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Committee for Medicinal Products for Human Use (CHMP)

Nexavar

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

International non-proprietary name: SORAFENIB

Procedure No. EMEA/H/C/000690/PSUV/0037

Period covered by the PSUR: 1 January 2011 – 31 December 2013

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Scientific conclusions

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

Evaluation of the signal hepatic/metabolic encephalopathy revealed three literature cases of toxic encephalopathy in advanced HCC patients with cirrhosis. Based on these cases a causal relationship between sorafenib treatment and encephalopathy was concluded and the adverse reaction encephalopathy is recommended to be included in the product information with a frequency of unknown.

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

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