BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant Janssen Cilag International N.V. submitted on 12 March 2001 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for EVRA, through the centralised procedure. After agreement by the CPMP on February 1999, 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. J.F.F. Lekkerkerker Co-Rapporteur: Prof. F. de Andres-Trelles

Scientific Advice:

The applicant did not seek scientific advice from the CPMP.

Licensing status:

The product was not licensed in any country at the time of submission of the application. EVRA has been authorised in the United States on 20 November 2001.

2. Steps taken for the assessment of the product

- The procedure started on 27 March 2001.
- The Rapporteur's first Assessment Report was circulated to all CPMP members on 20 June 2001. The Co-Rapporteur's first Assessment Report was circulated to all CPMP members on 6 July 2001.
- During the meeting on July 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 31 July 2001.
- The applicant submitted the responses to the CPMP consolidated List of Questions on 14 December 2001.
- The preliminary report of the inspection carried out at the manufacturing site Ortho McNeil Pharmaceutical Inc., 1000 Route 202 South Raritan, New Jersey 08869 United States of America on 1 February 2002 was issued on 15 February 2002.
- The preliminary report of the inspection carried out at the manufacturing site Ortho McNeil Pharmaceutical Inc., Drug Delivery Division, 701 Galveston Drive Redwood City, CA 94063, United States of America 28 January 2002 was issued on 15 February 2002.
- The Rapporteur/Co-rapporteur circulated the response Assessment Report on the applicant's responses to the List of Questions to all CPMP members on 29 January 2002.
- During the meeting on February 2002, 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 EVRA, transdermal patch on 21 February 2002.
- The applicant provided a letter of undertaking of the follow-up measures to be fulfilled post-authorisation dated 21 February 2002.
- During its 19-21 March 2002 meeting, further to comments received from independent environmental researchers, the CPMP agreed on the necessity to further evaluate the potential risks and environmental implications of the disposal of EVRA and to revise the CPMP opinion, if necessary. The applicant provided therefore supplementary information on the environmental

risk analysis associated with EVRA on 2 April 2002. The Rapporteur circulated an assessment report to all CPMP members on 11 April 2002.

- On 24 April 2002, the CPMP sent a letter to the European Commission to seek clarification on the legal framework with respect to the role of the environmental risk assessment of a medicinal product in the overall benefit/risk ratio assessment and the potential consequences in terms of the granting of a marketing authorisation before reaching a final recommendation.
- The European Commission provided the CPMP on 18 May 2002 with a written letter clarifying that, according to the current pharmaceutical legislation, the environmental risk assessment is not a criterion to be taken into account when recommending the granting of a marketing authorisation. It foresees, however, that if applicable, reasons for any precautionary and safety measures to be taken for the storage of the medicinal product, its administration to patients and for the disposal of waste products, together with the indication of any potential risks presented by the medicinal product for the environment should be considered.
- During the meeting in May 2002, the CPMP, in the light of the information submitted, the current legislative framework and the scientific discussion within the Committee, agreed to revise the sections 4.2 and 6.6 of the Summary of Product Characteristics to include new recommendations on the disposal of the patch and to amend the Labelling and Package Leaflet accordingly. In addition, at the request of the CPMP, the applicant undertook to include in the package prior to marketing the product in the European Union an appropriate disposal container for used patches. The applicant provided on 28 May 2002 a supplementary letter of undertaking to the one already adopted in February 2002. The CPMP adopted therefore a revised opinion by 27 out of 27 votes with 1 abstention for granting a Marketing Authorisation to EVRA, transdermal patch on 30 May 2002.
- The CPMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which issued the corresponding Decision on 22 August 2002.