1 BACKGROUND INFORMATION ON THE PROCEDURE

1.1 Submission of the dossier

The applicant Elan Pharma International Ltd submitted on 09 May 2003 an application for Marketing Authorisation to the European Medicines Agency (EMEA) through the centralised procedure for Prialt, which was designated as an orphan medicinal product EU/3/01/48 on 9 July 2001.

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

Rapporteur Prof. B. Flamion Co-Rapporteur Dr. P. Salmon

Orphan Drugs:

Prialt was designated as an orphan medicinal product in the following indication: Treatment of chronic pain requiring intraspinal analgesia.

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.

1.2 Steps taken for the assessment of the product

- The procedure started on 26 May 2003.
- The Rapporteur's first Assessment Report was circulated to all CHMP members on 08 August 2003. The Co-Rapporteur's first Assessment Report was circulated to all CHMP members on 11 August 2003.
- During the meeting on 23-25 September 2003, 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 25 September 2003.
- The applicant submitted the responses to the CHMP consolidated List of Questions on 25 May 2004.
- The Rapporteurs circulated the Joint Assessment Report on the applicant's responses to the List of Questions to all CHMP members on 7 July 2004.
- During the CHMP meeting on 27-29 July 2004, the CHMP agreed on a list of outstanding issues to be addressed in writing by the applicant.
- The Rapporteurs circulated the Joint Assessment Report on the applicant's responses to the List of Outstanding Issues to all CHMP members on 4 November 2004.
- During the meeting on 15-18 November 2004, 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 under exceptional circumstances to Prialt on 18 November 2004. The applicant provided the letter of undertaking on the specific obligations and follow-up measures to be fulfilled post-authorisation on 16 November 2004.
- The CHMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 21 February 2005.