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): vemurafenib

Procedure No. EMEA/H/C/PSUSA/00009329/201608

Period covered by the PSUR: 17 August 2015 to 16 August 2016

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Scientific conclusions

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

The signal of Dupuytren's contracture/Fibromatosis/Peyronie's disease was reviewed by the MAH. From an estimated exposure of 46,000 patients, there was in total 11 cases of Dupuytren's contracture and 4 cases of plantar fibromatosis where possible relationship to vemurafenib treatment was considered. The product information is updated to provide warnings and precautions for use in case of Dupuytren's contracture and plantar fascial fibromatosis. Both adverse drug reactions have been included in the Product Information with common and uncommon frequency respectively.

Therefore, in view of the data presented in the reviewed PSUR, the PRAC considered that changes to the product information of medicinal products containing vemurafenib were warranted.

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 vemurafenib the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing vemurafenib 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.