BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant Bristol-Myers Squibb Pharma EEIG submitted on 12 January 2006 an application for Marketing Authorisation to the European Medicines Agency (EMEA) for Sprycel, which was designated as an orphan medicinal product EU/3/05/338 (ALL) and EU/3/05/339 (CML) on 23 December 2005. Sprycel was designated as an orphan medicinal product for the tretment of chronic myeloid leukemia (CML) and for the treatment of acute lymphoblastic leukemia (ALL):. The calculated prevalence of this condition was 0.71 per 10,000 EU population (ALL) and 0.9 per 10,000 EU population (CML).

The applicant applied for the following therapeutic indication: Treatment of adult patients with chronic myeloid leukaemia (CML) with resistance or intolerance to prior therapy including imatinib mesylate, or with Philadelphia chromosome positive (Ph+) ALL with resistance or intolerance to prior therapy.

The legal basis for this application refers to:

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

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 Glivec and Evoltra.

Scientific Advice:
The applicant received Scientific Advice from the CHMP on 21 October 2004. The Scientific Advice pertained to clinical development 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 Co-Rapporteur: Beatriz Silva Lima

Steps taken for the assessment of the product

- The application was received by the EMEA on 12 January 2006.
- The procedure started on 1 February 2006.
- The Rapporteur's first Assessment Report was circulated to all CHMP members on 24 April 2006. The Co-Rapporteur's first Assessment Report was circulated to all CHMP members on 26. April 2006.
- The CHMP adopted a report on similarity of Sprycel with Glivec on 27 April 2006.
- During the meeting on 29 May to 1 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 1 June 2006.
- During the meeting on 26-29 June 2006, the CHMP agreed on an addendum to the consolidated List of Questions to be sent to the applicant. The addendum to the consolidated List of Questions was sent to the applicant on 4 July 2006.
- The applicant submitted the responses to the CHMP consolidated List of Questions on 13 July 2006.
- The Rapporteurs circulated the Joint Assessment Report on the applicant’s responses to the List of Questions to all CHMP members on 30 August 2006.

- The CHMP adopted a report on similarity of Sprycel with Evoltra on 21 September 2006.
- During the meeting on 18-21 September 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 Sprycel on 21 September 2006. The applicant provided the letter of undertaking on the follow-up measures to be fulfilled post-authorisation on 21 September 2006.
- The CHMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 20 November 2006.