EMA/10440/2022
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

Procedure No. EMEA/H/C/PSUSA/00010900/202109

Period covered by the PSUR: 17 March 2021 to 17 September 2021

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Scientific conclusions

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

In view of available data including in some cases a close temporal relationship, and in view of a plausible mechanism of action, the PRAC considers a causal relationship between cabotegravir and "suicidal ideation" as well as "suicide attempt" at least a reasonable possibility.

Consequently, the PRAC concluded that the PTs "suicidal ideation" and "suicide attempt" should be included in SmPC section 4.8 of the product information for all Cabotegravir-containing products, with a frequency *"uncommon"* based on the number of events from clinical trials, which is endorsed by the PRAC Rapporteur. The Package leaflet should be updated accordingly.

Since five of the nine patients already had a pre-existing history of depression or psychiatric illness, the following should be included in addition to the two PTs: - *"particularly in patients with a pre-existing history of psychiatric illness".*

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