18 March 2010
EMA/CHMP/143985/2010
Committee for medicinal products for human use (CHMP)

Summary of opinion[1] (initial authorisation)

Ribavirin Three Rivers

ribavirin

On 18 March 2010 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Ribavirin Three Rivers, 200mg, Capsule, Hard intended for the treatment of chronic hepatitis C. The applicant for this medicinal product is Three Rivers Global Pharma Limited. 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 Ribavirin Three Rivers is ribavirin, a purine nucleoside analogue which is active against a number of DNA and RNA viruses. Several mechanisms of action are proposed for ribavirin.

Ribavirin Three Rivers is a generic of Rebetol, which has been authorised in the EU since 7 May 1999. Studies have demonstrated the satisfactory quality of Ribavirin Three Rivers, and its bioequivalence with Rebetol. A question-and-answer document on generic medicines can be found here.

The approved indication is as follows: "Ribavirin Three Rivers is indicated for the treatment of chronic hepatitis C and must only be used as part of a combination regimen with interferon alfa-2b (adults, children (3 years of age and older) and adolescents). Ribavirin monotherapy must not be used. There is no safety or efficacy information on the use of Ribavirin with other forms of interferon (i.e., not alfa-2b)".

A pharmacovigilance plan for Ribavirin Three Rivers, as for all medicinal products, will be implemented as part of the marketing authorisation.

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 will be 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 Ribavirin Three Rivers and therefore recommends the granting of the marketing authorisation.