BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant Nycomed Amersham Plc submitted on 24 November 1998 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for DaTSCAN, through the centralised procedure. After agreement by the CPMP on 24 June 1998, this medicinal product was referred to Part B of the Annex to Council Regulation No (EEC) 2309/93 of 22 July 1993, as amended.

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

Rapporteur: Dr F Rotblat  Co-Rapporteur: Dr E Abadie
(replacing Dr D Jefferys)

Licensing status:
The product was not licensed in any country inside or outside the EU at the time of submission of the application.

2. Steps taken for the assessment of the product

• The applicant’s dossier was received on 24 November 1998
• The procedure started on 18 December 1998.
• The Rapporteur's first assessment report was circulated to all CPMP Members on 1 March 1999.
• The Co-Rapporteur's first assessment report was circulated to all CPMP Members on 22 February 1999.
• During the meeting on 20 – 22 April 1999 the CPMP agreed on the consolidated list of questions to be sent to the company. The final consolidated List of Questions was sent to the applicant on 22 April 1999.
• The applicant met with the Rapporteur and Co-Rapporteur at the EMEA on 17 May 1999 in order to clarify certain clinical issues in the List of Questions.
• On 11 June 1999 the applicant requested the CPMP to grant an extension to the timeframe allowed for their responses; this request was refused.
• The responses to the List of Questions were submitted on 7 October 1999.
• The Rapporteur circulated the Rapporteur/co-Rapporteur joint assessment report on the company’s responses to the List of Questions to all CPMP Members on 26 November 1999.
• The applicant submitted a revised SPC in line with the joint assessment report on 6 December 1999
• Following discussion at CPMP on 14 December 1999, it was decided to invite the applicant to give an oral explanation on a number of unresolved clinical issues, chiefly related to the clinical utility of this product and methodological concerns. A list of outstanding issues was adopted and sent to the applicant on 17 December 1999.
• At the January 2000 CPMP meeting the applicant gave an oral explanation on 19 January 2000. Following discussion of this case, the CPMP was unable to come to an opinion at this time and decided to seek the advice of an ad hoc group of experts in neurology, movement disorders, nuclear medicine and statistics. A list of relevant questions for the group to address was adopted. In addition, the applicant was required to furnish a response to questions which would assist the ad hoc group in reaching their conclusions. The clock was stopped until March 2000 at the request of the applicant.
• The ad hoc group of experts met on 13 March 2000 and their report and conclusions were placed before CPMP on 14 March 2000. Following discussion on 14 March 2000, the CPMP decided to hear the applicant again at an oral explanation to resolve residual concerns chiefly related to methodological issues.

• The applicant gave an oral explanation on 15 March 2000 focussed on the methodological issues. The company submitted a letter of undertaking dated 14 March 2000, to provide further information as followup measures.

• During the meeting on 14 – 16 March 2000 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 DaTSCAN on 16 March 2000, by a majority of 20 out of 24 votes with 4 abstentions. The Norwegian and Icelandic CPMP Members agreed with this opinion.

• The CPMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 27 July 2000.