BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Wyeth Europa Limited on 5 January 1998 submitted to the European Agency for the Evaluation of Medicinal Products (EMEA) an application for the Marketing Authorisation of the medicinal product Sonata falling within the scope of Part B of the Annex of the Council Regulation (EEC) 2309/93, of 22 July 1993.

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

Rapporteur: Dr David Lyons Co-Rapporteur: Ms Julia Yotaki

Licensing status:

An NDA was submitted in the USA in December 1997.

2. Steps taken for the assessment of the product

- The procedure started on 30 January 1998.
- The assessment report of the Rapporteur was circulated to all CPMP members by 9 April 1998. The assessment report of the Co-Rapporteur was circulated to all members of the CPMP by 9 April 1998.
- During its meeting on 26-27 May 1998, the CPMP agreed on a consolidated list of questions was agreed upon which was sent to the applicant on 28 May 1998.
- The applicant submitted the responses to the consolidated list of questions on 9 September 1998.
- The joint Rapporteur/Co-Rapporteur assessment of the responses was circulated to all CPMP members on 19 October 1998.
- A letter of undertaking on follow-up measures was signed by the future Marketing Authorisation Holder on 18 November 1998.
- The CPMP, on the basis of the favorable benefit/risk assessment, issued a positive opinion for granting a marketing authorisation to Sonata (Wyeth Europa Limited*)*.
- The European Commission adopted the decision concerning Sonata on the 12 March 1999.