BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant, Takeda Global R&D Centre (Europe) Ltd., submitted on 28 February 2005 an application for Marketing Authorisation to the European Medicines Agency (EMEA) for Competact, through the centralised procedure under Article 3(2)(b) of Regulation (EC) No 726/2004. The eligibility to the centralised procedure was agreed upon by the EMEA/CHMP on 20 January 2005 (Part B status, Annex to Council Regulation (EEC) No 2309/93). The eligibility to the centralised procedure under Article 3(2)(b) of Regulation (EC) No 726/2004 was based on the consideration of this fixed combination of active substances as a new active substance.

The legal basis for this application refers to:

Article 8.3 of Directive 2001/83/EC, as amended - complete and independent application

The applicant applied for the following indication:

Indicated in the treatment of type 2 diabetes mellitus patients, particularly overweight patients, who are unable to achieve sufficient glycaemic control at their maximally tolerated dose of oral metformin alone.

Licensing status:

The product was not licensed in any country at the time of submission of the application.

The Rapporteur and Co-Rapporteur appointed by the CHMP were:
Rapporteur: Dr. Patrick Salmon (IRL) Co-Rapporteur: Dr. Concepción Prieto Yerro (ES)

2. Steps taken for the assessment of the product

- The application was received by the EMEA on 28 February 2005.
- The procedure started on 28 March 2005.
- The Rapporteur's first Assessment Report was circulated to all CHMP members on 8 June 2005. The Co-Rapporteur's first Assessment Report was circulated to all CHMP members on 9 June 2005.
- During the meeting on 25-28 July 2005, the CHMP agreed on the consolidated List of Questions to be sent to the applicant. The final consolidated List of Questions was sent to the applicant on 28 July 2005.
- The applicant submitted the responses to the CHMP consolidated List of Questions on 8 December 2005.
- The Rapporteurs circulated the Joint Assessment Report on the applicant’s responses to the List of Questions to all CHMP members on 23 January 2006.
- During the CHMP meeting on 20-23 February 2006, the CHMP agreed on a List of Outstanding Issues to be addressed in writing and in an oral explanation by the applicant.
- The applicant submitted the responses to the List of Outstanding Issues on 17 March 2006.
- The Rapporteurs circulated the Joint Assessment Report on the applicant’s responses to the List of Outstanding Issues to all CHMP members on 7 April 2006.
- The applicant submitted a letter requesting the withdrawal of one product strength on 25 April 2006.
- The Rapporteurs circulated the Updated Overview of the Joint Assessment Report on the applicant’s responses to the List of Outstanding Issues to all CHMP members on 15 May 2006.
- During the meeting on 29 May to 1 June 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 Competact on 1 June 2006. The applicant provided the

letter of undertaking on the follow-up measures to be fulfilled post-authorisation within two months from the granting of the market authorisation.

- The CHMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 28 July 2006.