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): dimethyl fumarate (multiple sclerosis)

Procedure No. EMEA/H/C/PSUSA/00010143/201903

Period covered by the PSUR: 25 March 2017 to 25 March 2019

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

Scientific conclusions

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

There was no case explicitly reporting Fanconi syndrome in the Multiple Sclerosis (MS) indication; however, it has been reported in literature that that female patients with psoriasis treated long-term with fumaric acid esters seem to be at particular risk. The limited long-term experience with Tecfidera could contribute to the low evidence regarding a potential association of dimethyl fumarate and Fanconi syndrome in the MS indication. Since early diagnosis of Fanconi syndrome and discontinuation of the potentially causative drug, e.g. dimethyl fumarate, are important steps to prevent the onset of renal impairment and osteomalacia, the PRAC recommends the inclusion of a warning in SmPC section 4.4 to make physicians aware of the potential risk of Fanconi syndrome including the description of corresponding symptoms. The Package leaflet should be 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 dimethyl fumarate (multiple sclerosis) the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing dimethyl fumarate (multiple sclerosis) 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.