16 September 2021
EMA/508918/2021
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): dolutegravir, dolutegravir / abacavir / lamivudine, dolutegravir / lamivudine

Procedure No. EMEA/H/C/PSUSA/00010075/202101

Period covered by the PSUR: 17 January 2020 to 16 January 2021

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Scientific conclusions

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

In view of available data mostly on spontaneous reports including in some cases a close temporal relationship, and in view of a plausible mechanism of action, the PRAC considers a causal relationship between dolutegravir and "panic attack" is at least a reasonable possibility.

The data available indicate that not only patients with pre-existing psychiatric disorders are affected from this problem but also patients without any previously diagnosed psychiatric problems as well. Since there is enough evidence supporting a causal relationship between the administration of DTG-containing medicinal products and the onset of panic attack, the PRAC concluded the product information of product containing DTG should include "panic attack" as an ADR with a frequency allocation of 'uncommon'.

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 dolutegravir, dolutegravir / abacavir / lamivudine, dolutegravir / lamivudine the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing dolutegravir, dolutegravir / abacavir / lamivudine, dolutegravir / lamivudine 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.