SCIENTIFIC DISCUSSION

1. Introduction

This application has been submitted as an informed consent application in accordance with Article 10(c) of Directive 2001/83/EC, as amended.
Therefore, consent from the MAH of the XENICAL application, which had been submitted as a full application under Article 8(3) of Directive 2001/83/EC, has been given allowing access to Module 2 to Module 5 of the initial dossier of this authorised product and any subsequent post-marketing procedures submitted, assessed and approved.

As a consequence, quality, safety and efficacy of the Orlistat GSK medicinal product are identical to the up-to-date quality, safety and efficacy profile of XENICAL. Information on the scientific discussions can be found in the XENICAL CHMP assessment report and in the European Public Assessment Report (EPAR).

The approved indication is: "Orlistat GSK is indicated in conjunction with a mildly hypocaloric diet for the treatment of obese patients with a body mass index (BMI) greater or equal to 30 kg/m², or overweight patients (BMI $\geq$ 28 kg/m²) with associated risk factors.

Treatment with orlistat should be discontinued after 12 weeks if patients have been unable to lose at least 5% of their body weight as measured at the start of drug therapy".

2. Quality aspects

Since this application is an informed consent of the XENICAL application, the quality data in support of the Orlistat GSK application are identical to the up-to-date quality data of the XENICAL dossier which have been assessed and approved (including all post-marketing procedures).

3. Non-clinical aspects

Since this application is an informed consent of the XENICAL application, the non-clinical data in support of the Orlistat GSK application are identical to the up-to-date non-clinical data of the XENICAL dossier, which have been assessed and approved (including all post-marketing procedures).

4. Clinical aspects

Since this application is an informed consent of the XENICAL application, the clinical data in support of the Orlistat GSK application are identical to the up-to-date clinical data of the XENICAL dossier, which have been assessed and approved (including all post-marketing procedures).

- User Consultation

Consultation with target patient groups has not been undertaken for Orlistat GSK. The applicant has included justification for this based on the fact that the reference product was first approved in 1998 and the leaflet has been used by a large number of patients since that time.

5. Pharmacovigilance

Detailed description of the Pharmacovigilance system

The CHMP considered that the Pharmacovigilance system as described by the applicant fulfils the legislative requirements.

Risk Management Plan

The MAA submitted a risk management plan

Table Summary of the risk management plan

Safety issue	Proposed pharmacovigilance activities	Proposed risk minimisation activities
Gastrointestinal disorders	Close observation through routine pharmacovigilance system	No particular risk minimization activity is considered necessary; listed in the SPC (section 4.4 and 4.8) No detailed action plan for specific safety concerns is deemed necessary.
Hypersensitivity events	Close observation through routine pharmacovigilance system	No particular risk minimization activity is considered necessary; listed in the SPC (section 4.3 and 4.8) No detailed action plan for specific safety concerns is deemed necessary.
Hypoglycaemia	Close observation through routine pharmacovigilance system	No particular risk minimization activity is considered necessary; listed in the SPC (section 4.4) No detailed action plan for specific safety concerns is deemed necessary.
Hepatobiliary disorders	Close observation through routine pharmacovigilance system	No particular risk minimization activity is considered necessary; listed in the SPC (section 4.3 and section 4.4) No detailed action plan for specific safety concerns is deemed necessary.
Drug drug interaction by inhibition of absorption of anti-coagulants, cyclosporine and fat soluble vitamins	Close observation through routine pharmacovigilance system	No particular risk minimization activity is considered necessary; listed in the SPC (section 4.4 and section 4.5) No detailed action plan for specific safety concerns is deemed necessary.
Exposure of infants through lactation	Close observation through routine pharmacovigilance system	No particular risk minimization activity is considered necessary; the SPC contains a corresponding warning informing the physicians of the potential risk to infants of lactating and breastfeeding mothers (section 4.3 and information in section

		4.6) No detailed action plan for specific safety concerns is deemed necessary.
Misuse/off label use (patients with eating disorders, Patients with BMI < 30, Children < 12 Years)	Close observation through routine pharmacovigilance system	No particular risk minimization activity is considered necessary No detailed action plan for specific safety concerns is deemed necessary.

The CHMP, having considered the data of the reference product, is of the opinion that no additional risk minimisation activities are required beyond those included in the product information.

6. Overall conclusions, risk/benefit assessment and recommendation

Since this application is an informed consent of the XENICAL application, the CHMP considered that the risk-benefit balance of Orlistat GSK was favourable and therefore recommended the granting of the marketing authorisation for the following indication:

Orlistat GSK is indicated in conjunction with a mildly hypocaloric diet for the treatment of obese patients with a body mass index (BMI) greater or equal to 30 kg/m², or overweight patients (BMI $\geq$ 28 kg/m²) with associated risk factors.

Treatment with orlistat should be discontinued after 12 weeks if patients have been unable to lose at least 5% of their body weight as measured at the start of drug therapy.