



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

25 April 2014  
EMA/CHMP/208646/2014  
Committee for Medicinal Products for Human Use (CHMP)

## Summary of opinion<sup>1</sup> (post authorisation)

---

### Prolia

#### denosumab

On 25 April 2014, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a variation to the terms of the marketing authorisation for the medicinal product Prolia. The marketing authorisation holder for this medicinal product is Amgen Europe B.V. They may request a re-examination of the CHMP opinion, provided that they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The CHMP adopted a change to an indication as follows:

"Treatment of osteoporosis in postmenopausal women **and in men<sup>2</sup>** at increased risk of fractures. **In postmenopausal women** Prolia significantly reduces the risk of vertebral, non vertebral and hip fractures.

Treatment of bone loss associated with hormone ablation in men with prostate cancer at increased risk of fractures (see section 5.1). In men with prostate cancer receiving hormone ablation, Prolia significantly reduces the risk of vertebral fractures."

Detailed conditions for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR), and will be available in all official European Union languages after the variation to the marketing authorisation has been granted by the European Commission.

---

<sup>1</sup> Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued within 44 days (Type II variations) and 67 days (Annex II applications) from adoption of the opinion.

<sup>2</sup> Bold and underlined text is new.

