European Medicines Agency
Press office

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PRESS RELEASE
European Medicines Agency recommends authorisation of first generic medicine for human use

The European Medicines Agency (EMEA) today adopted a positive opinion recommending for the first time the granting of a marketing authorisation for a generic of a centrally authorised medicine for human use. The recommendation was made by the Agency's Committee for Medicinal Products for Human Use (CHMP) at its 16-19 July 2007 meeting.

This first positive opinion is for Zalasta (olanzapine), from Krka, d.d., Novo Mesto, which is intended for the treatment of schizophrenia and moderate to severe manic episode. The reference product for Zalasta is ZYPREXA from Eli Lilly Nederland BV, which has been authorised in the European Union since 1996.

New medicinal products authorised for use under the centralised procedure normally benefit from a period of data protection of 10 years, during which no generic medicine can be placed on the market. Once the protection period has expired, other companies can apply for a marketing authorisation for a generic medicine.

The centralised procedure for authorisation of medicines, for which the EMEA is responsible, was established in 1995 and the first marketing authorisations under the new procedure were granted in 1996. As the data protection period for more and more centrally authorised medicines expires, the EMEA is seeing an increase in applications for generic medicines. In 2006, the Agency received nine applications. Eight more generic applications are forecast for 2007.

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

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Notes:
1. A question-and-answer document with information about generic medicines is available.
2. A summary of opinion for Zalasta is available.
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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