EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee for Medicinal Products for Human Use (CHMP)

Afinitor

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

International non-proprietary name: EVEROLIMUS

Procedure No. EMEA/H/C/001038/PSUV/0039

Period covered by the PSUR: 1 April 2013 – 31 March 2014

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Scientific conclusions

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

Afinitor holds immunosuppressive properties and may predispose patients to infections with opportunistic pathogens. A warning for pneumocystis jirovecii pneumonia (PJP) has been included in the product labelling for Zortress (everolimus in Transplant setting).

In order to ensure that pneumocystis jirovecii (carinii) pneumonia (PJP, PCP) is considered in the differential diagnosis of interstitial lung disease and to harmonize Afinitor/Votubia labels globally, instrumental changes are proposed to the SmPC. Prophylaxis for PJP/PCP should be considered when concomitant use of corticosteroids of other immunosuppressive agents are required.

Therefore, in view of available data regarding pneumocystis jirovecii/carinii pneumonia, the PRAC considered that changes to the product information were warranted.

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 Afinitor, the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing the active substance EVEROLIMUS is favourable subject to the proposed changes to the product information.

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