EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

20 March 2014
EMA/CHMP/322518/2014
Committee for Medicinal Products for Human Use (CHMP)

PegIntron

International non-proprietary name: PEGINTERFERON ALFA-2B

Procedure No. EMEA/H/C/000280/PSUV/0117

Period covered by the PSUR: 25.07.2010 to 24.07.2013

Scientific conclusions and grounds recommending the variation to the terms of the Marketing Authorisation

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Scientific conclusions

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

The overall benefit of PegIntron in the authorised indications was not altered as a result of new information that became available during the reporting period of this PSUR.

Based on a review of data concerning tongue pigmentation provided in this PSUR as well as similar data provided in the PSUR of another peginterferon alfa containing product, the PRAC considered that tongue pigmentation should be added as an Adverse Drug Reaction to section 4.8 of the SmPC and that the package leaflet be 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 PegIntron, the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing the active substance Peginterferon alfa-2b is favourable subject to the proposed changes to the product information.

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