25 June 2020
EMA/322640/2020
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 alafenamide

Procedure No. EMEA/H/C/PSUSA/00010575/201911

Period covered by the PSUR: 10/11/2018 To: 09/11/2019

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Scientific conclusions

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

Based on available data from spontaneous reports including 21 renal events which occurred in patients without history of prior TDF use or pre-existing renal impairment, the PRAC considers mandatory to inform prescribers and health care professionals about the need to monitor renal function prior and during TAF therapy as clinically appropriate, and to consider discontinuation of treatment in case of clinically significant decreases in renal function or evidence of proximal renal tubulopathy .

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 tenofovir alafenamide the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing 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.