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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): bictegravir / emtricitabine / tenofovir alafenamide

Procedure No. EMEA/H/C/PSUSA/00010695/202002

Period covered by the PSUR: 7 October 2019 to 6 February 2020

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for bictegravir / emtricitabine / tenofovir alafenamide, the scientific conclusions of CHMP are as follows:

In view of available data on suicidal behaviour from the clinical trials, literature and spontaneous reports including in some cases a close temporal relationship, and in view of a plausible mechanism of action, the PRAC considers a causal relationship between bictegravir / emtricitabine / tenofovir alafenamide and suicidal behaviour is established and proposes to re-word "suicidal behaviour" into "suicidal ideation and suicide attempt" with the frequency remaining uncommon and to specify that such ADRs have been particularly reported in patients with a pre-existing history of depression or psychiatric illness. The PRAC concluded that the product information of products containing bictegravir / emtricitabine / tenofovir alafenamide 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 bictegravir / emtricitabine / tenofovir alafenamide the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing bictegravir / emtricitabine / tenofovir alafenamide 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.