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

gov.uk/mhra

Decision Cover Letter

Decision of the licensing authority to:

accept change(s) to the agreed paediatric investigation plan (MHRA-100648-PIP01-22-M01) and to the deferral

MHRA-100648-PIP01-22-M02

Scope of the Application

Active Substance(s)

TECOVIRIMAT MONOHYDRATE

Condition(s)

Treatment of orthopoxvirus disease (smallpox, mpox, cowpox, and vaccinia)

Pharmaceutical Form(s)

Capsule, hard, Powder for oral suspension

Route(s) of Administration

ORAL USE

Name / Corporate name of the PIP applicant

SIGA Technologies Netherlands B.V.

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, SIGA Technologies Netherlands B.V. submitted to the licensing authority on 13/02/2026 21:08 GMT an application for a Modification

The procedure started on 03/03/2026 17:21 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.

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

gov.uk/mhra

Final Decision Letter

MHRA-100648-PIP01-22-M02

Of 15/06/2026 15:09 BST

On the adopted decision for TECOVIRIMAT MONOHYDRATE (MHRA-100648-PIP01-22-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 TECOVIRIMAT MONOHYDRATE, Capsule, hard, Powder for oral suspension , ORAL USE .

This decision is addressed to SIGA Technologies Netherlands B.V., 4575 SW Research Way Suite 110, Corvallis, UNITED STATES OF AMERICA, 97333

ANNEX I

1. Waiver

1.1 Condition:

Not applicable

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of orthopoxvirus disease (smallpox, mpox, cowpox, and vaccinia)

2.2 Indication(s) targeted by the PIP:

Treatment of orthopoxvirus disease (smallpox, mpox, cowpox, and vaccinia)

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):

Capsule, hard Powder for oral suspension

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	1	Study 1 Development of powder for oral suspension.
Non-Clinical Studies	6	Study 2 (246-TX-007) Dose range-finding juvenile toxicity study to evaluate potential subchronic toxicity, and pharmacokinetics/ toxicokinetics of tecovirimat. Study 3 (2083-003-001-SN6) Dose range-finding juvenile toxicity study to evaluate the toxicity of tecovirimat, and to determine the reversibility of any toxic effects. Study 4 (MPI 1151-065) Repeat dosing pharmacokinetics of tecovirimat. Study 5 (FY10-087) Juvenile animal pharmacology study to evaluate pharmacokinetics and efficacy of tecovirimat after mpox virus (MPXV) challenge. Study 6 (AP-09-026G) Juvenile animal pharmacology study to determine the minimum effective dose of tecovirimat in treating symptomatic (lesional) disease in NHPs infected with MPXV. Study 7 (2083-003-001 SN9) Placental transfer and milk transfer study of tecovirimat.
Clinical Studies	0	Study 8 (SIGA-246-027) Deleted during procedure MHRA-100648-PIP01-22-M02. Study 9 (SIGA-246-029) Deleted during procedure MHRA-100648-PIP01-22-M02.
Extrapolation, Modeling & Simulation Studies	1	Study 10 Modelling and simulation study to determine dosing of

		tecovirimat in paediatric patients from birth to less than 18 years of age.
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:	31/03/2027
Deferral of one or more studies contained in the paediatric investigation plan:	Yes