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Public statement

Hepsera (adefovir dipivoxil)

Withdrawal of the marketing authorisation in the European Union

On 31 December 2022, the European Commission withdrew the marketing authorisation for Hepsera (adefovir dipivoxil) in the European Union (EU). The withdrawal was at the request of the marketing authorisation holder, Gilead Sciences Ireland UC, which notified the European Commission of its decision to permanently discontinue the marketing of the product for commercial reasons.

Hepsera was granted marketing authorisation in the EU on 6 March 2003 for the treatment of adults with chronic hepatitis B. The marketing authorisation was initially valid for a 5-year period. It was then granted unlimited validity in 2008.

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European Public Assessment Report (EPAR) for Hepsera will be updated to indicate that the marketing authorisation is no longer valid.

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