22 February 2024
EMA/176236/2024
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): avanafil

Procedure No. EMEA/H/C/PSUSA/00010066/202306

Period covered by the PSUR: 22 June 2020 to 21 June 2023

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Scientific conclusions

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

In view of available data on central serous chorioretinopathy from the literature and spontaneous reports including in one case a close temporal relationship, a positive de-challenge and in view of a plausible mechanism of action, the PRAC considers a causal relationship between avanafil and central serous chorioretinopathy is at least a reasonable possibility. The PRAC concluded that the product information of products containing avanafil 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 avanafil the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing avanafil 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.