

## **I BACKGROUND INFORMATION ON THE PROCEDURE**

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

The company Pfizer Ltd. submitted on 2 October 2002 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMA) for Draxxin, through the centralised procedure. After agreement by the CVMP on 13 February 2002, this veterinary 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 CVMP were:

Rapporteur: R. Kroker

Co-Rapporteur: M. Arboix

#### **Licensing status:**

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 16 October 2002.
- The Rapporteur's first assessment report was circulated to all CVMP Members on 20 December 2003. The Co-Rapporteur's critique of the Rapporteur's assessment report was circulated to all CVMP Members on 8 January 2003.
- During the meeting on 11-13 February 2003 the CVMP 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 13 February 2003.
- The company submitted the responses to the consolidated list of questions on 22 May 2003.
- The Rapporteur circulated the joint response assessment report on the company's responses to the list of questions to all CVMP Members on 1 July 2003.
- During the meeting on 22-24 July 2003 the CVMP, 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 Draxxin on 23 July 2003.
- The CVMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 11 November 2003.

## **II GENERAL CONDITIONS FOR THE MARKETING AUTHORISATION**

### **1. Manufacturing Authorisation Holder**

#### **Manufacturer(s) of the active substance**

Pfizer Inc.  
Eastern Point Road, Croton  
Connecticut, 06340, USA

#### **Manufacturer(s) of the finished product**

Pfizer PGM  
Z.I d'Amboise  
F-37530 Pocé-sur-Cisse  
France

## **Manufacturer responsible for batch release**

Name and address of the manufacturer responsible for batch release

Pfizer PGM  
Z.I d'Amboise  
F-37530 Pocé-sur-Cisse  
France

Manufacturing Authorisation issued on 21. 06. 2001 by Agence Nationale Du Medicament Veterinaire, France

## **2. Conditions or restrictions regarding supply and use**

Veterinary medicinal product subject to prescription.