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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): tenofovir disoproxil

Procedure No. EMEA/H/C/PSUSA/00002892/201903

Period covered by the PSUR: 31 March 2018 to 30 March 2019

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Scientific conclusions

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

Given the declining use of didanosine in combination with tenofovir disoproxil and in the absence of cases of lactic acidosis reported with this co-administration since 2015, it is considered appropriate to remove the description of the warnings regarding this co-administration in section 4.4 of the SmPC and remove them completely from section 4.8 of the SmPC, while revising the information currently in section 4.5 of the SmPC.

On the basis of the data accumulated so far with the use of tenofovir disoproxil in the context of the prevention of Mother-To-Child transmission (MTCT) of Hepatitis B virus (HBV) infection, a statement is added in section 4.6 of the SmPC to provide the main safety data from three studies evaluating tenofovir disoproxil in this context.

Based on an updated cumulative review on lactic acidosis submitted by the MAH, with particular focus on the 55 new cases reported since the last review performed in 2014, the PRAC recommends the addition of a statement in section 4.8 of the SmPC due to the seriousness of the cases (2 fatal outcomes).

The CHMP agrees with the scientific conclusions made by the PRAC.

Grounds for the variation to the terms of the marketing authorisations

On the basis of the scientific conclusions for tenofovir disoproxil, the CHMP is of the opinion that the benefit-risk balance of the medicinal products containing tenofovir disoproxil is unchanged, subject to the proposed changes to the product information.

The CHMP recommends that the terms of the marketing authorisations should be varied.