EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee for Medicinal Products for Human Use (CHMP)

Scientific conclusions and grounds recommending the variation to the terms of the marketing authorisation

International non-proprietary name: simeprevir

Procedure No. EMEA/H/C/PSUSA/00010255/201411

Period covered by the PSUR: 22 May 2014 – 21 November 2014

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR for simeprevir, the scientific conclusions of CHMP are as follows:

Hepatic decompensation and hepatic failure, including fatal cases, have been reported post-marketing in patients treated with simeprevir in combination with peginterferon alfa and ribavirin and in combination with sofosbuvir. Although causality is difficult to establish due to background advanced liver disease, a potential risk cannot be excluded. Therefore, a warning on the risk of hepatic decompensation and hepatic failure has been included in the product information for simeprevir, indicating that liver function tests should be monitored before and as clinically indicated during simeprevir combination therapy in patients who are at high risk for hepatic decompensation or hepatic failure.

Two cases of bradycardia have been observed when simeprevir is used in combination with sofosbuvir and concomitant amiodarone. Cases are potentially life threatening; therefore, warnings have been included in relevant sections in the product information providing recommendations should concomitant use of simeprevir and amiodarone be considered necessary.

Therefore, in view of available data regarding simeprevir, the PRAC considered that changes to the product information were warranted.

The CHMP agrees with the scientific conclusions made by the PRAC.

Grounds recommending the variation to the terms of the Marketing Authorisation

On the basis of the scientific conclusions for simeprevir the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing simeprevir is favourable subject to the proposed changes to the product information.

The CHMP recommends that the terms of the Marketing Authorisation(s) should be varied.