BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant Chiron S.r.l. submitted on 12 January 2006 an application for Marketing Authorisation to the European Medicines Agency (EMEA) for Focetria, through the centralised procedure falling within the Article 3(1) and point 1 of Annex of Regulation (EC) No 726/2004. The applicant's name Chiron S.r.l was changed into Novartis Vaccines and Diagnostics S.r.l in October 2006 further to the Novartis acquisition. As a consequence the applicant now of this application is Novartis Vaccines and Diagnostics S.r.l.

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 received Scientific Advice from the CHMP on 15 December 2006 (EMEA/420093/2005). The Scientific Advice pertained to quality, non-clinical and clinical aspects of the dossier.

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: Dr Pasqualino Rossi Co-Rapporteur: Dr Frits Lekkerkerker

2. Steps taken for the assessment of the product

- The application was received by the EMEA on 12 January 2006.
- Accelerated Assessment procedure was agreed-upon by CHMP on 15 December 2005.
- The procedure started on 1 February 2006.
- The Rapporteur's first Assessment Report was circulated to all CHMP members on 3 April 2006. The Co-Rapporteur's first Assessment Report was circulated to all CHMP members on 31 March 2006. In accordance with Article 6(3) of Regulation (EC) No. 726/2004, the Rapporteur and Co-Rapporteur declared that they had completed their assessment report in less than 80 days.
- The BWP discussed Focetria during their meeting on 19-20 April 2006 and adopted a BWP report to the CHMP.
- During the meeting on 24-27 April 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 27 April 2006.
- The applicant submitted the responses to the CHMP consolidated List of Questions on 14 July 2006 and 24 October 2006.
- The Rapporteurs circulated the Joint Assessment Report on the applicant's responses to the List of Questions to all CHMP members on 5 January 2007.

- The VWP discussed Focetria during their meeting on 9-11 January 2007 and adopted a Report to the CHMP.

- The BWP discussed Focetria during their meeting on 15-16 January 2007 and adopted a Report to the CHMP.

- During the CHMP meeting on 22-24 January 2007, the CHMP agreed on a List of Outstanding Issues to be addressed in writing by the applicant

- The applicant submitted the responses to the CHMP List of Outstanding Issues on 30 January 2007.

- The Rapporteurs circulated the Joint Assessment Report on the applicant's responses to the List of Outstanding Issues to all CHMP members on 7 February 2007.

- The BWP discussed Focetria during their meeting on 12-14 February 2007 and adopted a Report to the CHMP

- During the meeting on 19-22 February 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 under exceptional circumstances to Focetria on 22 February 2007. The applicant provided the letter of undertaking on the specific obligations and follow-up measures to be fulfilled post-authorisation on 22 February 2007.