BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Eli Lilly Nederland B.V. submitted on 5 June 1997 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for Celvista (now referred to as Optruma), through the centralised procedure. After agreement by the CPMP on 17-19 March 1997, this medicinal product is referred to Part B of the Annex to Council Regulation No (EC) 2309/93 of 22 July 1993.

The Rapporteur and Co-Rapporteur appointed by the CPMP:

Rapporteur: Dr. E. Alhava Co-Rapporteur: Pharm. G. De Greef

Licensing status:

The product was not licensed in any country at the time of submission of the application. Applications were simultaneously submitted in the United States, Canada, Australia, Poland, Czech Republic, New Zealand and South Africa.

It has been approved in the USA on 9 December 1997. It has also been approved in Mexico, Brazil, Israel, Lebanon, Argentina and Peru.

2. Steps taken for the assessment of the product

- The procedure started on 25 July 1997.
- The Rapporteur's first assessment report was circulated to all CPMP Members on 3 October 1997. The Co-Rapporteur's first assessment report was circulated to all CPMP Members on 1 October 1997.
- During the November 1997 meeting, 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 1997.
- The company submitted the responses to the consolidated list of questions on 8 December 1997. The clock restarted on 19 December 1997.
- The Rapporteur and Co-Rapporteur circulated the joint assessment report on the company’s responses to the list of questions to all CPMP Members on 23 January 1998. The joint assessment report on responses to the outstanding points on Part II was circulated on 10 March 1998.
- During the February 1998 meeting, the CPMP adopted the Rapporteur’s proposed questions for oral explanation to be addressed by the company in March 1998. Company’s written responses to these proposed questions were provided in advance of the oral explanation. However, upon the CPMP request, the hearing was postponed to April 1998 in order to allow an assessment of the data and evaluation of the overall benefit/risk ratio of the medicinal product.
- The Rapporteur circulated to all CPMP Members on 18 March 1998 a draft assessment report on the company’s responses to the pending issues for oral explanation, and additional assessment was given on 16 April 1998.
- The CPMP adopted the revised list of pending issues for the oral explanation on 20 April 1998. A hearing was held on 21 April 1998, at the CPMP meeting to address the remaining questions regarding data on mortality, endometrial thickness/carcinoma, breast cancer incidence, cardiovascular effects, risk of venous thromboembolism and risk to benefit balance of raloxifene in comparison to estrogen/HRT.

- During the meeting on 20-22 April 1998 the CPMP, in the light of the overall data submitted and the scientific discussion within the Committee issued a positive opinion (majority) for granting a Marketing Authorisation to Optruma on 22 April 1998.
- The CPMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 5 August 1998.