European Medicines Agency
Evaluation of Medicines for Human Use

London, 23 October 2008
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COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
POST-AUTHORISATION SUMMARY OF POSITIVE OPINION*
for
PEGASYS

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

On 23 October 2008 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 Pegasys. The Marketing Authorisation Holder for this medicinal product is Roche Registration Ltd.

The CHMP adopted a change to an indication as follows:

"The optimal way to use Pegasys in patients with chronic hepatitis C is in combination with ribavirin.

The combination of Pegasys and ribavirin is indicated in naive patients and patients who have failed previous treatment with interferon alpha (pegylated or non-pegylated) alone or in combination therapy 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.

For information, the full indication for Pegasys will be as follows***:

Chronic hepatitis B:
Pegasys is indicated for the treatment of HBeAg-positive or HBeAg-negative chronic hepatitis B in adult patients with compensated liver disease and evidence of viral replication, increased ALT and histologically verified liver inflammation and/or fibrosis (see sections 4.4 and 5.1).

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

The optimal way to use Pegasys in patients with chronic hepatitis C is in combination with ribavirin. **The combination of Pegasys and ribavirin is indicated in naive patients and patients who have failed previous treatment with interferon alpha (pegylated or non-pegylated) alone or in combination therapy with ribavirin.**

Monotherapy is indicated mainly in case of intolerance or contraindication to ribavirin.

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* 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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