European Medicines Agency
Press office

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PRESS RELEASE
European Medicines Agency concludes new advice to doctors and patients for Champix needed

The European Medicines Agency (EMEA) has concluded that updated warnings to doctors and patients are needed to increase awareness of cases of suicidal ideation and suicide attempts reported in patients using Champix (varenicline), a medicine indicated for smoking cessation in adults.

The Committee for Medicinal Products for Human Use (CHMP) has been closely monitoring the safety of Champix since it was first authorised in the European Union (EU) in September 2006. As part of the routine pharmacovigilance activities, all adverse reactions for Champix are analysed on a regular basis. Cases of suicidal ideation and suicide were reviewed in July, October and November 2007.

At its December 2007 meeting, the CHMP concluded that there is a need to update the product information for Champix to warn doctors and patients that depression has been reported in patients who are trying to stop smoking using Champix. The symptoms of this depression may include suicidal ideation and suicide attempt.

The CHMP has requested that the marketing authorisation holder, Pfizer, submits a variation to the marketing authorisation for Champix before 19 December 2007 to implement these changes to the product information.

The EMEA will continue to keep this issue under close scrutiny and take appropriate actions if further concerns arise.

-- ENDS --

Notes:
1. More information is available in a question-and-answer document.
2. More information about Champix is available here: http://www.emea.europa.eu/humandocs/Humans/EPAR/champix/champix.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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