BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant Instituto Grifols S.A. submitted on 05 September 2006 an application for Marketing Authorisation to the European Medicines Agency (EMEA) for Flebogammadif, through the centralised procedure under Article 3 (2) (b) of Regulation (EC) No 726/2004. The eligibility to the centralised procedure was agreed upon by the EMEA/CHMP on 29 March 2006. The eligibility to the centralised procedure under Article 3(2)(b) of Regulation (EC) No 726/2004 was based on demonstration of significant technical innovation.

The legal basis for this application refers to Article 8.3 of Directive 2001/83/EC, as amended - complete and independent application.

Licensing status:
Flebogammadif (Flebogamma 5% DIF) has been given a Marketing Authorisation in US on 21 December 2006.
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 and the evaluation teams were:
Rapporteur: Manfred Haase Co-Rapporteur: Concepción Prieto Yerro

2. Steps taken for the assessment of the product

- The application was received by the EMEA on 05 September 2006.
- The procedure started on 27 September 2006.
- The Rapporteur's first Assessment Report was circulated to all CHMP members on 8 December 2007. The Co-Rapporteur's first Assessment Report was circulated to all CHMP members on 12 December 2007. In accordance with Article 6(3) of Regulation (EC) No 726/2004, the Rapporteur and Co-Rapporteur declared that they had completed their assessment report in less than 80 days.
- During the meeting on 22-25 January 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 25 January 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 25 May 2007.
- During the meeting on 18-21 June 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 Flebogammadif on 21 June 2007. The applicant provided the letter of undertaking on the follow-up measures to be fulfilled post-authorisation on 19 June 2007.