BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant Merck Santé S.A.S. submitted on 29 November 2006 an application for Marketing Authorisation to the European Medicines Agency (EMEA) for Cyanokit, through the centralised procedure under Article 3 (2) (b) of Regulation (EC) No 726/2004, based on interest of patients at Community level. The eligibility to the centralised procedure was agreed upon by the EMEA/CHMP on 27 April 2006.

The legal basis for this application refers to:
Article 8(3) of Directive 2001/83/EC, as amended - complete and independent application

Licensing status:
Cyanokit has been given a Marketing Authorisation in France (1996), Hong Kong (1999) and USA (2006)

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

Rapporteur: Dr. Pierre Demolis Co-Rapporteur: Dr. Ian Hudson

2. Steps taken for the assessment of the product

- The application was received by the EMEA on 29 November 2006.
- The procedure started on 27 December 2006.
- The Rapporteur's first Assessment Report was circulated to all CHMP members on 20 March 2007. The Co-Rapporteur's first Assessment Report was circulated to all CHMP members on 16 March 2007.
- During the meeting on 23-26 April 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 27 April 2007.
- The applicant submitted the responses to the CHMP consolidated List of Questions on 11 July 2007.
- The Rapporteurs circulated the Joint Assessment Report on the applicant’s responses to the List of Questions to all CHMP members on 24 August 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 Cyanokit on 20 September 2007. The applicant provided the letter of undertaking on the follow-up measures to be fulfilled post-authorisation on 18 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 23 November 2007.