18 December 2014
EMA/133081/2015

Committee for Medicinal Products for Human Use (CHMP)

Sutent

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

International non-proprietary name: SUNITINIB

Procedure No. EMEA/H/C/000687/PSUV/0052

Period covered by the PSUR: 1 May 2013 – 30 April 2014

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Scientific conclusions

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

Overall, based on the assessment of the cumulative and interval safety information available as of the data lock point for current PSUR period, the PRAC considers that the benefit-risk assessment for sunitinib in the approved treatment indication remains favourable. However, the PRAC considered that the MAH existing warning on QT interval prolongation required to be updated to recommend caution with use in patients who are taking medicinal products that can prolong QT interval in order to better minimize the important identified risk of Torsade de Points /QTc prolongation of sunitinib. Consequently, the warning in section 4.4 of the SmPC is updated. No changes to the package leaflet are warranted as the existing information is considered adequate.

Therefore, in view of available data regarding QT interval prolongation, 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 Sutent, the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing the active substance SUNITINIB is favourable subject to the proposed changes to the product information.

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