1 BACKGROUND INFORMATION ON THE PROCEDURE

1.1 Submission of the dossier

The applicant Nycomed Danmark ApS submitted on 11 March 2005 an application for a Marketing Authorisation to the European Medicines Agency (EMEA) for Preotact (parathyroid hormone) through the centralised procedure.

The legal basis for this application refers to:

Article 8.3 of Directive 2001/83/EC, as amended - complete and independent application

Scientific Advice
The applicant did not seek scientific advice at the CHMP.

Licensing status:
The product was not licensed in any country at the time of submission of the application.

The Rapporteur and Co-Rapporteur appointed by the CHMP were:

Rapporteur: Dr Steffen Thirstrup Co-Rapporteur: Dr Gonzalo Calvo Rojas

1.2 Steps taken for the assessment of the product

- The application was received by the EMEA on 11 March 2005.
- The procedure started on 28 March 2005.
- The Rapporteur's first Assessment Report was circulated to all CHMP members on 13 June 2005 The Co-Rapporteur's first Assessment Report was circulated to all CHMP members on 10 June 2005
- During the 18-20 July 2005 meeting the BWP adopted the BWP report with a recommendation to the CHMP to incorporate additional questions in the CHMP List of Questions.
- During the meeting on 25-28 July 2005, the CHMP agreed on the consolidated List of Questions to be sent to the applicant. The final consolidated List of Questions was sent to the applicant on 28 July 2005.
- A clarification meeting with the Rapporteur on the CHMP List of Questions was held on 19 August 2005.
- The applicant submitted the responses to the CHMP consolidated List of Questions on 21 September 2005.
- The Rapporteurs circulated the Joint Assessment Report on the applicant's responses to the List of Questions to all CHMP members on 16 November 2005.
- During the CHMP meeting on 12-14 December 2005, the CHMP agreed on a list of outstanding issues to be addressed in writing by the applicant.
- The applicant submitted responses to the CHMP list of outstanding issues on 22 December 2005.
- The Rapporteurs circulated an updated Joint Assessment Report on the applicant's responses to the list of outstanding issues on 2 February 2006.
- During the meeting on 20-23 February 2006, the CHMP, in the light of the overall data submitted and the scientific discussion within the Committee, issued a positive opinion for granting a Marketing Authorisation to Preotact on 23 February 2006. The applicant provided the letter of undertaking on the follow-up measures to be fulfilled post-authorisation on 21 February 2006 .
- The CHMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 24 April 2006.