



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

23 May 2014
EMA/319773/2014
Human Medicines Development and Evaluation

Public statement on

Preotact (PTH (parathyroid hormone))

Withdrawal of the marketing authorisation in the European Union

On 24 April 2006 the European Commission issued a marketing authorisation valid throughout the European Union for the medicinal product Preotact (PTH(parathyroid hormone)) for treatment of osteoporosis in postmenopausal women who are at high risk of fractures.

The marketing authorisation holder (MAH) responsible for Preotact was NPS Pharma Holdings Limited (NPS Pharma). The European Commission was notified by a letter dated 21 March 2014 of the MAH's decision to voluntarily withdraw the marketing authorisation as of the Commission Decision date for Preotact for commercial reasons. Preotact was not marketed anywhere in the European Union.

On 16 May 2014 the European Commission issued a decision to withdraw the marketing authorisation for Preotact.

Pursuant to this decision the European Public Assessment Report for Preotact will be updated to reflect that the marketing authorisation is no longer valid.

Medicinal product no longer authorised

