Steps taken for the Assessment of the Product

Following a request from Fort Dodge Laboratories, the company was advised in April 1992 that its product Pentofel fell under the definition of list A of Council Directive 87/22/EEC and could be authorised in accordance with the concertation procedure laid down by Council Directive 87/22/EEC.

With the entry into force on 1 January 1995 of Council Regulation (EEC) No 2309/93, the former concertation procedure was replaced by a centralised Community authorisation procedure.

In early 1995, Fort Dodge Laboratories informed the EMEA that they were ready to submit their application. On the basis of the information received, the CVMP confirmed in March 1995 that the product Pentofel fell under the scope of part A of the Annex to Council Regulation (EEC) No 2309/93 on the grounds that genome molecular cloning, involving recombinant DNA methods, was performed during the development process to select the subtype A of the Feline Leukaemia strain.

Licensing status :
The formulation proposed for marketing was marketed previously in Spain only. This marketing authorisation was however withdrawn on 17 May 1995, as Fort Dodge applied to the EMEA for the granting of a Community marketing authorisation. Outside the European Union, the formulation proposed for marketing has not been marketed previously. However, products containing the same active ingredients and adjuvant system as Pentofel have been approved and are licensed, under different names, in the US, Singapore, South Africa and Switzerland.

- The company Fort Dodge Laboratories submitted an application to the EMEA on 26 April 1995 for the granting of a Community marketing authorisation for Pentofel in accordance with Council Regulation (EEC) No 2309/93. This application was validated on 16 June 1995.

- The centralised procedure started on 30 June 1995.

- The initial rapporteur's assessment report was circulated to all CVMP Members on 20 September 1995.

- The initial co-rapporteur's assessment report was circulated to all CVMP Members on 22 September 1995.

- At the request of the rapporteur and co-rapporteur, out-standing questions on the initial assessment reports were discussed during the meeting of the CVMP immunological working party held on 14 November 1995.

- The consolidated list of questions as agreed by the CVMP during its meeting held on 15-16 November 1995, was sent to the applicant.

- During its meeting held on 19-22 March 1996, the CVMP decided that the three questions regarding the GMP status of the manufacturing facility, which, in the view of the Rapporteur, should be addressed prior to the CVMP opinion would be put to the applicant with a request to address them in parallel to the other questions of the CVMP. It was subsequently agreed that the other GMP issues could await the next bi-annual inspection to be carried out by the Irish authorities in the Autumn of 1996.

- The applicant circulated the responses to the CVMP list of questions on 15 July 1996.

- The joint Rapporteur and Co-rapporteur assessment report on the responses on the consolidated list of questions was circulated to all CVMP Members on 14 August 1996.

- The applicant submitted on 18 September 1996 a letter of commitments for providing additional data on some quality issues as required by the Committee.

- The CVMP in the light of the current scientific knowledge issued on 18 September 1996 a positive opinion for granting a marketing authorisation for Pentofel.

GENERAL CONDITIONS FOR THE MARKETING AUTHORISATION

A. HOLDER(S) OF THE MANUFACTURING AUTHORISATION(S)

Manufacturer(s) of the active substances

Fort Dodge Laboratories Ireland
Finisklin Industrial Estate
Sligo, Ireland

Manufacturing Authorisation issued on 9 August 1995 by the Irish Department of Health.

Fort Dodge Animal Health
2000 Rockford Road
Charles City
Iowa 50616
USA

Manufacturer(s) responsible for batch release

Fort Dodge Laboratories Ireland
Finisklin Industrial Estate
Sligo, Ireland

Manufacturing Authorisation issued on 9 August 1995 by the Irish Department of Health.

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Product subject to prescription.