BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company SmithKline Beecham Plc submitted on 3 December 1998 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for Avandia through the centralised procedure. After agreement by the CPMP during its 21-23 July 1998 meeting, this medicinal product has been referred to Part B of the Annex to Council Regulation No (EEC) 2309/93 of 22 July 1993.

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

Initial assessment

Rapporteur Prof Odlind Co-Rapporteur: Dr van Der Giesen

Appeal

Rapporteur: Prof Hildebrandt Co-Rapporteur: Dr Brasseur

Licensing status:

Avandia was granted a Marketing Authorisation in the USA on 25 May 1999 and in Switzerland on 29 September 1999. At the time of the opinion it was also authorised in several South American, Middle Eastern, Far Eastern and African countries.

2. Steps taken for the assessment of the product

- The procedure started on 18 December 1998.
- The Rapporteur's first assessment report was circulated to all CPMP members on 25 February 1999. The Co-Rapporteur's first assessment report was circulated to all CPMP Members on 26 February 1999.
- During the meeting on 20-22 April 1999 the CPMP agreed on the consolidated list of questions to be sent to the company. The final consolidated list of questions was sent to the company on 22 April 1999.
- The applicant submitted the responses to the CPMP consolidated list of questions on 9 June 1999.
- The summary report of the inspection carried out at the manufacturing site of the finished product between 10-13 May 1999 was issued on 3 June 1999.
- An expert panel meeting was convened on 14 July 1999.
- The Rapporteur and Co-Rapporteur circulated the response assessment report on the company's responses to the list of questions to all CPMP Members on 17 August 1999.
- Some additional data on the responses to the List of Questions was submitted by the applicant on 9 September 1999.
- The applicant requested on 15 September 1999 to defer the CPMP oral explanation / opinion from the September 1999 meeting to the October 1999 meeting. This request was based on the submission of additional safety data.
- Additional data (Safety Update) was submitted by the applicant on 13 September 1999.
- During the September 1999 CPMP meeting the applicant's request was adopted to postpone the CPMP oral explanation / opinion until the October 1999 CPMP meeting.

- The List of Questions to be addressed during the oral explanation was adopted on 22 September 1999 at the CPMP meeting.

- During the CPMP meeting on 19 October 1999, outstanding issues were addressed by the applicant during an oral explanation before the CPMP.

- During the meeting on 19-21 October 1999 the CPMP, in the light of the overall data submitted and the scientific discussion within the Committee, issued a negative opinion (majority) for granting a Marketing Authorisation to Avandia on 21 October 1999. Some CPMP members held a divergent position.

3. Steps taken for the appeal procedure

- A valid intent for appeal against the CPMP Opinion on Avandia was submitted by the applicant, SmithKline Beecham, on 13 November 1999.

- During its meeting on 16-18 November, the CPMP appointed Prof. Hildebrandt as Rapporteur and Dr Brasseur as Co-Rapporteur for the appeal procedure.

- Grounds for appeal were submitted by the applicant on 17 December 1999.

- An expert panel meeting was organised on 14 February 2000.

- The report of the expert panel meeting was circulated to all CPMP members on 17 February 2000.

- The Rapporteur/Co-Rapporteur's joint assessment report was circulated to all CPMP members on 28 February 2000.

- Supplementary information was provided by the applicant on 2 March 2000.

- The Rapporteur/Co-Rapporteur's assessment reports were circulated to all CPMP members on 8 March 2000.

- An oral explanation was provided by the applicant on 14 March 2000.

During the meeting on 14-16 March 2000, the CPMP, in the light of the overall data submitted and the scientific discussion within the Committee, issued a positive opinion (majority) for granting a Marketing Authorisation to Avandia. Some CPMP members held a divergent position.