15 September 2022
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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/00010695/202202

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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 the CHMP are as follows:

The existing Product Information of bictegravir/emtricitabine/tenofovir alafenamide containing medicinal products reflects the need of renal function monitoring during tenofovir therapy. However, based on the cumulative review data, an update to the existing warning on nephrotoxicity is considered appropriate in order to inform prescribers on the observed cases of acute renal failure and proximal renal tubulopathy in the post marketing setting.

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.