BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant Norton Healthcare Limited submitted on 29 October 1997 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for Paxene, through the centralised procedure. This medicinal product falls within the scope of Part B of the Annex to Council Regulation No (EC) 2309/93 of 22 July 1993, as amended.

The Rapporteur and Co-Rapporteur appointed by the CPMP were:
Rapporteur: M. Teeling Co-Rapporteur: B. Odlind

Licensing status:

The product was not authorised in any country inside or outside the EU at the time of submission of the application. It has been reported that the applicant has received tentative approval from the FDA for its NDA for Paxene, but that in view of Taxol's orphan drug exclusivity for a related indication, the application for Paxene may not be finally approved until 4th August 2004.

2. Steps taken for the assessment of the product

- The procedure started on 21 November 1997.
- The Rapporteur's first assessment report was circulated to all CPMP Members on 6 February 1998.
- The Co-Rapporteur's first assessment report was circulated to all CPMP Members on 30 January 1998.
- During the meeting on 24-25 March 1998 the CPMP 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 March 1998.
- The applicant submitted the responses to the consolidated list of questions on 25 September 1998.
- The Rapporteur circulated the joint response assessment report on the applicant's responses to the list of questions to all CPMP Members on 23 November 1998.
- During the meeting on 15-17 December 1998 the CPMP agreed on a list of outstanding issues to be sent to the applicant. The final list of outstanding issues was sent to the applicant on 18 December 1998.
- The applicant submitted further responses to questions related to pharmaceutical and clinical issues on 11 January 1999.
- The Rapporteur circulated the response assessment report on the applicant's responses to the list of outstanding issues on 15 January 1999.
- During the meeting on 26-28 January 1999 the CPMP, 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 Paxene on 27 January 1999.
- The CPMP Opinion was forwarded, in all official languages of the European Union, to the European Commission on 4 March 1999.
- In a letter dated 23 March 1999, the European Commission informed the EMEA that the procedure for the granting of the Marketing Authorisation was suspended and the Commision requested the CPMP to provide further clarification.
- On 22 April 1999 the CPMP provided satisfactory clarification to the Commission Services
- The suspension of the decision making process was therefore lifted and subsequently a favourable Opinion was given by the Standing Committee.
- The European Commission adopted the Decision on 19 July 1999.