BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant Genetics Institute of Europe B.V. (Germany) submitted on 9 March 2001 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for InductOs, 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.

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

Rapporteur: Dr. Barbara van Zwieten-Boot Co-Rapporteur: Dr. Markku Toivonen

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 16 March 2001.
- The Rapporteur's first Assessment Report was circulated to all CPMP members on 12 June 2001. The Co-Rapporteur's first Assessment Report was circulated to all CPMP members on 4 June 2001.
- During the meeting on 24-26 July 2001 the CPMP 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 26 July 2001.
- The company submitted the responses to the CPMP consolidated List of Questions on 13 November 2001.
- The summary report of the inspection carried out at the Integra LifeSciences Corporation manufacturing site (manufacturer of the absorbable collagen sponge) between 22-24 January 2002, and of 10-11 April 2002 (follow-up inspection) by the MCA was issued on 10 May 2002.
- The Rapporteur circulated the response Assessment Report on the company's responses to the List of Questions to all CPMP members on 15 January 2002.
- During the meeting on 11-13 February 2002, the BWP discussed the outstanding quality issues. A report to the CPMP was prepared.
- During the CPMP meeting on 19-21 February 2002 the CPMP adopted a list of questions to be addressed during an oral explanation.
- During the CPMP meeting of 23-25 April 2002, the CPMP agreed that there was no need for an oral explanation. A list of outstanding issues to be addressed in writing prior to the opinion was issued.
- The company submitted answers to the outstanding quality questions on 18 April 2002. The Rapporteur circulated an assessment report of these answers to all CPMP members on 17 May 2002.
- The company submitted written responses to the Part IV-Clinical/SPC issues on 22 May 2002.
- During the meeting on 21-23 May 2002 the BWP discussed the responses on the outstanding quality questions, and prepared a final report to the CPMP.
- During the meeting on 28-30 May 2002 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 InductOs on 30 May 2002.
- The CPMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 9 September 2002.