19 September 2013
EMA/729431/2013
Committee for Medicinal Products for Human Use (CHMP)

Firmagon

International non-proprietary name: DEGARELIX

Procedure No. EMEA/H/C/000986/PSUV/0020

Period covered by the PSUR: 18 February2012 to 17 February 2013

Scientific conclusions and grounds recommending the variation to the terms of the Marketing Authorisation

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7523 7455
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

Scientific conclusions

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

The risk of cardiovascular disease is considered a potential risk for degarelix as it is inherent to deprivation therapy. Current data indicate that among 34 reported cases in relation with cardiovascular diseases in this PSUR, there were 9 cases of myocardial infarction and 13 cases of stroke. Based on the available safety information, the product information should be amended to include a warning on cardiovascular disease.

Grounds recommending the variation to the terms of the Marketing Authorisation

On the basis of the scientific conclusions for Firmagon the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing the active substance degarelix is favourable subject to the proposed changes to the product information.

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