European Medicines Agency
Evaluation of Medicines for Human Use

London, 23 October 2008
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COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
POST-AUTHORISATION SUMMARY OF POSITIVE OPINION[*]
for
ALLI

International Nonproprietary Name (INN): ***orlistat***

On 23 October 2008, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion[**] to recommend an extension to the terms of the marketing authorisation for the medicinal product alli. The Marketing Authorisation Holder for this medicinal product is Glaxo Group Limited.

The extension adopted by the CHMP is to add a new strength (60 mg hard capsules) to the existing product range.

The approved indication for alli 60 mg hard capsules is 'weight loss in adults who are overweight (body mass index, BMI, ≥28 kg/m^2), when taken in conjunction with a mildly hypocaloric, lower-fat diet'. The legal status is 'medicinal product not subject to medical prescription'.

Detailed conditions for the use of this product will be described in the updated Summary of Product Characteristics (SPC) which will be published in the revised European Public Assessment Report (EPAR) and will be available in all official European Union languages after the extension to the marketing authorisation has been granted by the European Commission.

[*] Summaries of positive opinion are published without prejudice to the Commission Decision, which will normally be issued within 44 days (Type II variations) and 67 days (Annex II applications) from adoption of the Opinion.

[**] Marketing Authorisation Holders may request a re-examination of any CHMP opinion, provided they notify the EMEA in writing of their intention to request a re-examination within 15 days of receipt of the opinion.

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