BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Bracco International B V submitted on 21 July 1999 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for SonoVue, through the centralised procedure. After agreement by the CPMP on 17 September 1998, this medicinal product has been referred to Part B of the Annex to Council Regulation No (EEC) 2309/93 of 22 July 1993.

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

Rapporteur: Dr E Abadie Co-Rapporteur: Dr W v d Giesen

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 27 August 1999
- The Rapporteur's first assessment report was circulated to all CPMP Members on 5 November 1999. The Co-Rapporteur's first assessment report was circulated to all CPMP Members on 5 November 1999.
- During the meeting on 14 – 16 December 1999 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 16 December 1999.
- The summary report of the inspection carried out at the manufacturing sites between 29 February and 2 March 2000, dated 13 March 2000, was issued on 15 March 2000.
- The company submitted the responses to the CPMP consolidated list of questions on 13 June 2000, and the clock started for the second evaluation phase on 23 June 2000.
- The Rapporteur circulated the joint assessment report on the company's responses to the list of questions to all CPMP Members on 21 August 2000.
- Arising from the Joint Assessment Report, a number of issues of concern were identified by the CPMP and a list of unresolved issues was adopted at the September 2000 meeting and sent to the applicant, with a view to a future oral explanation.
- The applicant subsequently requested an extension to the time allowed for preparation for the oral explanation, and this was agreed by CPMP.
- During the CPMP meeting on 12-14 December 2000, outstanding issues were addressed by the applicant during a hearing before the CPMP. Following discussion of the applicant's presentation, 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 SonoVue on 14 December 2000.
- The CPMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 26 March 2001.