



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): apremilast

Procedure No. EMEA/H/C/PSUSA/00010338/201603

Period covered by the PSUR: 21 September 2015 to 20 March 2016



Scientific conclusions

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

Psoriasis and Psoriatic Arthritis are associated with impairments in health-related quality of life even in mild cases. These events may lead to potential adverse effects on mental health such as depression and suicidal ideation and behaviour. Therefore, suicidal related events and depression are more common in patients with psoriasis and psoriasis arthritis than in the general population.

However, based on a cumulative review on "depression" and "suicidal ideation and behaviour", there is evidence to suggest a casual association between depression and suicidal ideation and behaviour with the use of apremilast.

In terms of depression, 220 initial cases post-marketing, 42 of them were considered serious were reported during the PSUR reporting period. Among these 42 serious cases: 25 required permanent discontinuation, 5 also experienced suicidal ideation, 1 case had positive dechallenge and rechallenge. In the clinical trials, 11 Depression SAEs were reported in apremilast group versus 0 in the placebo group.

In relation to suicidal ideation and behaviour, 19 initial cases post-marketing were reported: 2 completed suicide, 13 suicidal ideation, 3 depression suicide and 1 suicidal behaviour. Apremilast was permanently discontinued in 16 of the 19 cases. In the cumulative review, 32 cases out of 65 reported positive dechallenge.

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

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

Grounds for the variation to the terms of the marketing authorisation

On the basis of the scientific conclusions for apremilast the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing apremilast is unchanged subject to the proposed changes to the product information.

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