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Committee for Medicinal Products for Human Use (CHMP

Prolia

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

Active substance: DENOSUMAB (indicated for bone resorption, osteoporosis and postmenopausal)

Procedure no.: EMEA/H/C/PSUSA/00000954/201409

Period covered by the PSUR: 27.09.13 - 26.09.14

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR for DENOSUMAB (indicated for the treatment of osteoporosis in postmenopausal women and in men at increased risk of fractures, and for the treatment of bone loss associated with hormone ablation in men with prostate cancer at increased risk of fractures), 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 optimize risk minimisation.

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, 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 for the treatment of osteoporosis in postmenopausal women and in men at increased risk of fractures, and for the treatment of bone loss associated with hormone ablation in men with prostate cancer at increased risk of fractures) the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing DENOSUMAB is favourable subject to the proposed changes to the product information

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