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Public statement

Ribavirin Mylan

Withdrawal of the marketing authorisation in the European Union

On 27 October 2020, the European Commission withdrew the marketing authorisation for Ribavirin Mylan (ribavirin) in the European Union (EU). The withdrawal was at the request of the marketing authorisation holder, Mylan S.A.S, which notified the European Commission of its decision not to market the product in the EU for commercial reasons.

Ribavirin Mylan was granted marketing authorisation in the EU on 10 June 2010 for treatment of chronic hepatitis C. The marketing authorisation was initially valid for a 5-year period. It was then granted unlimited validity in 2015. The product had not been marketed in the EU since June 2018.

Ribavirin Mylan is a generic medicine of Rebetol. There are other generic medicinal products of Rebetol authorised and marketed in the EU.

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Public Assessment Report (EPAR) for Ribavirin Mylan will be updated to indicate that the marketing authorisation is no longer valid.

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