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Committee for Medicinal Products for Human Use (CHMP)

Scientific conclusions and grounds for the variation to the terms of the marketing authorisation(s)

Active substance(s): tecovirimat

Procedure No. EMEA/H/C/PSUSA/00010971/202401

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Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for tecovirimat, the scientific conclusions of PRAC are as follows:

In view of available data on risk(s) of treatment failure from the literature and spontaneous reports, the PRAC Rapporteur concluded in line with one member state's comment that the product information of Tecovirimat SIGA should be amended accordingly. These changes are also highly important in view of the current mpox outbreaks (WHO Public Health Emergency of International Concern).

Having reviewed the PRAC recommendation, the CHMP agrees with the PRAC overall conclusions and grounds for recommendation.

Grounds for the variation to the terms of the marketing authorisation(s)

On the basis of the scientific conclusions for tecovirimat the CHMP is of the opinion that the benefit-risk balance of the medicinal product Tecovirimat SIGA is unchanged subject to the proposed changes to the product information

The CHMP recommends that the terms of the marketing authorisation(s) should be varied.