BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant Takeda Global Research and Development Centre (Europe) Ltd. submitted on 17 July 2007 an application for Marketing Authorisation to the European Medicines Agency (EMEA) for Pioglitazone / metformin hydrochloride Takeda 15 mg/850 mg film-coated tablets, through the centralised procedure according to Regulation (EC) No 726/2004.

The legal basis for this application refers to Article 10(c) of Directive 2001/83/EC, as amended, relating to informed consent from the marketing authorisation holder, Takeda Global Research and Development Centre (Europe) Ltd, for the authorised medicinal product Competact (EU/1/06/354/001-009).

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

Licensing status:
The initial product, Competact, has been given a Community Marketing Authorisation on 28 July 2006.

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

Rapporteur: Patrick Salmon (IRL) Co-Rapporteur: Concepcion Prieto Yerro (ES)

2. Steps taken for the assessment of the product

- The application was received by the EMEA on 17 July 2007.
- The procedure started on 23 July 2007.
- The Rapporteur's first Assessment Report was circulated to all CHMP members on 24 August 2007. The Co-Rapporteur's first Assessment Report was circulated to all CHMP members on 27 August 2007.
- During the meeting on 17 - 20 September 2007, 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 Pioglitazone / metformin hydrochloride Takeda 15 mg/850 mg film-coated tablets on 20 September 2007.
- The CHMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 11 December 2007.