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/00010840/202011

Period covered by the PSUR: 07 May 2020 to 06 November 2020

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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 sinus bradycardia from spontaneous reports, including some cases with a close temporal relationship and a positive de-challenge, the PRAC Rapp considers a causal relationship between remdesivir and sinus bradycardia is at least a reasonable possibility. Additionally, as the mean age of patients admitted to hospital with COVID-19 is about 70 years, and many have cardiovascular disease or hypertension and often take β-blockers which could cause bradycardia too, it is important that treating physicians will be informed about all new consequences. Therefore, the product information section 4.8 should be amended accordingly.

Update of section 4.8 of the SmPC to add the adverse reaction of sinus bradycardia with a frequency of not known. The Package leaflet is updated 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.