12 October 2017
EMA/CHMP/634272/2017
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Pegasys

peginterferon alfa-2a

On 12 October 2017, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a change to the terms of the marketing authorisation for the medicinal product Pegasys. The marketing authorisation holder for this medicinal product is Roche Registration Limited.

The CHMP adopted an extension to an existing indication as follows:

"Pegasys is indicated for the treatment of HBeAg-positive CHB in non-cirrhotic children and adolescents 3 years of age and older with evidence of viral replication and persistently elevated serum ALT levels. With respect to the decision to initiate treatment in paediatric patients see sections 4.2, 4.4 and 5.1."

For information, the full indications for Pegasys will be as follows [2]:

"Chronic hepatitis B

Adult patients

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

Paediatric patients 3 years of age and older

Pegasys is indicated for the treatment of HBeAg-positive CHB in non-cirrhotic children and adolescents 3 years of age and older with evidence of viral replication and persistently elevated serum ALT levels. With respect to the decision to initiate treatment in paediatric patients see sections 4.2, 4.4 and 5.1.

Chronic hepatitis C

Adult patients

[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
[2] New text in bold

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Pegasys is indicated in combination with other medicinal products, for the treatment of chronic hepatitis C (CHC) in patients with compensated liver disease (see sections 4.2, 4.4 and 5.1).

For hepatitis C virus (HCV) genotype specific activity, see sections 4.2 and 5.1.

Paediatric patients 5 years of age and older

Pegasys in combination with ribavirin is indicated for the treatment of CHC 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 recommendations 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 a decision on this change to the marketing authorisation has been granted by the European Commission.