



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

22 June 2017
EMA/384974/2017
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (post authorisation)

Harvoni

ledipasvir / sofosbuvir

On 22 June 2017, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a change to the terms of the marketing authorisation for the medicinal product Harvoni. The marketing authorisation holder for this medicinal product is Gilead Sciences International Ltd.

The CHMP adopted an extension to the existing indication as follows:²

“Harvoni is indicated for the treatment of chronic hepatitis C (CHC) in adults **and in adolescents aged 12 to < 18 years** (see sections 4.2, 4.4 and 5.1).

For hepatitis C virus (HCV) genotype-specific activity see sections 4.4 and 5.1.”

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR), and will be available in all official European Union languages after a decision on this change to the marketing authorisation has been granted by the European Commission.

¹ Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

² New text in bold

