Tecovirimat SIGA

Procedural steps taken and scientific information after the authorisation

Application number	Scope	Opinion/ Notification [1] issued on	Commission Decision Issued [2] / amended on	Product Information affected [3]	Summary
PSUSA/10971 /202401	Periodic Safety Update EU Single assessment - tecovirimat	19/09/2024	14/11/2024	PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/10971/202401.
S/0010	Annual re-assessment.	30/05/2024	n/a		The CHMP, having reviewed the evidence of compliance with the specific obligations and the impact of the data submitted by the MAH on the benefit/risk profile of the

[1] Notifications are issued for type I variations and Article 61(3) notifications (unless part of a group including a type II variation or extension application or a worksharing application). Opinions are issued for all other procedures.
[2] A Commission decision (CD) is issued for procedures that affect the terms of the marketing authorisation (e.g. summary of product characteristics, annex II, labelling, package leaflet). The CD is issued within two months of the opinion for variations falling under the scope of Article 23.1a(a) of Regulation (EU) No. 712/2012, or within one year for other procedures.
[3] SmPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).

					medicinal product, concluded that marketing authorisation of Tecovirimat SIGA should be maintained.
PSUSA/10971 /202307	Periodic Safety Update EU Single assessment - tecovirimat	08/02/2024	n/a		PRAC Recommendation - maintenance
S/0004	Annual re-assessment.	12/10/2023	07/12/2023	Annex II	The CHMP, having reviewed the evidence of compliance with the specific obligations and the impact of the data submitted by the MAH on the benefit/risk profile of the medicinal product, concluded that marketing authorisation of Tecovirimat SIGA should be varied, updating Annex II with a new specific obligation: "To ensure adequate monitoring of safety and efficacy of Tecovirimat in the treatment of the Smallpox, Mpox, Cowpox viral infections and complications due to replication of vaccinia virus following vaccination against smallpox in adults and children with body weight at least 13 kg, the MAH shall provide yearly updates on any new information concerning the safety and efficacy of tecovirimat."
II/0006	C.I.11.b - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH where significant assessment is required	12/10/2023	07/12/2023	Annex II	
PSUSA/10971 /202301	Periodic Safety Update EU Single assessment - tecovirimat	31/08/2023	n/a		PRAC Recommendation - maintenance
II/0005	Update of section 4.2 of the SmPC in order to introduce a new posology regimen for those with a body weight of 120 kg and above based on final	26/04/2023	31/05/2023	SmPC and PL	As a result of this variation, sections 4.1, 4.2 and 5.1 of the SmPC are being updated to add the new posology and to change monkeypox to mpox.

	results from study SIGA-246-022 and study report 865, which is a PopPK modelling and simulation report. Study SIGA-246-022 is a multiple-dose, open-label, safety, tolerability, and pharmacokinetic study of tecovirimat in adults weighing more than 120 kg. The Package Leaflet has been updated accordingly. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data				For more information, please refer to the Summary of Product Characteristics.
II/0003/G	This was an application for a group of variations. C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority	16/03/2023	n/a		

IB/0007	B.II.a.3.z - Changes in the composition (excipients) of the finished product - Other variation	15/03/2023	31/05/2023	SmPC	
PSUSA/10971 /202207	Periodic Safety Update EU Single assessment - tecovirimat	09/02/2023	n/a		PRAC Recommendation - maintenance
IB/0001	The RMP has been updated to include follow up forms and communication for prescribers (DHPC) for use in pregnancy and lactation and use in immunocompromised subjects in line with the agency request in the D195 JAR. C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	20/07/2022	n/a		The RMP has been updated to include follow up forms and communication for prescribers (DHPC) for use in pregnancy and lactation and use in immunocompromised subjects in line with the agency request in the D195 JAR.