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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): mycophenolate mofetil, mycophenolic acid

Procedure No. EMEA/H/C/PSUSA/00010550/201705

Period covered by the PSUR: 3 May 2016 - 2 May 2017

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSURs for mycophenolate mofetil, mycophenolic acid, the scientific conclusions of CHMP are as follows:

Following a review of all available information regarding pregnancies following paternal exposure to mycophenolate mofetil or mycophenolic acid, including a review of all non-clinical data and information on transmission of mycophenolic acid via the semen, the PRAC concluded that the data does not highlight any patterns or an increase in congenital malformations or spontaneous abortions. The PRAC therefore recommended to amend the product information, to update information on teratogenic effects and pregnancy as well as the contraception recommendations for male patients. Additional amendments have been made regarding use of contraception in women and pregnancy testing, to clarify the requirements.

The CHMP agrees with the scientific conclusions made by the PRAC.

Grounds for the variation to the terms of the marketing authorisations

On the basis of the scientific conclusions for mycophenolate mofetil, mycophenolic acid, the CHMP is of the opinion that the benefit-risk balance of the medicinal products containing mycophenolate mofetil, mycophenolic acid is unchanged subject to the proposed changes to the product information.

The CHMP recommends that the terms of the marketing authorisations should be varied.