I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant Fujisawa GmbH submitted on 28 July 2000 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for Protopic, through the centralised procedure. After agreement by the CPMP on 16 March 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.

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

Rapporteur:	Dr. Mary Teeling	Co-Rapporteur:	Prof. Hans Winkler
	Dr. Patrick Salmon		Prof. Heribert Pittner

Scientific Advice:

The applicant did not seek scientific advice at the CPMP.

Licensing status:

Protopic has been given a Marketing Authorisation in Japan on 16 June 1999, in USA on 8 December 2000 and in Canada on 25 June 2001.

2. Steps taken for the assessment of the product

- The procedure started on 16 August 2000.
- The Rapporteur's first Assessment Report was circulated to all CPMP members on 10 November 2000. The Co-Rapporteur's first Assessment Report was circulated to all CPMP members on 20 November 2000.
- During the meeting on 12-14 December 2000, 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 company on 15 December 2000.
- The applicant submitted the responses to the CPMP consolidated List of Questions on 12 June 2001.
- The Rapporteur and Co-Rapporteur circulated the response Assessment Report on the company's responses to the List of Questions to all CPMP members on 15 August 2001.
- During the CPMP meeting on 18-20 September 2001, the CPMP agreed on a List of Outstanding Issues.
- Written explanations were provided by the applicant on 1 October 2001.
- The Rapporteur and Co-Rapporteur circulated a Joint Assessment Report on the company's responses to the List of Outstanding Issues to all CPMP members on 10 October 2001.
- During the CPMP meeting on 16-18 October 2001, outstanding issues were addressed by the applicant during a hearing before the CPMP.
- During the meeting on 16-18 October 2001, 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 Protopic on 18 October 2001.

II GENERAL CONDITIONS FOR THE MARKETING AUTHORISATION

1. Manufacturing authorisation holder

Manufacturer of the active substance

Fujisawa Pharmaceutical Co., Ltd., Toyama Plant, 2-178 Kojin-cho, Toyama 930, Japan.

Manufacturers of the finished product

Bulk product manufacturing and tube filling
Fujisawa Healthcare, Inc., 3125 Staley Road, Grand Island, NY 14072, USA.

Finished product manufacture/packaging (carton and package leaflet)
Fujisawa Ireland Ltd., Killorglin, Co. Kerry, Ireland.

Manufacturer responsible for batch release

Fujisawa Ireland Ltd., Killorglin, Co. Kerry, Ireland.

Manufacturing Authorisation issued on 27th June 2000 by the Irish Medicines Board (Earlsfort Centre, Earlsfort Terrace, Dublin)

2. Conditions or restrictions regarding supply and use

Medicinal product subject to restricted medical prescription (See Annex I: Summary of Product Characteristic, 4.2).

3. Follow-up measures of the Marketing Authorisation Holder

As requested by the CPMP, the Applicant agreed to submit follow-up measures related to the clinical part.