European Medicines Agency
Press office

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PRESS RELEASE
European Medicines Agency recommends first switch from prescription-only to non-prescription for a centrally authorised medicine

The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has recommended for the first time that the status for supply of a centrally authorised medicine in the European Union be switched from prescription-only to non-prescription. This will enable patients to buy the medicine over-the-counter.

The medicine concerned is Alli (orlistat), from Glaxo Group Limited, an anti-obesity medicine. The switch was part of an extension of the marketing authorisation, when the marketing authorisation holder applied for a lower dose capsule (60 mg) with a new classification as a non-prescription medicine. Alli (60 mg) is used in conjunction with dieting for the treatment of overweight patients who have a body mass index (BMI) of 28 or above.

When assessing a request to switch the marketing authorisation status, the CHMP looks carefully at whether the benefits of the medicine continue to outweigh its risks, even when it is used without direct supervision by a healthcare professional. The Committee looks in particular at the safety profile of the medicine, at the quality and usefulness of the information provided to patients and at the likelihood that patients will use the medicine correctly.

Following review of the required data for Alli 60 mg, the CHMP concluded that the switch could be recommended because:

- the 60 mg dose was effective in helping patients to lose weight when taken in conjunction with dieting;
- its side effects were milder than those with the existing 120 mg dose;
- the package leaflet and the label will enable patients to use the medicine correctly and appropriately.

The Committee was also reassured that patients taking Alli 60 mg would be encouraged to continue seeing healthcare professionals for weight-related issues, such as blood pressure checks or tests for diabetes. Information instructing patients to continue to see their doctor will be printed on the outside of the boxes containing the medicine and in the Package Leaflet.

The CHMP's recommendation will now be sent to the European Commission for the adoption of a decision.

-- ENDS --

Notes:

1. The 'guideline on changing the classification for the supply of a medicinal product for human use' is available on the website of the European Commission: http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/vol-2/c/switchguide_160106.pdf
2. For more information on Alli, see the European public assessment report: http://www.emea.europa.eu/humandocs/Humans/EPAR/alli/alli.htm
3. This press release, together with other information on the work of the EMEA, can be found on the EMEA website: www.emea.europa.eu

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