Summary of risk management plan for Tecovirimat SIGA (tecovirimat monohydrate)

This is a summary of the risk management plan (RMP) for Tecovirimat SIGA. The RMP details important risks of Tecovirimat SIGA, how these risks can be minimised, and how more information will be obtained about Tecovirimat SIGA's risks and uncertainties (missing information).

Tecovirimat SIGA's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Tecovirimat SIGA should be used.

This summary of the RMP for Tecovirimat SIGA should be read in the context of all this information including the assessment report of the evaluation and its plain-language summary, all which is part of the European Public Assessment Report (EPAR).

Important new concerns or changes to the current ones will be included in updates of Tecovirimat-SIGA's RMP.

I. The medicine and what it is used for

Tecovirimat-SIGA is authorised for the treatment of viral infections (cowpox, monkeypox, smallpox) and to treat complications due to replication of vaccinia virus following vaccination against smallpox in adults and children with body weight at least 13 kg (see SmPC for the full indication). It contains tecovirimat monohydrate as the active substance and it is given by mouth as hard capsules.

Further information about the evaluation of Tecovirimat SIGA's benefits can be found in Tecovirimat-SIGA's EPAR, including in its plain-language summary, available on the EMA website, under the medicine's webpage <link to the EPAR summary landing page>.

II. Risks associated with the medicine and activities to minimise or further characterise the risks

Important risks of Tecovirimat SIGA, together with measures to minimise such risks and the proposed studies for learning more about Tecovirimat SIGA's risks, are outlined below.

Measures to minimise the risks identified for medicinal products can be:

- Specific information, such as warnings, precautions, and advice on correct use, in the package leaflet and SmPC addressed to patients and healthcare professionals;
- Important advice on the medicine's packaging;
- The authorised pack size — the amount of medicine in a pack is chosen so to ensure that the medicine is used correctly;
- The medicine's legal status — the way a medicine is supplied to the patient (e.g. with or without prescription) can help to minimise its risks.

Together, these measures constitute *routine risk minimisation* measures.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed, including PSUR assessment so that immediate action can be taken as necessary. These measures constitute *routine pharmacovigilance activities*.

If important information that may affect the safe use of Tecovirimat SIGA is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Tecovirimat SIGA are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely taken. Important risks can be regarded as identified or potential. Identified risks are concerns for which there is sufficient proof of a link with the use of Tecovirimat SIGA. Potential risks are concerns for which an association with the use of this medicine is possible based on available data, but this association has not been established yet and needs further evaluation. Missing information refers to information on the safety of the medicinal product that is currently missing and needs to be collected (e.g. on the long-term use of the medicine);

List of important risks and missing information	
Important identified risks	None
Important potential risks	None
Missing information	Use in pregnancy and lactation Use in immunocompromised patients

II.B Summary of important risks

Missing information No. 1: Use in pregnancy and lactation	
Risk minimisation measures	Routine risk minimisation measures: *SmPC section 4.6* *PL section 2* *Pack size* *Legal status* Additional risk minimisation measures: *None*
Additional pharmacovigilance activities	Additional pharmacovigilance activities: SIGA-246-021, A Phase 4, Observational Field Study to Evaluate the Safety and Clinical Benefit in TPOXX® (Tecovirimat)-Treated Patients Following Exposure to Variola Virus and Clinical Diagnosis of Smallpox Disease See section II.C of this summary for an overview of the post-authorisation development plan.
Missing information No. 2: Use in immunocompromised patients	
Risk minimisation measures	Routine risk minimisation measures: *SmPC section 4.4* *PL section 2* *Pack size* *Legal status* Additional risk minimisation measures:

	None
Additional pharmacovigilance activities	Additional pharmacovigilance activities: SIGA-246-021, A Phase 4, Observational Field Study to Evaluate the Safety and Clinical Benefit in TPOXX® (Tecovirimat)-Treated Patients Following Exposure to Variola Virus and Clinical Diagnosis of Smallpox Disease See section II.C of this summary for an overview of the post-authorisation development plan.

II.C Post-authorisation development plan

II.C.1 Studies which are conditions of the marketing authorisation

The following studies are conditions of the marketing authorisation:

Study short name: SIGA-246-021, *A Phase 4, Observational Field Study to Evaluate the Safety and Clinical Benefit in TPOXX® (Tecovirimat)-Treated Patients Following Exposure to Variola Virus and Clinical Diagnosis of Smallpox Disease*

Purpose of the study: Observational field study to further characterise the efficacy and safety of tecovirimat in the treatment of smallpox.

II.C.2 Other studies in post-authorisation development plan

There are no other studies in post-authorisation development plan.