25 April 2024
EMA/340999/2024
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): cobicistat / elvitegravir / emtricitabine / tenofovir disoproxil

Procedure No. EMEA/H/C/PSUSA/00010082/202308

Period covered by the PSUR: 27 August 2020 To 26 August 2023

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Scientific conclusions

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

In view of available data on bone mineral density decrease from clinical trials, the literature, spontaneous reports, the PRAC considers that a causal relationship between cobicistat / elvitegravir / emtricitabine / tenofovir disoproxil and bone mineral density decrease is at least a reasonable possibility. The PRAC also considered that the current warning/precaution on Bone effects should be further strengthened. The PRAC concluded that the product information of products containing cobicistat / elvitegravir / emtricitabine / tenofovir disoproxil should be amended accordingly.

Having reviewed the PRAC recommendation, the CHMP agrees with the PRAC overall conclusions and grounds for recommendation.

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

On the basis of the scientific conclusions for cobicistat / elvitegravir / emtricitabine / tenofovir disoproxil the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing cobicistat / elvitegravir / 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.