BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant Elan Pharma submitted on 06 November 2003 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for Zonegran, through the centralised procedure. On 04 May 2004 Elan Pharma transferred its ownership rights for the Zonegran application to Eisai Limited. After agreement by the CHMP on 22 March 2003, this medicinal product has been referred to Part B of the Annex to Council Regulation No (EEC) 2309/93 of 22 July 1993 as amended.

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

Rapporteur: Dr Patrick Salmon Co-Rapporteur: Dr Barbara van Zwieten-Boot

Licensing status:

Zonegran has been given a Marketing Authorisation in Japan and Korea in 1989 and 1990. respectively, in the United States of America on 27 March 2000 and in Mexico on 19 July 2002.

2. Steps taken for the assessment of the product

- The application was received by the EMEA on 06 November 2003.
- The procedure started on 24 November 2003.
- The Rapporteur's first Assessment Report was circulated to all CHMP members on 11 February 2004 . The Co-Rapporteur's first Assessment Report was circulated to all CHMP members on 11 February 2004.
- During the meeting on 23-24 March 2004, 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 24 March 2004.
- The applicant submitted the responses to the CHMP consolidated List of Questions on 16 September 2004.
- The Rapporteurs circulated the Joint Assessment Report on the applicant’s responses to the List of Questions to all CHMP members on 22 October 2004.
- During the CHMP meeting on 15-18 November 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 on 06 December 2004.
- During the meeting on 13 –15 December 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 to Zonegran on 15 December 2004. The applicant provided the letter of undertaking on the follow-up measures to be fulfilled post-authorisation on 16 December 2004.
- The CHMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 10 March 2005.