BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Nycomed Imaging AS, submitted on 28 June 1996 to the European Agency for the Evaluation of Medicinal Products (EMEA) an application for marketing authorisation of the medicinal product Teslascan (mangafodipir). After agreement at the CPMP meeting 16-18 January 1996 this medicinal product was referred to Part B of the Annex of the Council Regulation (EEC) 2309/93, of the 22 July 1993.

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

Rapporteur: Dr. M. Teeling Co-Rapporteur: Dr. W.F. van der Giesen

Licensing status

An NDA (NDA 20-652) was submitted in the USA on 8 September 1995.

2. Steps taken for the assessment of the product

- A request for the re-inspection of the finished product-manufacturing site in the USA was agreed during the September 1996 CPMP meeting, to be performed by the Norwegian and Belgian Inspectorates. The Norwegian Board of Health between 17-18 January 1996 had originally inspected the site.
- The assessment report of the Co-Rapporteur was circulated to all members of the CPMP on 25 September 1996.
- The draft assessment of the Rapporteur was circulated to all members of the CPMP on 30 September 1996.
- During the November 1996 CPMP meeting, a consolidated list of questions was agreed upon which was sent to the applicant on 20 November 1996.
- The applicant submitted the responses to the consolidated list of questions on 4 December 1996.
- The joint rapporteur/co-rapporteur assessment of the responses was circulated to all CPMP members on 17 January 1997.
- The re-inspection of the finished product manufacturing facilities took place between 18-20 December 1996.
- The applicant signed a letter of undertaking on follow-up measures on 17 February 1997.
- The CPMP on the basis of the favorable benefit-risk assessment issued a positive opinion for granting a marketing authorisation to Teslascan solution for infusion on 18 February 1997.