BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the initial dossier

The company Syntex Pharmaceuticals Ltd submitted an application to all EU Member States for CellCept capsules and tablets through the Concertation procedure (No 82) on 31 October 1994.

A List B status as in the Annex to Directive 87/22/EEC was agreed by the CPMP in its June meeting 1994.

In application to Article 2 of Directive 93/41/EEC, on 22 December 1994, the company Syntex Pharmaceuticals Ltd transferred to the European Agency for the Evaluation of Medicinal Products, into the new centralised procedure, the application for Marketing Authorisation for CellCept falling within the scope of Part B, indent 7 of the Annex to Council Regulation (EEC) 2309/93 of 22 July 1993.

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

Rapporteur: Dr Jefferys Co-Rapporteur: Dr Lyons

Licensing status at the time of submission

The medicinal product was authorised on 3 May 1995 in the USA.

2. Steps taken for the assessment of the product

- The Rapporteur's initial Assessment Report was circulated to all Members of CPMP on 10 January 1995. The Co-Rapporteur's initial Assessment Report was circulated to all Members of CPMP on 5 December 1994.
- The CPMP consolidated list of comments was sent to the applicant on 3 May 1995.
- The company submitted the responses to the consolidated list of comments on 20 June 1995.
- The Rapporteur’s first “responses” Assessment Report was circulated to all CPMP Members on 7 August 1995.
- The Co-Rapporteur’s first “responses” preclinical and clinical Assessment Report was circulated to all CPMP Members on 1 August 1995 and the Co-Rapporteur’s first “responses” pharmaceutical responses Assessment Report on 4 August 1995.
- The company provided a revised Summary of Product Characteristics (SPC) and Package Leaflet (PL) on 22 August and 6 September 1995.
- The company provided a revised SPC on 12 September 1995.
- The CPMP considered on 12-13 September 1995 the written clarifications given by the company on some minor outstanding points as well as the revised Summary of Product Characteristics and Package Leaflet. The CPMP agreed on the SPC and requested a new PL, specifically a new wording of the “Undesirable Effects” section.
- The company provided a new PL on 5 October 1995 in all 11 languages.
- The company submitted on 10 October 1995 their letter of commitment for providing information on quality points.
- In the light of the overall data submitted and the scientific discussion within the Committee, the CPMP issued a positive opinion for granting a Marketing Authorisation for two different oral presentations of CellCept on 17 October 1995. The CPMP opinions were forwarded, in all official languages of the European Union to the European Commission, which adopted the corresponding Decisions on 14 February 1996.