BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant Alcon Laboratories (UK) Ltd. submitted on 18 December 2006 an application for Marketing Authorisation to the European Medicines Agency (EMEA) for NEVANAC, 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 27 June 2007.

The legal basis for this application refers to:

A - Centralised / Article 8(3) / New active substance.

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

Licensing status:
NEVANAC has been given a Marketing Authorisation in the following countries outside the EEA:

USA	19 August 2005
Argentina	19 January 2006
Aruba	31 January 2006
Chile	31 March 2006
Guatemala	19 July 2006
Kenya	01 November 2006
Mexico	26 September 2006
Nicaragua	06 September 2006
Surinam	05 January 2006
Trinidad and Tobago	17 January 2006
Uruguay	04 October 2006
Venezuela	17 August 2006

A new application was filed in the following countries:

New Zealand	22 May 2006
Brazil	30 September 2005
China	31 March 2006
Columbia	01 August 2005
Costa Rica	30 June 2006
Dominican Republic	20 September 2006
El Salvador	21 August 2006
Honduras	17 May 2006
Hong Kong	23 September 2005
Kuwait	28 November 2005
Panama	19 July 2006
Paraguay	13 November 2006
Serbia	12 December 2005
Taiwan	31 January 2006
Thailand	19 December 2005
Turkey	17 November 2006
United Arab Emirates	23 April 2006
Vietnam	07 October 2006

The Rapporteur and Co-Rapporteur appointed by the CHMP were:
Rapporteur: **Gonzalo Calvo Rojas** Co-Rapporteur: **Steffen Thirstrup**

2. Steps taken for the assessment of the product

- The application was received by the EMEA on 18 December 2006.
- The procedure started on 24 January 2007.
- The Rapporteur's first Assessment Report was circulated to all CHMP members on 18 April 2007 (Annex 1). The Co-Rapporteur's first Assessment Report was circulated to all CHMP members on 17 April 2007.
- During the meeting on 21-24 May 2007, 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 May 2007.
- The applicant submitted the responses to the CHMP consolidated List of Questions on 5 July 2007.
- The Rapporteurs circulated the Joint Assessment Report on the applicant's responses to the List of Questions to all CHMP members on 29 August 2007.
- During the CHMP meeting on 17-20 September 2007, the CHMP agreed on a list of outstanding issues to be addressed in writing and by the applicant.
- The applicant submitted written explanations to the CHMP List of Outstanding Issues on 20 September 2007.
- The Rapporteurs circulated the Joint Assessment Report on the CHMP List of Outstanding Issues to all CHMP members on 8 October 2007.
- During the meeting on 16-18 October 2007, 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 for NEVANAC on 18 October 2007. The applicant provided the letter of undertaking on the follow-up measures to be fulfilled post-authorisation on 10 October 2007.
- The CHMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 11 December 2007.