BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The Applicant Scotia Pharmaceuticals Limited submitted on 5 October 1999 an application for Marketing Authorization to the European Agency for the Evaluation of Medicinal Products (EMEA) for FOSCAN, in accordance with the centralised procedure falling within the scope of Part B of the Annex to Council Regulation No (EEC) 2309/93 of 22 July 1993.

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

Rapporteur: Dr. W.F. van der Giesen Co-Rapporteur: Dr. J. Ersbøll

During the appeal procedure the Rapporteur and Co-Rapporteur were as follows:

Rapporteur: Dr. T. Salmonsson Co-Rapporteur: Dr. D. Lyons

Licensing status:

The product was not licensed in any country at the time of submission of the application. In the USA, Foscan was designated an orphan drug status in October 1999.

2. Steps taken for the assessment of the product

- The procedure started on 22 October 1999.
- The Rapporteur's initial Assessment Report was circulated to all CPMP members on 3 January 2000. The Co-Rapporteur's first Assessment Report was circulated to all CPMP members on 10 January 2000.
- During the meeting on 15-17 February 2000, 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 17 February 2000.
- The summary report of the inspection carried out between 24 and 27 March 2000 of the manufacturing sites Nycomed Amersham, Gloucester, UK and Scotia Pharmaceuticals Limited, Carlisle, UK was issued on 31 March 2000.
- The Applicant submitted the responses to the CPMP consolidated List of Questions on 17 August 2000.
- The Rapporteur circulated the Joint Response Assessment Report on the Applicant’s responses to the List of Questions to all CPMP members on 19 September 2000.
- During the meeting on 17-19 October 2000 the CPMP agreed on the List of Outstanding Issues to be sent to the Applicant. The final List of Outstanding Issues was sent to the Applicant on 17 October 2000.
- The Applicant submitted written responses to the consolidated List of Outstanding Issues on 30 October 2000.
- The Rapporteur circulated the Joint Response Assessment Report on the company’s responses to the List of Outstanding Issues to all CPMP members on 7 November 2000.
- During the CPMP meeting on 12-14 December 2000 outstanding issues were addressed by the Applicant during a an oral explanation before the CPMP. A List of Outstanding Issues to be addressed at an expert meeting was adopted.
- On 22 January 2001, an Expert Group meeting took place addressing the List of Outstanding Issues.

- During the meeting on 23-25 January 2001, the CPMP, in the light of the overall data submitted and the scientific discussion within the Committee, issued a negative opinion for granting a Marketing Authorisation to Foscan.

- On 14 February 2001 the Applicant provided the formal notice of appeal against the negative Opinion of the CPMP dated 25 January 2001.

- On the 5 April 2001 the Applicant submitted grounds for appeal.

- The Rapporteur circulated the Joint Assessment Report on the grounds for appeal submitted by the Applicant 4 June 2001.

- On 25 June 2001 an ad hoc Expert Meeting took place addressing the grounds for refusal raised in the negative opinion.

- During its meeting on 26-27 June 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 under exceptional circumstances to Foscan.

- Data on the CPMP Assessment Report providing additional clarifications were accepted by the CPMP on 13 July 2001.