



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

15 December 2016
EMA/CHMP/816690/2016
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (post authorisation)

Tivicay dolutegravir

On 15 December 2016, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a change to the terms of the marketing authorisation for the medicinal product Tivicay. The marketing authorisation holder for this medicinal product is ViiV Healthcare UK Limited.

The CHMP adopted an extension to the existing indication as follows ²:

"Tivicay is indicated in combination with other anti-retroviral medicinal products for the treatment of Human Immunodeficiency Virus (HIV) infected adults, ~~and~~ adolescents and children above ~~12~~ **6** years of age."

In addition, the CHMP recommended authorisation of two new strengths of tablets, 10 mg and 25 mg.

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR), and will be available in all official European Union languages after a decision on this change to the marketing authorisation has been granted by the European Commission.

¹ Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

² **New text in bold, removed text as strikethrough**

