

## BACKGROUND INFORMATION ON THE PROCEDURE

### 1. Submission of the dossier

The company Sanquin, CLB, Products Division submitted on 24 January 2000 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for Nonafact, in accordance with the centralised procedure falling within the scope of Part A of the Annex to Council Regulation No (EEC) 2309/93 of 22 July 1993, as amended.

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

Rapporteur: Dr. Hans van Bronswijk                      Co-Rapporteur: Dr. Tomas Salmonson

#### Licensing status:

The product was not licensed in any country at the time of submission of the application.

### 2. Steps taken for the assessment of the product

- The procedure started on 18 February 2000.
- The Rapporteur's first Assessment Report was circulated to all CPMP members on 28 April 2000. The Co-Rapporteur's first Assessment Report was circulated to all CPMP Members on 28 April 2000.
- During the meeting on 27-29 June 2000 the CPMP agreed on the consolidated List of Questions to be sent to the company. The final consolidated List of Questions was sent to the company on 29 June 2000.
- The company submitted the responses to the CPMP consolidated List of Questions on 11 December 2000.
- The Rapporteur circulated the response Assessment Report on the company's responses to the List of Questions to all CPMP members on 22 January 2001.
- The company submitted written responses to outstanding points identified in the response Assessment Report on 16 February 2001.
- The Rapporteur circulated the assessment of the responses to the outstanding points on 19 February 2001.
- During the meeting on 27-28 February 2001 and 1 March 2001 the CPMP, 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 Nonafact on 1 March 2001.
- The CPMP opinion was forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 3 July 2001.