EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

23 April 2015
EMA/CHMP/509036/2015
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: denosumab (indicated in fractures, bone neoplasm metastasis)

Procedure No. EMEA/H/C/PSUSA/00009119/201409

Period covered by the PSUR: 27 September 2013 - 26 September 2014

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR for denosumab (indicated in fractures, bone neoplasm metastasis), the scientific conclusions of CHMP are as follows:

With regards to the risk of Osteonecrosis of the jaw (ONJ), it is recommended that the product information is revised to reflect the current knowledge on ONJ and to optimise risk minimisation. Changes to the product information include the addition of a contraindication to ensure that treatment is not initiated while there are any unhealed lesions in the mouth from dental or oral surgery.

In addition, although the risk for ONJ may be well known for the prescribers, further awareness on such risk is needed for the patients. Thus, it is considered warranted to implement a patient reminder card as an additional risk minimisation measure for ONJ. The wording for the reminder card has been agreed by the PRAC.

Therefore, in view of available data regarding denosumab (indicated in fractures, bone neoplasm metastasis), the PRAC considered that changes to the product information and conditions of the marketing authorisation 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 denosumab (indicated in fractures, bone neoplasm metastasis) the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing denosumab (indicated in fractures, bone neoplasm metastasis) is favourable subject to the proposed changes to the product information.

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