EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee for Medicinal Products for Human Use (CHMP)

Scientific conclusions and grounds for the variation to the terms of the marketing authorisation(s)

Active substance(s): regorafenib

Procedure No. EMEA/H/C/PSUSA/00010133/201709

Period covered by the PSUR: 27 Sep 2016 – 26 Sep 2017

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for regorafenib, the scientific conclusions of CHMP are as follows:

Based on postmarketing data and data from a placebo controlled study, a possible causal association with regorafenib and peripheral neuropathy cannot be excluded; therefore, PRAC considered that section 4.8 of the SmPC should be updated to include 'peripheral neuropathy' with the frequency common; the package leaflet is updated accordingly.

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 regorafenib the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing regorafenib is unchanged subject to the proposed changes to the product information

The CHMP recommends that the terms of the marketing authorisation(s) should be varied.