BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant sanofi-aventis submitted on 5 September 2005 an application for Marketing Authorisation to the European Medicines Agency (EMEA) for ZIMULTI, through the centralised procedure.

The legal basis for this application refers to:

Article 8.3 of Directive 2001/83/EC, as amended - complete and independent application.

The application submitted is a complete dossier: composed of administrative information, complete quality data, non-clinical and clinical data based on applicants' own tests and studies and/or bibliographic literature substituting/supporting certain test(s) or study(ies).

Scientific Advice
The applicant did not seek scientific advice at the CHMP.

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 were:
Rapporteur: T. Salmonson
Co-Rapporteur: B. van Zwieten-Boot

CHMP Peer reviewers: A. Irs, S. Thirstrup

2. Steps taken for the assessment of the product

- The application was received by the EMEA on 5 September 2005.
- The procedure started on 15 September 2005. This application forms part of a multiple application for rimonabant. The initial application was submitted by sanofi-aventis (EMEA/H/C/666). The review processes for both applications were integrated at the time of List of Questions, allowing the CHMP opinion to be adopted in the same timeframe as EMEA/H/C/666.
- During the meeting on 12 – 15 September 2005, 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 16 September 2005.
- The applicant submitted the responses to the CHMP consolidated List of Questions on 17 November 2005.
- The summary report of the inspection carried out at the following sites: Emotional Brain B.V.- Almere (Netherlands) and Karolinska universitetssjukhuset – Huddinge in Sweden between 9-11 November, 2005 and 28-29 November, 2005, respectively was issued on 11 January 2006.
- The Rapporteurs circulated the Joint Assessment Report on the applicant's responses to the List of Questions to all CHMP members on 2 January 2006.
- During the CHMP meeting on 23-26 January 2006, the CHMP agreed on a list of outstanding issues to be addressed in writing and/or in an oral explanation by the applicant.
- The applicant submitted the responses to the list of outstanding issues on 13 February 2006.
- The Rapporteurs circulated the Joint Assessment Report on the applicant's responses to the list of outstanding issues to all CHMP members on 3 March 2006.
- The applicant submitted additional updated responses to the list of outstanding issues on 10 March 2006.

- The Rapporteurs circulated the Updated Joint Assessment Report on the applicant's responses to the list of outstanding issues to all CHMP members on 16 March 2006.
- During the CHMP meeting on 20-23 March 2006, outstanding issues were addressed by the applicant during an oral explanation before the CHMP on 22 March 2006. A new list of outstanding issues was adopted.
- The applicant submitted the responses to the second list of outstanding issues on 30 March 2006.
- The Rapporteurs circulated the Joint Assessment Report on the applicant's responses to the second list of outstanding issues to all CHMP members on 10 April 2006.
- During the meeting on 24-27 April 2006, 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 ZIMULTI on 27 April 2006. The applicant provided the letter of undertaking on the follow-up measures to be fulfilled post-authorisation on 25 April 2006.
- The CHMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 19 June 2006.