EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee for Medicinal Products for Human Use (CHMP)

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

International non-proprietary name: temsirolimus

Procedure No. EMEA/H/C/PSUSA/00002887/201503

Period covered by the PSUR: 30 May 2012 - 31 March 2015

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Scientific conclusions

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

Based on a PRAC request received after data lock point of this PSUR, the MAH provided a cumulative review of available information on Myocardial infarction (MI) and closely related terms events. Although, the outcome of this review was inconclusive regarding an association of temsirolimus with myocardial infarction, temsirolimus is known to increase risk factors for MI such as hyperlipidaemia, hypercholesterolemia, hyperglycaemia and cardiovascular disorders. PRAC considers that an association between temsirolimus and the risk of MI cannot be excluded and therefore a warning should be added to the product information.

Cumulatively, there were respectively 26, 20 and 514 reports of decreased red blood cells, decreased platelets and malignancy reported with temsirolimus. PRAC considers that an association between temsirolimus and the risk of anaemia and malignancies cannot be excluded and therefore a warning should be added to the product information.

Therefore, in view of the data presented in the reviewed PSUR(s), the PRAC considered that changes to the product information of medicinal products containing temsirolimus were warranted.

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

Grounds for the variation to the terms of the Marketing Authorisation(s)

On the basis of the scientific conclusions for temsirolimus the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing temsirolimus is favourable subject to the proposed changes to the product information

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