BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant Novartis Europharm Ltd. submitted on 5 October 2006 an application for Marketing Authorisation to the European Medicines Agency (EMEA) through the centralised procedure for Tasigna, which was designated as an orphan medicinal product EU/3/06/375on 22 May 2006 (CML) and EU/3/07/447 on 13 April 2007. Tasigna was designated as an orphan medicinal product in the following indications: treatment of chronic myeloid leukaemia and treatment of gastrointestinal stromal tumours. The calculated prevalence of those conditions was 2.4 per 100,000 EU population for chronic myeloid leukaemia and 4.13 per 100,000 EU population for gastrointestinal stromal tumours.

The applicant applied for the following indication:

Treatment of chronic phase and accelerated phase Philadelphia chromosome positive chronic myelogenous leukaemia (CML) in adult patients resistant to or intolerant to at least one prior therapy including imatinib.

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 tests or studies

Information relating to Orphan Market Exclusivity

Similarity
Pursuant to Article 8 of Regulation (EC) No. 141/2000 and Article 3 of Commission Regulation (EC) No 847/2000, the application contained a critical report addressing the possible similarity with authorised orphan medicinal products

Market Exclusivity
Pursuant to Article 8 of Regulation (EC) No. 141/2000 and Article 3 of Commission Regulation (EC) No 847/2000, the application contained a justification addressing the following derogation laid down in Article 8.3 of the same Regulation; the holder of the marketing authorisation for the original orphan medicinal product has given his consent to the applicant.

Scientific Advice:
The applicant received Scientific Advice from the CHMP on 22 April 2006 and 18 November 2006. The Scientific Advice pertained to clinical aspects of the dossier.

Licensing status:
A new application was filed in the following countries: U.S.A.
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: Jens Ersbøll (DK) Co-Rapporteur Harald Enzmann (DE)

EMEA Product Team Leader: Maria Nieto-Gutierrez

2. Steps taken for the assessment of the product

- The application was received by the EMEA on5 October 2006.
- The procedure started on 25 October 2006.
- The Rapporteur's first Assessment Report was circulated to all CHMP members on 17 January 2007. The Co-Rapporteur's first Assessment Report was circulated to all CHMP members on 21 January 2007.
- During the meeting on 19 – 22 February 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 22 February 2007.
- The CHMP adopted a report on similarity of Tasigna with Glivec on 22 March 2007.
- The applicant submitted the responses to the CHMP consolidated List of Questions on 12 April 2007.
- The Rapporteurs circulated the Joint Assessment Report on the applicant's responses to the List of Questions to all CHMP members on 29 May 2007.
- During the CHMP meeting on 18 – 21 June 2007, the CHMP agreed on a list of outstanding issues to be addressed in writing or in an oral explanation by the applicant.
- The CHMP adopted a report on similarity of Tasigna with Sprycel on 21 June 2007.
- The applicant submitted the responses to the CHMP consolidated List of Outstanding Issues on 24 August 2007.
- The Rapporteurs circulated the Joint Assessment Report on the applicant's responses to the List of Outstanding Issues to all CHMP members on 11 September 2007.
- During the meeting on 17 – 20 September 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 to Tasigna on 20 September 2007. The applicant provided the letter of undertaking on the specific obligations and follow-up measures to be fulfilled post-authorisation on 19 September 2007.
- The CHMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 19 November 2007.