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EMA/CHMP/51083/2014
Committee for Medicinal Products for Human Use (CHMP)

Pegasys

Scientific conclusions and grounds recommending the variation to the terms of the marketing authorisation

International non-proprietary name: Peginterferon alfa-2a

Procedure No. EMEA/H/C/000395/PSUV/0072

Period covered by the PSUR: 5 July 2012 – 4 July 2013

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR for Pegasys, the scientific conclusions of PRAC are as follows:

PRAC has recommended labelling changes to include tongue pigmentation as an adverse drug reaction and to include a warning concerning glucose monitoring.

At the request of the PRAC the MAH carried out a review in August 2013 to assess the possible association between tongue pigmentation and exposure to peginterferon alfa-2a.

Based on the available information and analyses there are sufficient data to indicate a reasonable causal association between the event of tongue pigmentation and the use of Pegasys. On this basis PRAC requested the MAH to update section 4.8 of the SmPC and section 4 of the package leaflet to reflect the new adverse drug reaction tongue pigmentation

The PRAC also raised a concern associated with glucose monitoring. Hepatitis C therapy with pegylated interferon plus ribavirin has been reported to cause a significant fall in A1C values without a change to fasting plasma glucose levels in diabetic patients. As such the PRAC requested the MAH to add a warning to section 4.4 of the SmPC concerning glucose monitoring during therapy with Pegasys. The package leaflet is updated accordingly.

The CHMP agrees with the scientific conclusions made by the PRAC.

Grounds recommending the variation to the terms of the Marketing Authorisation

On the basis of the scientific conclusions for Pegasys, the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing the active substance Peginterferon alfa-2a is favourable subject to the proposed changes to the product information.

The CHMP recommends that the terms of the Marketing Authorisation should be varied.