25 September 2014
EMA/CHMP/572137/2014
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Harvoni

Ledipasvir / sofosbuvir

On 25 September 2014, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Harvoni, 400 mg / 90 mg, film coated tablet, intended for chronic hepatitis C (CHC) in adults. The applicant for this medicinal product is Gilead Sciences International Ltd. They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The active substance of Harvoni is ledipasvir / sofosbuvir, a fixed dose combination of two direct acting antivirals (ATC code not yet assigned). The active metabolite of sofosbuvir is a pangenotypic inhibitor of the hepatitis C virus (HCV) NS5B RNA polymerase, while ledipasvir targets the NS5A protein of the virus.

The benefits with Harvoni with or without ribavirin are very high efficacy against genotypes 1, 3 and -4, including patients post-transplant and/or with compensated cirrhosis. The most common side effects are fatigue and headache.

A pharmacovigilance plan for Harvoni will be implemented as part of the marketing authorisation.

The approved indication is: "Harvoni is indicated for the treatment of chronic hepatitis C (CHC) in adults (see sections 4.2, 4.4 and 5.1). For HCV genotype specific activity see sections 4.4 and 5.1." It is proposed that Harvoni is prescribed by physicians experienced in the treatment of chronic hepatitis C (CHC) in adults.

Detailed recommendations for the use of this product will be described in the Summary of Product Characteristics (SmPC), which will be published in the European Public Assessment Report (EPAR) and made available in all official European Union languages after 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.

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The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit-to-risk balance for Harvoni and therefore recommends the granting of the marketing authorisation.