BACKGROUND INFORMATION ON THE PROCEDURE

1.1 Submission of the dossier

The applicant Roche Registration Ltd. submitted on 25 April 2006 an application for Marketing Authorisation to the European Medicines Agency (EMEA) for MIRCERA, through the centralised procedure falling within the Article 3(1) and point 1 of Annex of Regulation (EC) No 726/2004. The eligibility to the centralised procedure was agreed upon by the EMEA/CHMP on 13 October 2005

The legal basis for this application refers to:

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

The application submitted is a complete dossier composed of administrative information, complete quality data, non-clinical and clinical data based on applicants' own tests and studies and bibliographic literature substituting and supporting certain tests or studies.

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 and the evaluation teams were:
Rapporteur: **Gonzalo Calvo Rojas** Co-Rapporteur: **Pekka Kurki**

1.2 Steps taken for the assessment of the product

- The application was received by the EMEA on 25 April 2006.
- The procedure started on 24 May 2006.
- The Rapporteur's first Assessment Report was circulated to all CHMP members on 11 August 2006. The Co-Rapporteur's first Assessment Report was circulated to all CHMP members on 17 August 2006.
- The BWP adopted a final report on 13 September 2006 to be included in the List of questions.
- A clarification meeting with the Rapporteurs on the List of Questions was held on 19 September 2006.
- During the meeting on 18-21 September 2006 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 21 September 2006.
- The applicant submitted the responses to the CHMP consolidated List of Questions on 8 January 2007.
- The Rapporteurs circulated the Joint Assessment Report on the applicant's responses to the List of Questions to all CHMP members on 22 February 2007.
- The BWP adopted a further final report on 14 March 2007.
- A clarification meeting with Rapporteurs on the list of outstanding issues was held on 21 March 2007.
- During the CHMP meeting on 19-22 March 2007 the CHMP agreed on a list of outstanding issues to be addressed in writing and in an oral explanation by the applicant.
- The applicant submitted the responses to the CHMP list of outstanding issues to be addressed in writing on 12 April 2007.
- The Rapporteurs circulated an updated Joint Assessment Report on the applicant's responses to the list of outstanding issues to all CHMP members on 7 May 2007.
- A clarification teleconference with the Rapporteurs took place on 10 May 2007.
- The BWP adopted a further final report on 16 May 2007 after an oral explanation by the applicant before the BWP on 14 May 2007.

- The outstanding issues were addressed in a written response submitted by the applicant on 16 May 2007.
- During the meeting on 21-24 May 2007 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 MIRCERA on 24 May 2007. The applicant provided the letter of undertaking on the follow-up measures to be fulfilled post-authorisation on 23 May 2007.
- The CHMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 20 July 2007.