European Medicines Agency
Press office

London, 20 November 2008
Doc. Ref. EMEA/619122/2008

PRESS RELEASE
Pfizer withdraws its application to change the marketing authorisation for Viagra 50 mg (sildenafil) from prescription-only to non-prescription

The European Medicines Agency (EMEA) has been formally notified by Pfizer Limited of its decision to withdraw its application for a change to the marketing authorisation for the medicine Viagra (sildenafil) 50 mg film-coated tablets. The change concerned switching the classification of the medicine from 'medicinal product subject to medical prescription' to 'medicinal product not subject to medical prescription' (an over-the-counter [OTC] medicine).

Viagra has been authorised in the European Union (EU) since 14 September 1998 for the treatment of men with erectile dysfunction. It is available on prescription as 25, 50 and 100 mg film-coated tablets.

Viagra 50 mg was expected to be used for the same indication but without a prescription, as an OTC medicine.

The application for the change to the marketing authorisation for Viagra 50 mg was submitted to the EMEA on 8 November 2007. In its official letter, the company stated that the withdrawal is due to its wish to fully consider the comments from the Committee for Medicinal Products for Human Use (CHMP), recognising that there were some concerns regarding the proposed supply of Viagra 50 mg tablets without a prescription in the pharmacy setting across the EU.

More information about Viagra 50 mg for OTC use and the state of the scientific assessment at the time of the withdrawal will be made available in a question-and-answer document. This document, together with the withdrawal letter from the company, will be published on the EMEA website in due course.

Viagra 25, 50 and 100 mg film-coated tablets remain available as prescription-only medicines.

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Notes:

1. The European Public Assessment Report for Viagra is available at the EMEA website at http://www.emea.europa.eu/humandocs/Humans/EPAR/viagra/viagra.htm
2. Withdrawal of an application does not prejudice the possibility of a company making a new application at a later stage.
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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