25 April 2013
EMA/CHMP/256042/2013
Committee for Medicinal Products for Human Use (CHMP)

Xenical

orlistat

Procedure no. EMEA/H/C/000154/PSU/0017

Scientific conclusions and grounds recommending the variation to the terms of the Marketing Authorisation

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8416
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union

Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for Xenical, the scientific conclusions of PRAC are as follows:

In view of available data regarding orlistat, the PRAC considered that changes to the product information were warranted (see below).

Update of section 4.4 of the SmPC to provide clearer information regarding renal toxicity and in section 4.8 to provide updated clarification on renal and hepatic toxicities

Update of section 4.5 of the SmPC to add information regarding interactions with antidepressant, antipsychotics and Lithium.
The Package leaflet is also updated accordingly.

The CHMP agrees with the scientific conclusions made by the PRAC.

Grounds recommending the variation to the terms of the Marketing Authorisation

On the basis of the scientific conclusions for Xenical the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing the active substance orlistat is favourable subject to the proposed changes to the product information.

The CHMP recommends that the terms of the Marketing Authorisation should be varied.