

MESSAGE FROM PROFESSOR G DUFF, CHAIRMAN, COMMITTEE
ON SAFETY OF MEDICINES.

29 September 2005

CEM/CMO/2005/

Dear Colleague,

Strattera[?] (atomoxetine) – Risk of suicidal thoughts/behaviour

I am writing to inform you about new evidence relating to an increased risk of suicidal thoughts or behaviour in association with the use of Strattera (atomoxetine), which is indicated for the treatment of Attention-Deficit/Hyperactivity Disorder (ADHD) in children of 6 years and older and in adolescents.

New analyses of clinical trial data (12 trials involving 1357 Strattera treated children/adolescents) showed an increase in the risk of suicidal thoughts/behaviour in Strattera treated individuals compared with those receiving placebo. Suicide related behaviours occurred at a frequency of approximately 4 in 1000 Strattera treated patients (6 out of 1357, one case of suicide attempt and five of suicidal ideation). There were no events in the placebo group (n=851). The age range of children experiencing these events was 7 to 12 years. It should however be noted that the number of adolescent patients included in the clinical trials was low. There were no completed suicides in these trials.

Strattera has been marketed in the UK since July 2004 but has been available in the United States since November 2002. Worldwide exposure is estimated at 3.5 million patients. It is an effective treatment for ADHD, and is authorised for use in children of 6 years and older and in adolescents as part of a comprehensive treatment programme. Treatment must be initiated by, or under the supervision of, a physician with appropriate knowledge and experience in treating ADHD.

In the UK, a total of 169 reports of suspected adverse drug reactions in association with Strattera have been received through the Yellow Card Scheme, including 11 reports of suicidal thoughts and behaviour (8 cases of suicidal thoughts, 2 cases of suicide attempt and a case of intentional overdose). Up to 15,000 patients have been treated with Strattera in the UK.

Advice to prescribers:

- Patients should be monitored for signs of depression, suicidal thoughts or suicidal behaviour and referred for appropriate treatment if necessary.
- In accordance with good clinical practice, individuals with a history of depression and/or suicidal behaviour may be at a greater risk of suicidal thoughts or suicide attempts, and should receive careful monitoring during treatment.
- Patients and parents should be informed about this risk and advised to watch for any clinical worsening, irritability or agitation, suicidal thoughts or behaviour or other unusual changes in behaviour.

The Committee on Safety of Medicines (CSM) and the Medicines and Healthcare products Regulatory Agency (MHRA) are monitoring closely the safety of Strattera.

This particular safety signal is being investigated and available information on the risks and benefits of Strattera evaluated and, if necessary, new guidance will be issued.

Please report any suspected adverse reactions to Strattera via the Yellow Card Reporting Scheme to the CSM/MHRA

For further information please call the Medicines and Healthcare products Regulatory Agency on 020 7084 2000 or visit the website (www.mhra.gov.uk).

Yours sincerely,

**Professor Gordon Duff
Chairman, Committee on Safety of Medicines**