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Public statement

Dutrebis

Withdrawal of the marketing authorisation in the European Union

On 24 April 2017, the European Commission withdrew the marketing authorisation for Dutrebis (lamivudine / raltegravir) in the European Union (EU). The withdrawal was at the request of the marketing authorisation holder, Merck Sharp & Dohme Limited, which notified the European Commission of its decision to not to market the product in the EU for commercial reasons.

Dutrebis was granted marketing authorisation in the EU on 26 March 2015 for treatment of human immunodeficiency virus (HIV-1). The marketing authorisation was initially valid for a 5-year period.

The European Public Assessment Report (EPAR) for Dutrebis will be updated accordingly to indicate that the marketing authorisation is no longer valid.

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