**BACKGROUND INFORMATION ON THE PROCEDURE**

## 1. Submission of the dossier

The applicant Janssen-Cilag International NV submitted on 04 January 2006 an application for Marketing Authorisation to the European Medicines Agency (EMEA) for PREZISTA, through the centralised procedure falling within the Article 3(1) and point 3 of Annex of Regulation (EC) No 726/2004. The eligibility to the centralised procedure was agreed upon by the EMEA/CHMP on 27 July 2005 and re-confirmed on 15 December 2005.

The legal basis for this application refers to:

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

**Scientific Advice:**
The applicant received Scientific Advice from the CHMP on 23 May 2003 and 21 January 2005. The Scientific Advice pertained to quality, non-clinical and clinical aspects of the dossier.

**Licensing status:**
PREZISTA has been given a Marketing Authorisation in the United States on 23 June 2006, in Canada on 28 July 2006, in Russia on 22 September 2006, and in Argentina on 30 November 2006.
A new application was filed in the following countries: Turkey, Australia, Mexico, New Zealand, Taiwan, Singapore, Israel and Hong Kong SAR

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

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| Rapporteur: | B. van Zwieten-Boot | Co-Rapporteur: | I. Hudson |

## 2 Steps taken for the assessment of the product

- The application was received by the EMEA on 04 January 2006.
- Accelerated assessment procedure was rejected by the CHMP on 26 January 2006.
- The procedure started on 01 February 2006.
- The Rapporteur's first Assessment Report was circulated to all CHMP members on 19 April 2006. The Co-Rapporteur's first Assessment Report was circulated to all CHMP members on 31 March 2006. In accordance with Article 6(3) of Regulation (RC) No 726/2004, the Rapporteur and Co-Rapporteur declared that they had completed their assessment report in less than 80 days.
- During the meeting on 1st June 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 2 June 2006.
- The applicant submitted the responses to the CHMP consolidated List of Questions on 8 August 2006.
- The Rapporteurs circulated the Joint Assessment Report on the applicant's responses to the CHMP List of Questions to all CHMP members on 22 September 2006 and 26 September 2006.
- During the CHMP meeting on 18 October 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 CHMP list of outstanding issues on 14 November 2006.
- The Rapporteurs circulated the Joint Assessment Report on the applicant's responses to the list of outstanding issues provided by the applicant on 1st December 2006
- During the meeting in December 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 conditional Marketing Authorisation to PREZISTA on 14 December 2006. The applicant provided the letter of undertaking on the specific obligations and follow-up measures to be fulfilled post-authorisation on 14 December 2006.