BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Sanofi Pharma Bristol-Myers Squibb SNC, France submitted to the EMEA on 26 November 1997 an application for marketing authorisation through the centralised procedure. This medicinal product was referred to Part B of the Annex of the Council Regulation EEC No 2309/93, indent 7 as it contains a new active substance.

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

Rapporteur: Prof. F. de Andrés-Trelles Co-Rapporteur: Dr. M. Toivonen

Licensing status

Irbesartan 150 mg/hydrochlorotiazide 12.5 mg was approved by the US Food and Drug Administration on 30 September 1997. Irbesartan 300 mg/hydrochlorotiazide 12.5 mg was submitted to the Food and Drug Administration for approval in December 1997.

2. Steps taken for the assessment of the product

- An application for Marketing Authorisation was submitted to the EMEA on 26 November 1997. The centralised procedure started on 19 December 1997.
- The Rapporteur's assessment report was circulated to all CPMP Members on 18 March 1998. The Co-Rapporteur's assessment report was circulated to all CPMP Members on 4 March 1998.
- The Rapporteur's and Co-Rapporteur's assessment reports and the comments from other CPMP Members were discussed during the CPMP meeting in April 1998 and the CPMP consolidated list of questions was adopted on 23 April 1998.
- The responses to the consolidated list of questions were provided on 11 May 1998.
- The joint Rapporteur's and Co-Rapporteur's assessment report on the responses provided by the applicant was sent to all CPMP Members on 3 July 1998.
- An addendum to the joint Rapporteur and Co-Rapporteur assessment report on written clarifications provided by the company regarding quality issues was received on 14 July 1998.
- A hearing was held at the CPMP meeting on 22 July 1998, to address the remaining outstanding clinical issues.
- During the July 1998 CPMP meeting, 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 on 22 July 1998**.**
- The European Commission issued on 16 October 1998, a Marketing Authorisation valid throughout the European Union for the medicinal product Karvezide which contains irbesartan and hydrochlorothiazide.