BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Stryker Biotech B.V. (The Netherlands) submitted on 3 June 1999 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for OP-1 Implant, 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. Markku Toivonen Co-Rapporteur: Dr. Patrick Salmon

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 30 July 1999.
- The Rapporteur's first assessment report was circulated to all CPMP Members on 12 October 1999. The Co-Rapporteur's first assessment report was circulated to all CPMP Members on 11 October 1999.
- The CPMP at its meeting of 16-18 November 1999 decided that there was a need for a GMP inspection of the active substance and finished product manufacturing sites and the sterilisation site of OP-1 Implant. During the May CPMP meeting, an additional inspection was requested of the QC site of Stryker Biotech in Hopkinton, US.
- During the meeting on 16-18 November 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 18 November 1999.
- The company submitted the responses to the CPMP consolidated list of questions on 17 May 2000.
- The Rapporteur circulated the response assessment report on the company's responses to the list of questions to all CPMP Members on 22 June 2000.
- During the BWP meeting on 20-21 July 2000, the BWP issued a list of outstanding viral issues and decided to invite the applicant for an oral explanation during the September BWP meeting.
- During the CPMP meeting on 25-27 July 2000, the CPMP issued a list of outstanding questions to be addressed by the applicant during an oral explanation. The list of outstanding viral issues prepared during the July BWP meeting was attached to this list of questions.
- In preparation of the oral explanation during the September BWP, the applicant submitted to the EMEA on 28 August 2000 background information on the outstanding viral issues. The documentation was sent to all the BWP members.
- On 12 September 2000, the outstanding viral issues were addressed by the applicant during an oral explanation before the BWP.
- During the September BWP meeting, the BWP issued a recommendation to the CPMP on the viral safety of OP-1 Implant.
- The applicant submitted to the EMEA and the CPMP members on 7 November 2000 written responses to the outstanding preclinical and clinical questions, in preparation for the oral explanation.

- On 26 October 2000, the applicant Stryker Biotech B.V. informed the EMEA that due to a merger, they were obliged to change the applicant for the application for Marketing Authorisation to Howmedica International S.de.R.L. (Ireland). There are no changes in the persons responsible for quality defects, pharmacovigilance or scientific information.

- On 27 October 2000, the Rapporteur and Co-rapporteur issued a Joint Assessment report to the applicant's responses to the list of outstanding questions. A revised list of questions for the oral explanation was attached to this assessment report.

- During the CPMP meeting of 14-16 November 2000, the outstanding issues were addressed by the applicant during an oral explanation before the CPMP.

- On 21 November 2000, the Rapporteur circulated an addendum to the Rapporteur's Assessment report, Risk Benefit Assessment and Recommendations, which took into account the oral explanation by the applicant and the CPMP discussions at the November 2000 meeting.

- During the meeting on 12-14 December 2000, 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 OP-1 Implant on 14 December 2000.