BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant Glaxo Group Ltd submitted on 15 March 2007 an application for Marketing Authorisation to the European Medicines Agency (EMEA) for Orlistat GSK, through the centralised procedure of 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, Roche Registration Limited, for the authorised medicinal product XENICAL (EU/1/98/071/001-006).

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

Licensing status:
The initial product, XENICAL, has been given a Community Marketing Authorisation on 29 July 1998.

The Rapporteur and Co-Rapporteur appointed by the CHMP were:
Rapporteur: **Julia Dunne** Co-Rapporteur: **George Aislaitner**

2. Steps taken for the assessment of the product

- The application was received by the EMEA on 15 March 2007.
- The procedure started on 25 March 2007.
- The Rapporteur's first Assessment Report was circulated to all CHMP members on 1 May 2007. The Co-Rapporteur's first Assessment Report was circulated to all CHMP members on 30 April 2007.
- The Rapporteurs circulated the Joint Assessment Report to all CHMP members on 21 May 2007.
- During the meeting on 21-24 May 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 Orlistat GSK on 24 May 2007. The applicant provided the letter of undertaking on the follow-up measures to be fulfilled post-authorisation on 17 May 2007.
- The CHMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 23 July 2007.