25 February 2016
EMA/CHMP/155866/2016
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Descovy

emtricitabine / tenofovir alafenamide

On 25 February 2016, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Descovy, intended for the treatment of HIV infection. The applicant for this medicinal product is Gilead Sciences International Ltd.

Descovy will be available as film-coated tablets (200 mg/10 mg and 200 mg/25 mg). The active substances of Descovy are the antiretrovirals emtricitabine and tenofovir alafenamide (ATC code: J05AR17). Emtricitabine and tenofovir alafenamide are substrates and competitive inhibitors of HIV reverse transcriptase. After phosphorylation, they are incorporated into the viral DNA chain, resulting in chain termination.

Descovy is an alternative treatment option to the licensed tenofovir disoproxil and is expected to have similar efficacy. The most common side effect is nausea. Descovy has low impact on renal safety and bone mineral density compared with tenofovir disoproxil.

The full indication is: "Descovy is indicated in combination with other antiretroviral agents for the treatment of adults and adolescents (aged 12 years and older with body weight at least 35 kg) infected with human immunodeficiency virus type 1 (HIV 1) (see sections 4.2 and 5.1)." It is proposed that Descovy be prescribed by physicians experienced in the in the management of HIV infection.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after 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

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5520
Send a question via our website www.ema.europa.eu/contact