



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: lapatinib

Procedure No. EMEA/H/C/PSUSA/00001829/201409

Period covered by the PSUR: 13 March 2014 - 12 September 2014



Scientific conclusions

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

In the clinical trial program for lapatinib there were two cases of erythema multiforme (EM) while no cases of Stevens-Johnson Syndrome (SJS) or toxic epidermal necrolysis (TEN) were reported. Out of the 41 cases retrieved from the MAH worldwide safety database, six cases were further reviewed. It is recognised that these cases were confounded by concomitant medications. However, in one case of SJS (as judged by the dermatologist but argued against by the MAH as not entirely consistent with SJS) there was a positive rechallenge when lapatinib alone was reintroduced.

Based on the available data the PRAC concluded that section 4.4 should be updated to include a warning about serious skin reactions and that the product should be discontinued if these reactions are suspected. In addition, section 4.8 should be updated to add serious cutaneous reactions with a frequency "unknown" and the PL should be updated accordingly.

Therefore, in view of available data regarding serious cutaneous 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 lapatinib the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing lapatinib is favourable subject to the proposed changes to the product information

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