17 January 2013
EMA/CHMP/29025/2013
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Pegasys

peginterferon alfa-2a

On 17 January 2013, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a 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. They may request a re-examination of the CHMP opinion, provided that they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The extension adopted by the CHMP is to add a new strength (90 µg) to the existing product range.

The CHMP also adopted a new indication, as follows:

Paediatric patients 5 years of age and older:

Pegasys in combination with ribavirin is indicated for the treatment of chronic hepatitis C in treatment-naïve children and adolescents 5 years of age and older, who are positive for serum HCV-RNA.

When deciding to initiate treatment in childhood, it is important to consider growth inhibition induced by combination therapy. The reversibility of growth inhibition is uncertain. The decision to treat should be made on a case by case basis (see section 4.4).

Detailed conditions for the use of this product will be described in the updated summary of product characteristics (SmPC), 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 indications for Pegasys will be as follows[2]:

Chronic hepatitis B

Pegasys is indicated for the treatment of hepatitis B envelope antigen (HBeAg)-positive or HBeAg-negative chronic hepatitis B (CHB) in adult patients with compensated liver disease and evidence of

[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.
[2] The text in bold represents the new or the amended indication.

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viral replication, increased ALT and histologically verified liver inflammation and/or fibrosis (see sections 4.4 and 5.1).

Chronic hepatitis C

Adult patients

Pegasys is indicated for the treatment of chronic hepatitis C (CHC) in adult patients who are positive for serum hepatitis C virus ribonucleic acid (HCV-RNA). This includes 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 treatment-naïve patients and in adult 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.

Paediatric patients 5 years of age and older:

Pegasys in combination with ribavirin is indicated for the treatment of chronic hepatitis C in treatment-naïve children and adolescents 5 years of age and older who are positive for serum HCV-RNA.

When deciding to initiate treatment in childhood, it is important to consider growth inhibition induced by combination therapy. The reversibility of growth inhibition is uncertain. The decision to treat should be made on a case by case basis (see section 4.4).