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
PEGINTRON

International Nonproprietary Name (INN): ***peginterferon alfa-2b***

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 PegIntron. 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***:

Adult patients:
PegIntron is indicated for the treatment of adult patients with chronic hepatitis C who are positive for HCV-RNA, including **patients with compensated cirrhosis and/or co-infected** with clinically stable HIV (see section 4.4).

The best way to use PegIntron in this indication is in combination with ribavirin.

This combination is indicated in naïve patients including patients with clinically stable HIV co-infection and in patients who have failed previous treatment with interferon alpha (pegylated or nonpegylated) and ribavirin combination therapy or interferon alpha monotherapy (see section 5.1).

Interferon monotherapy, including PegIntron, is indicated mainly in case of intolerance or contraindication to ribavirin.

Children 3 years of age and older and adolescents :
PegIntron is indicated in a combination regimen with ribavirin 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 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).

Please refer also to the ribavirin Summary of Product Characteristics (SPC) **for capsules or oral solution** when PegIntron is to be used in combination with ribavirin.

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.

* 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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