox, mpox and related orthopoxvirus infection and

		disease. Study 6 (Added during procedure MHRA-101097-PIP01-23-M01) Open label, multicentre immunogenicity and safety study of MVABN-smallpox vaccine in children from birth to less than 12 years of age for the prevention of smallpox, mpox and related orthopoxvirus infection and disease.
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:	31/12/2024
Deferral of one or more studies contained in the paediatric investigation plan:	Yes