BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant Takeda Global Research and Development Centre (Europe) Ltd. submitted on 29 July 2005 an application for Marketing Authorisation to the European Medicines Agency (EMEA) for Tandemact, through the centralised procedure. After agreement by the CHMP on 23 June 2005, this medicinal product has been referred to Part B of the Annex to Council regulation No (ECC) 2309/93 of July 1993 as amended.

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: treatment of patients with type 2 diabetes mellitus who are already treated with a combination of PIOG and SU or whose diabetes is insufficiently controlled with SU monotherapy.

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

The Rapporteur and Co-Rapporteur appointed by the CHMP and their evaluation teams were:
Rapporteur: Patrick Salmon (IRL) Co-Rapporteur Ian Hudson (UK)

Steps taken for the assessment of the product

- The application was received by the EMEA on 29 July 2005.
- The procedure started on 17 August 2005.
- The Rapporteur's first Assessment Report was circulated to all CHMP members on 28 October 2005 . The Co-Rapporteur's first Assessment Report was circulated to all CHMP members on 2 November 2005.
- During the meeting on 12-14 December 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 16 December 2005.
- The applicant submitted the responses to the CHMP consolidated List of Questions on 23 June 2006.
- The Rapporteurs circulated the Joint Assessment Report on the applicant’s responses to the List of Questions to all CHMP members on 25 August 2006.
- During the CHMP meeting on 18-21 September 2006, the CHMP agreed on a list of outstanding issues to be addressed in writing by the applicant. The final list of outstanding issues was sent to the applicant on 21 September 2006.
- The applicant submitted the responses to the list of outstanding issues on 26 September 2006.
- The Rapporteurs circulated the Joint Assessment Report on the applicant’s responses to the list of outstanding issues to all CHMP members on 5 October 2006.
- During the meeting on 16-19 October 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 Tandemact on 19 October 2006. The applicant provided the letter of undertaking on the follow-up measures to be fulfilled post-authorisation on 18 October 2006.
- The CHMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 8 January 2007.