17 October 2024
EMA/596127/2024
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): cabotegravir (for treatment of human immunodeficiency virus type 1 (HIV-1)

Procedure No. EMEA/H/C/PSUSA/00010900/202403

Period covered by the PSUR: 18 March 2023 To: 17 March 2024

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for cabotegravir (for treatment of human immunodeficiency virus type 1 (HIV-1), the scientific conclusions of PRAC are as follows:

- In view of available data on the risk of severe cutaneous adverse reactions from the signal assessment provided by the MAH, including one key case with a close temporal relationship which has to be assed as probable, the PRAC considers that a causal relationship between cabotegravir and the severe cutaneous adverse reactions Stevens-Johnson syndrome/ Toxic epidermal necrolysis (SJS/TEN) is at least a reasonable possibility. The PRAC concluded that the product information of products containing cabotegravir should be amended accordingly.

- In view of available data on gait disturbance from clinical trials and spontaneous reports including >100 cases with a close temporal relationship in the context of injection site reactions, the PRAC considers a causal relationship between cabotegravir and injection site reactions (gait disturbance) is at least a reasonable possibility. The PRAC concluded that the product information of medicinal products containing cabotegravir (for injection) 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 cabotegravir (for treatment of human immunodeficiency virus type 1 (HIV-1) the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing cabotegravir (for treatment of human immunodeficiency virus type 1 (HIV-1) 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.