1 BACKGROUND INFORMATION ON THE PROCEDURE

1.1 Submission of the dossier

The applicant Schering-Plough Europe submitted on 06 October 2005 an application for Marketing Authorisation to the European Medicines Agency (EMEA) for Suboxone, through the centralised procedure under Article 3 (2) (a) of Regulation (EC) No 726/2004. The eligibility to the centralised procedure was agreed upon by the EMEA/CHMP on 15 December 2004.

The legal basis for this application refers to:

Article 10(b) of Directive 2001/83/EC, as amended – relating to applications new fixed combination products.

Scientific Advice:

The applicant did not seek scientific advice at the CHMP.

Licensing status:
Suboxone has been given a Marketing Authorisation in the United States of America in October 2002, in New Zealand in January 2005 and in Australia in July 2005.

The Rapporteur and Co-Rapporteur appointed by the CHMP were:
Rapporteur: Dr Karl Broich Co-Rapporteur: Dr Patrick Salmon

1.2 Steps taken for the assessment of the product

- The application was received by the EMEA on 06 October 2005.
- The procedure started on 26 October 2005.
- The Rapporteur's first Assessment Report was circulated to all CHMP members on 05 January 2006. The Co-Rapporteur's first Assessment Report was circulated to all CHMP members on 9 January 2006.
- During the meeting on 20-23 February 2006, 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 February 2006.
- The applicant submitted the responses to the CHMP consolidated List of Questions on 02 June 2006.
- The Rapporteurs circulated the Joint Assessment Report on the applicant's responses to the List of Questions to all CHMP members on 26 May 2006.
- During the CHMP meeting on 26-28 June 2006, the CHMP agreed on a list of outstanding issues to be addressed in writing and in an oral explanation by the applicant.
- The Rapporteurs circulated the Joint Assessment Report on the applicant's responses to the List of Outstanding Issues to all CHMP members on 18 July 2006.
- During the meeting on 24-27 July 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 Suboxone on 27 July 2006. The applicant provided the letter of undertaking on the follow-up measures to be fulfilled post-authorisation on 26 July 2006.
- The CHMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 26 September 2006.