MHRA
10 South Colonnade
Canary Wharf
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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-101097-PIP01-23-M01) and to the deferral

MHRA-101097-PIP01-23-M02

Scope of the Application

Active Substance(s)

Modified Vaccinia Ankara – Bavarian Nordic Live virus

Condition(s)

Prevention of smallpox, mpox and diseases caused by vaccinia virus

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 21/05/2026 16:45 BST an application for a

The procedure started on 16/06/2026 14:06 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 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-M02

Of 04/09/2026 16:46 BST

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

This decision is addressed to Bavarian Nordic A/S, Philip Heymans Alle 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 diseases caused by vaccinia virus.

2.2 Indication(s) targeted by the PIP:

Active immunisation against smallpox, mpox and diseases caused by vaccinia virus

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	7	Study 1 Extrapolation from Modified Vaccinia Ankara - Bavarian Nordic virus (MVA-BN)-smallpox and mpox 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 and mpox 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 and mpox vaccine in children from 12 years to less than 18 years of age compared to young adults for the prevention of smallpox, mpox and diseases caused by vaccinia

		virus. Study 6 (Added during procedure MHRA-101097-PIP01-23-M01) Open label, multicentre immunogenicity and safety study of MVA-BN-smallpox and mpox vaccine in children from 2 years to less than 12 years of age for the prevention of smallpox, mpox and diseases caused by vaccinia virus (compared to adults). Study 7 (Added during procedure MHRA-101097-PIP01-23-M02) Open-label, randomised immunogenicity and safety study of MVA-BN - smallpox and mpox vaccine in children from 4 months to less than 2 years of age (compared to adults). Study 8 (Added during procedure MHRA-101097-PIP01-23-M02) Open-label, randomised immunogenicity and safety study of MVA-BN - smallpox and mpox vaccine in children from birth to less than 6 months of age for the prevention of smallpox, mpox and diseases caused by vaccinia virus.
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:	30/09/2030
Deferral of one or more studies contained in the paediatric investigation plan:	Yes