

## **BACKGROUND INFORMATION ON THE PROCEDURE**

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

The applicant Voisin Consulting SARL Limited submitted on 1 December 2000 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMA) through the centralised procedure for Trisenox, which was designated as an Orphan Medicinal Product (EU/3/00/008) on 18 October 2000. On 1 December 2000 the EMA was notified that following transfer of the Orphan Designation from Voisin Consulting SARL to Cell Therapeutics (UK) Limited, the applicant was also changed to Cell Therapeutics (UK) Limited.

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

Rapporteur: Dr Eric Abadie

Co-Rapporteur: Prof Silvio Garattini

### **Licensing status:**

Trisenox has been given a Marketing Authorisation in USA on 25 September 2000.

### **2. Steps taken for the assessment of the product**

- The procedure started on 27 February 2001.
- The Rapporteur's first Assessment Report was circulated to all CPMP members on 8 May 2001 (Annex 1). The Co-Rapporteur's first Assessment Report was circulated to all CPMP members on 13 April 2001 (Annex 2).
- During the meeting on 26-28 June 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 27 June 2001 (Annex 3).
- The company submitted the responses to the CPMP consolidated List of Questions on 7 August 2001.
- The summary report of the inspection carried out at the manufacturing sites between 23-25 April 2001 was issued on 17 September 2001 (Annex 4).
- 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 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 Trisenox on 18 October 2001, under exceptional circumstances.