BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant Bristol-Myers Squibb Pharma EEIG submitted on 6 September 2006 an application for Marketing Authorisation to the European Medicines Agency (EMEA) for Irbesartan Hydrochlorothiazide BMS, through the centralised procedure according to Regulation (EC) No 726/2004.

The legal basis for this application refers to Article 10c of Directive 2001/83/EC, as amended – relating to informed consent from the marketing authorisation holder, Bristol-Myers Squibb Pharma EEIG, for the authorised medicinal product KARVEZIDE (EU/1/98/085/001-022).

Scientific Advice:
The applicant did not seek scientific advice at the CHMP.

Licensing status:
The initial product, KARVEZIDE, has been given a Community Marketing Authorisation on 16 October 1998.

The Rapporteur and Co-Rapporteur appointed by the CHMP and the evaluation teams were:
Rapporteur: Concepción Prieto Yerro Co-Rapporteur: Pirjo Laitinen-Parkkonen

2. Steps taken for the assessment of the product

- The application was received by the EMEA on 6 September 2006.
- The procedure started on 27 September 2006.
- The Rapporteur's first Assessment Report was circulated to all CHMP members on 16 October 2006. The Co-Rapporteur's first Assessment Report was circulated to all CHMP members on 13 October 2006.
- The Rapporteur circulated an updated Assessment Report to all CHMP members on 13 November 2006.
- During the meeting on 13-16 November 2006, the CHMP, 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 Irbesartan Hydrochlorothiazide BMS on 16 November 2006. The applicant provided the letter of undertaking on the follow-up measures to be fulfilled post-authorisation on 14 November 2006.
- The CHMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 19 January 2007.