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Public statement

Sustiva (efavirenz)

Withdrawal of the marketing authorisation in the European Union

On 1 February 2024, the European Commission withdrew the marketing authorisation for Sustiva (efavirenz) in the European Union (EU). The withdrawal was at the request of the marketing authorisation holder, Bristol-Myers Squibb Pharma EEIG, which notified the European Commission of its decision to permanently discontinue the marketing of the product for commercial reasons.

Sustiva was granted marketing authorisation in the EU on 28 May 1999 for treatment of HIV-1 infection. The marketing authorisation was initially valid for a 5-year period. It was subsequently renewed for an additional 5-year period in 2004, and in 2009. It was then granted unlimited validity in 2014.

There are generic medicinal products of efavirenz authorised and marketed in the EU.

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European Public Assessment Report (EPAR) for Sustiva will be updated to indicate that the marketing authorisation is no longer valid.

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