1. **Submission of the dossier**


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 EMA 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.