EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee for Medicinal Products for Human Use (CHMP)

Stivarga

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

International non-proprietary name: regorafenib

Procedure No. EMEA/H/C/002573/PSUV/0004

Period covered by the PSUR: 26 September 2013 – 26 March 2014

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Scientific conclusions

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

Following a request from the PRAC, the MAH submitted a cumulative review of cases of Drug-induced Hypersensitivity Syndrome / Drug reaction with eosinophilia and systemic symptoms (DIHS/DRESS) with the present PSUR. 15 cases were identified and assessed by the MAH as suggestive for systemic hypersensitivity reactions (HSRs) with organ involvement, i.e. to be further evaluated as suspected DIHS/DRESS cases. The MAH stated that from the cases evaluated, none would qualify as DIHS/DRESS according to either of the diagnostic criteria systems. However, some of the cases suggest systemic hypersensitivity reactions with organ involvement such as increased liver function tests. Therefore, the MAH proposed to include the term 'hypersensitivity reaction' as a new adverse drug reaction in the SmPC, in order to alert physicians of potential clinically relevant regorafenib-associated hypersensitivity reactions not covered by adverse drug reactions already listed in the SmPC.

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

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