

## **BACKGROUND INFORMATION ON THE PROCEDURE**

### **1. Submission of the dossier**

The applicant Allergan Sales Ltd submitted on 11 December 2000 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMA) for Lumigan, through the centralised procedure. After agreement by the CPMP on 27 July 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. On 31 July 2001 Allergan Sales Ltd requested the applicant for Lumigan to be changed to Allergan Pharmaceuticals (Ireland) Ltd.

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

Rapporteur: Dr. Ainsworth

Co-Rapporteur: Prof Andres-Trelles

### **Licensing status:**

A new application was filed in the following country: USA

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 26 December 2000.
- The Rapporteur's first Assessment Report was circulated to all CPMP members on 6 March 2001 (Annex 1). The Co-Rapporteur's first Assessment Report was circulated to all CPMP members on 20 March 2001 (Annex 2)
- During the meeting on 24-26 April 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 April 2001 (Annex 3).
- The company submitted the responses to the CPMP consolidated List of Questions on 1 August 2001.
- The Rapporteur circulated the response Assessment Report on the company's responses to the List of Questions to all CPMP members on 17 September 2001 (Annex 5)
- During the CPMP meeting on October 2001, a List of Outstanding Issues to be addressed in writing was adopted.
- The company submitted the responses to the List of Outstanding Issues to all CPMP members on 31 October 2001.
- The Rapporteur circulated a response Assessment Report on the written responses on 7 November 2001.
- During the meeting on 13-15 November 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 Lumigan on 15 November 2001.
- The CPMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decision on 8 March 2002.