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Committee for Medicinal Products for Human Use (CHMP)

Aubagio

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

Active substance:TERIFLUNOMIDE

Procedure no.: EMEA/H/C/PSUSA/00010135/201409

Period covered by the PSUR: 26-Feb-2014 to 12-Sep-2014

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Scientific conclusions

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

During the reporting period of this PSUR, there have been two cases of Stevens-Johnson syndrome and two cases reported with skin exfoliation, seven cases of Stevens-Johnson syndrome and 27 cases reporting skin exfoliation cumulatively. Therefore, the PRAC considered that the information in the section 4.4 of the SmPC on the lack of severe skin reactions from clinical trials should be amended as it does not reflect the current safety profile of this medicinal product. In addition, section 4.8 of the SmPC should be updated to include information on the fact that cases of severe skins reactions have been reported with teriflunomide post-marketing. The PL should be updated accordingly.

Therefore, in view of available data regarding severe skin reactions, 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 TERIFLUNOMIDE the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing TERIFLUNOMIDE is favourable subject to the proposed changes to the product information

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