EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee for Medicinal Products for Human Use (CHMP)

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

International non-proprietary name: fingolimod

Procedure No. EMEA/H/C/PSUSA/00001393/201502

Period covered by the PSUR: 01 March 2014 – 28 February 2015

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Scientific conclusions

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

During this PSUR (EU PSUR 7) the MAH discussed risks related to fingolimod, and presented the data from spontaneous reporting, notably for skin cancers, infection risks including opportunistic infections and hypersensitivity. Especially vigilance for skin lesions is warranted and a dermatological assessment is needed in case suspicious lesions are detected. In addition, cases of infections with opportunistic pathogens such as viral or bacterial have been reported and this information should be made available to healthcare professionals. Upon treatment initiation hypersensitivity reactions including rash, urticaria and angioedema have been reported. The MAH proposed wording for amendments to the product information in relation to all the above mentioned cases.

In addition the MAH submitted data from spontaneous reporting for adverse events including cases of lymphoma, T-wave inversion, peripheral oedema and nausea. After review of this data the PRAC considered that information should also be presented in the list of adverse events in the product information to increase vigilance by the healthcare professionals. Especially for lymphoma a statement is already included under section 4.8 of the summary of product characteristics; this preferred term should also be listed in the ADR table in the same section, and in the relevant section of the package leaflet.

In conclusion and in view of all 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 fingolimod the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing fingolimod is favourable subject to the proposed changes to the product information

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