EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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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): remdesivir

Procedure No. EMEA/H/C/PSUSA/00010840/202111

Period covered by the PSUR: 06 May 2021 To: 06 November 2021

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Scientific conclusions

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

In view of available data on anaphylactic shock from spontaneous reports including cases with a close temporal relationship (four cases with at least possible causal association, two of them with TTO during administration of the infusion) and in view of the fact that hypersensitivity and anaphylactic reactions are already listed the PRAC considers a causal relationship between remdesivir and anaphylactic shock is at least a reasonable possibility. The PRAC concluded that the product information of products containing remdesivir should be amended accordingly.

The CHMP agrees with the scientific conclusions made by the PRAC.

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

On the basis of the scientific conclusions for remdesivir the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing remdesivir 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.