European Medicines Agency
Evaluation of Medicines for Human Use

London, 24 September 2009
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COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
POST-AUTHORISATION SUMMARY OF POSITIVE OPINION*
for
REBETOL

International Nonproprietary Name (INN): ***ribavirin***

On 24 September 2009 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion** to recommend the variation to the terms of the marketing authorisation for the medicinal product Rebetol. The Marketing Authorisation Holder for this medicinal product is Schering-Plough Europe.

The CHMP adopted a change to an indication and a new indication as follows***:

Rebetol is indicated for the treatment of chronic hepatitis C virus (HCV) infection in adults, **children 3 years of age and older and adolescents** and must only be used as part of a combination regimen with peginterferon alfa-2b or interferon alfa-2b. Rebetol monotherapy must not be used.

There is no safety or efficacy information on the use of Rebetol with other forms of interferon (i.e., not alfa-2b).

Naïve patients
Adult patients: Rebetol is indicated, in combination with interferon alfa-2b or peginterferon alfa-2b, for the treatment of adult patients with chronic hepatitis C, not previously treated, without liver decompensation, with elevated alanine aminotransferase (ALT), who are positive for hepatitis C viral ribonucleic acid (HCV-RNA). In combination with peginterferon alfa-2b also patients with **compensated cirrohosis and/or** clinically stable HIV co-infection are included (see section 4.4).

Children **3 years of age and older** and adolescents: Rebetol is indicated, in a combination regimen with **peginterferon alfa-2b** or interferon alfa-2b, for the treatment of children 3 years of age and older and adolescents, who have chronic hepatitis C, not previously treated, without liver decompensation, and who are positive for HCV-RNA.
When deciding to not to defer treatment until adulthood, it is important to consider that the combination therapy induced a growth inhibition. The reversibility of growth inhibition is uncertain. The decision to treat should be made on a case by case basis (see section 4.4).

Previously treated patients
Adult patients: Rebetol is indicated, in combination with interferon alfa-2b, for the treatment of adult patients with chronic hepatitis C who have previously responded (with normalisation of ALT at the end of treatment) to interferon alfa monotherapy but who have subsequently relapsed. Rebetol is indicated, in combination with peginterferon alfa-2b, for the treatment of adult patients with chronic hepatitis C who have failed previous treatment with interferon alpha (pegylated or non-pegylated) alone or in combination with ribavirin (see section 5.1)**.**

* Summaries of positive opinion are published without prejudice to the Commission Decision, which will normally be issued within 44 days (Type II variations) and 67 days (Annex II applications) from adoption of the Opinion.

** Marketing Authorisation Holders may request a re-examination of any CHMP opinion, provided they notify the EMEA in writing of their intention to request a re-examination within 15 days of receipt of the opinion.

*** The text in bold represents the new or the amended indication.

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Detailed conditions for the use of this product will be described in the updated Summary of Product Characteristics (SPC) which will be published in the revised European Public Assessment Report (EPAR) and will be available in all official European Union languages after the variation to the marketing authorisation has been granted by the European Commission.