

MESSAGE FROM PROFESSOR G DUFF, CHAIRMAN, COMMISSION ON HUMAN MEDICINES.

16th February 2006

CEM/CMO/2006/

Dear Colleague,

Strattera[▼] (atomoxetine) – conclusions of risk:benefit review

I wrote to you in September 2005 to inform you about new evidence of an increased risk of suicidal thoughts or behaviour in association with the use of Strattera (atomoxetine). Strattera is authorised for the treatment of Attention-Deficit/Hyperactivity Disorder (ADHD) in children of 6 years and older, and in adolescents, as part of a comprehensive treatment programme. It must be initiated by, or under the supervision of, a physician with appropriate knowledge and experience in treating ADHD.

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 3.7 million patients as of November 2005. In light of the concern about the increased risk of suicidal thoughts and behaviour, a Europe wide review of available data on the risks and benefits of Strattera was initiated. This review has concluded that the overall balance of risks and benefits of Strattera remains positive in the treatment of ADHD in children of 6 years and older and in adolescents. However, in order to optimise the safe use of Strattera it is important that prescribers are aware of the following:

New Advice to prescribers

- Seizures are a potential risk with Strattera and therefore it should be introduced with caution in patients with a history of seizure. Discontinuation of Strattera should be considered in any patient developing seizure or if there is an increase in seizure frequency.
- Reports of QT interval prolongation have been received in association with Strattera. Therefore, it should be used with caution in those with congenital or acquired long QT or a family history of QT prolongation. This risk may be increased if Strattera is used concomitantly with other drugs that produce QT prolongation, drugs that can cause electrolyte disturbances and those that inhibit cytochrome P450 2D6.

Reminder of previous advice

- Due to concerns about an increased risk of suicidal thoughts and behaviour, patients should be monitored for signs of depression, suicidal thoughts or suicidal behaviour and referred for appropriate treatment if necessary.
- There is a risk of rare, but sometimes severe, hepatic disorders. Strattera should be discontinued in patients with jaundice or laboratory evidence of liver injury, and should not be restarted.

The Strattera product information for prescribers (the Summary of Product Characteristics) and patients (the Patient Information Leaflet) are currently being updated to include appropriate warnings about the risk of seizures and QT interval prolongation.

Please report any suspected adverse reactions to Strattera via the Yellow Card Reporting Scheme to the CHM/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, Commission on Human Medicines**