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Public statement

Incivo

Expiry of the marketing authorisation in the European Union

The marketing authorisation for Incivo (telaprevir) expired on 22 September 2016 following the decision of the marketing authorisation holder, Janssen-Cilag International N.V., not to apply for a renewal of the marketing authorisation.

Janssen-Cilag International N.V. confirmed that it did not apply for renewal of the authorisation due to the fast reduction in the use of telaprevir after the introduction and approval of newer protease inhibitors and of interferon-free treatment combinations. This decision is not driven by any safety, efficacy or quality issue.

Incivo was granted marketing authorisation in the European Union (EU) on 19 September 2011 for treatment of genotype 1 chronic hepatitis C. The marketing authorisation was valid for a 5-year period.

The European Public Assessment Report (EPAR) for Incivo will be updated accordingly to reflect the fact that the marketing authorisation is no longer valid.

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