BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant Orphan Europe SARL submitted on 8 May 2003 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for Pedea, through the centralised procedure. After agreement by the CPMP on 16 November 2000, this medicinal product has been referred to Part B of the Annex to Council Regulation No (EEC) 2309/93 of 22 July 1993 as amended.

Pedea was designated as an orphan medicinal product EU/3/01/20 on 14 February 2001.

The Rapporteur and Co-Rapporteur appointed by the CPMP were:
Rapporteur: Dr D. Lyons Co-Rapporteur: Dr I. Hudson

Orphan Drugs:

Ibuprofen was designated as an orphan medicinal product in the following indication: Treatment of Patent Ductus Arteriosus. The calculated prevalence of this condition was 2.13 per 10,000 EU populations.

Scientific Advice:
The applicant did not seek scientific advice at the CPMP.

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 21 July 2003.
- The Rapporteur's first Assessment Report was circulated to all CPMP members on 1 October 2003. The Co-Rapporteur's first Assessment Report was circulated to all CPMP members on 29 September 2003.
- During the CPMP meeting on 18 – 20 November 2003, 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 21 November 2003.
- The applicant submitted the responses to the CPMP consolidated List of Questions on 13 January 2004.
- The Rapporteurs circulated the Joint Assessment Report on the applicant's responses to the List of Questions to all CPMP members on 25 February 2004.
- During the CPMP meeting on 23-24 March 2004, the CPMP agreed on a List of Outstanding Issues to be addressed in writing by the applicant.
- The applicant submitted written responses to the CPMP List of Outstanding Issues on 5 April 2004.
- The Rapporteurs circulated the Joint Review on the applicant's responses to the List of Outstanding Issues to all CPMP members on 16 April 2004.
- During the meeting on 20 – 22 April 2004, the CPMP, in the light of the overall data and justifications submitted and the scientific discussion within the Committee, issued a positive opinion for granting a Marketing Authorisation to Pedea on 22 April 2004. The applicant provided the letter of undertaking on the follow-up measures to be fulfilled post-authorisation on 20 April 2004.
- The CPMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 29 July 2004.