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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): denosumab (indicated for osteoporosis and for bone loss associated with hormone ablation in prostate cancer)

Procedure No. EMEA/H/C/PSUSA/00000954/201609

Period covered by the PSUR: 27 September 2015-26 September 2016

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for denosumab (indicated for osteoporosis and for bone loss associated with hormone ablation in prostate cancer), the scientific conclusions of CHMP are as follows:

Osteonecrosis of external auditory canal (OEAC) has now been reported in patients treated with Prolia. The underlying mechanism is considered similar to osteonecrosis of the jaw. OEAC is an identified risk for bisphosphonates since some years but was considered initially as a potential risk for denosumab on the basis of only two cases out of which the other was radionecrosis. OEAC should be included in the adverse drug reactions (ADRs) for Prolia and a relevant warning should be introduced, similar to the warning in the product information of bisphosphonates.

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 denosumab (indicated for osteoporosis and for bone loss associated with hormone ablation in prostate cancer) the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing denosumab (indicated for osteoporosis and for bone loss associated with hormone ablation in prostate cancer) 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.