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Public statement

Rebetol (ribavirin)

Withdrawal of the marketing authorisation in the European Union

On 18 October 2023, the European Commission withdrew the marketing authorisation for Rebetol (ribavirin) in the European Union (EU). The withdrawal was at the request of the marketing authorisation holder, Merck Sharp & Dohme B.V., which notified the European Commission of its decision to permanently discontinue the marketing of the product for commercial reasons.

Rebetol was granted marketing authorisation in the EU on 7 May 1999 for the treatment of hepatitis C. The marketing authorisation was initially valid for a 5-year period. It was subsequently renewed for an additional 5-year period in 2004. It was then granted unlimited validity in 2009.

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European Public Assessment Report (EPAR) for Rebetol will be updated to indicate that the marketing authorisation is no longer valid.

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