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Public statement

Zerit

Withdrawal of the marketing authorisation in the European Union

On 24 June 2020, the European Commission withdrew the marketing authorisation for Zerit (stavudine) 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.

Zerit was granted marketing authorisation in the EU on 8 May 1996 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 2006. It was then granted unlimited validity in 2011. The product had not been marketed in the EU since 2020.

The European Public Assessment Report (EPAR) for Zerit will be updated to indicate that the marketing authorisation is no longer valid.

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