I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Laboratoire HRA Pharma submitted on 2 October 2002 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for Lysodren, through the centralised procedure. After agreement by the CPMP on 23 July 2002, this medicinal product has been referred to Part B of the Annex to Council Regulation No (EEC) 2309/93 of 22 July 1993.

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

Rapporteur: Dr Gonzalo Calvo Rojas Co-Rapporteur: Prof Silvio Garattini

Licensing status:

Lysodren has been given a Marketing Authorisation in Brazil on 25 July 1988, in Canada on 14 December 1978, in Hong-Kong on 20 June 1989, in Malaysia on 15 December 1986, in South Korea on 9 October 2001, in the USA on 8 July 1970 and in Singapore (approved SIN3544P).

2. Steps taken for the assessment of the product

- The procedure started on 18 November 2002.
- The Rapporteur's first assessment report was circulated to all CPMP Members on 29 January 2003. The Co-Rapporteur's first assessment report was circulated to all CPMP Members on 28 January 2003.
- During the meeting on 18-19 March 2003 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 19 March 2003.
- The company submitted the responses to the consolidated list of questions on 27 July 2003.
- The Rapporteurs circulated the response assessment report on the company's responses to the list of questions to all CPMP Members on 22 September 2003.
- During the meeting on 21-22 October 2003 the CPMP agreed on a List of Outstanding Issues to be addressed in writing by the applicant.
- The applicant submitted answers to the List of Outstanding Issues on 7 November 2003.
- The Joint Rapporteur/Co-Rapporteur Assessment Report on the applicant's responses was circulated on 5 December 2003.
- During the meeting on 21-22 October 2003 the CPMP agreed on a List of Questions to be answered by TAG in Oncology on 17 November 2003.
- Answers to the questions were given by the TAG in Oncology on 17 November 2003.
- During the meeting on 18-20 November 2003, the CPMP adopted a Second List of Outstanding Issues. The second List of Outstanding Issues was sent to the Applicant on 20 November 2003.
- The Joint Rapporteur/Co-Rapporteur Assessment Report on the applicant's responses to the Second List of Outstanding Issues was circulated on 9 January 2004.
- During the meeting on 20-21 January 2004 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 Lysodren on 21 January 2004. The applicant provided a letter of undertaking on the follow-up measures to be fulfilled post-authorisation on 18 January 2004.
- The CPMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 28 April 2004.

II GENERAL CONDITIONS FOR THE MARKETING AUTHORISATION

1. Manufacturing Authorisation Holder and inspection status

Manufacturer(s) of the active substance

Mitotane
ISP Chemical Inc.
1979 Atlas Street
Colombus
OHIO 43228
USA

Manufacturer(s) of the finished product

Bristol-Myers Squibb Spa
Via del Murillo Km 2800
04010 Sermoneta (Latina)
ITALY

Manufacturer responsible for batch release

Bristol-Myers Squibb
Via del Murillo Km 2800
04010 Sermoneta
ITALY

Manufacturer responsible for import and batch release in the European Economic Area

Bristol-Myers Squibb
Via del Murillo Km 2800
04010 Sermoneta
ITALY

2. Conditions or restrictions regarding supply and use

Medicinal product subject to restricted medical prescription.