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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): emtricitabine / tenofovir disoproxil

Procedure No. EMEA/H/C/PSUSA/00001210/202004

Period covered by the PSUR: 03 April 2019 to 02 April 2020

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR for emtricitabine/tenofovir disoproxil, the scientific conclusions of the CHMP are as follows:

Having reviewed the cumulative safety review on osteopenia/osteoporosis, the PRAC considers that section 4.4 and section 5.1 of the emtricitabine/tenofovir disoproxil Summary of Product Characteristics need changing to enhance the information on bone effects. Annex II and the Package leaflet are 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 emtricitabine/tenofovir disoproxil the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing emtricitabine/tenofovir disoproxil 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.