

Press release

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Subject: Strattera®

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Updated warnings on the risk of suicidal thoughts with Strattera®

The Medicines and Healthcare products Regulatory Agency (MHRA) is to look into the health risks and benefits of Strattera®, a prescription-only medicine used to treat attention deficit hyperactivity disorder (ADHD). This follows new clinical trial data which identified an increased risk of suicidal thoughts and behaviour in children treated with Strattera®.

Strattera® is not extensively used in the UK for the treatment of ADHD, but patients together with parents and guardians are being advised of this risk and should be made aware of any possible signs and symptoms.

Dr June Raine, Director of Medicines post-licensing at the MHRA said, "We are advising healthcare professionals that patients should be carefully monitored for signs of depression, suicidal thoughts or suicidal behaviour and referred for alternative treatment if necessary. Children who are doing well on this medication should continue their treatment. Those who experience any unusual symptoms, or are concerned, should speak to their doctor to discuss the best course of action."

Updated warnings will be put on the patient information leaflet (PIL) for Strattera® about the risk of suicidal thoughts and behaviour.

Patients and healthcare professionals are urged to report any suspected adverse reactions to Strattera® via the Yellow Card Scheme. They are available directly from the Yellow Card hotline on freephone 0808 100 3352 or can be completed on the web at www.yellowcard.gov.uk.

Ends

Notes to Editor:

1. Strattera® (atomoxetine) is used to help control the symptoms of attention deficit hyperactivity disorder (ADHD - inability to pay attention and impulsiveness and hyperactivity) in children and adolescents. It was licensed in the UK in July 2004.
2. It is estimated that approximately 15,000 patients have been treated with Strattera® in the past year. It is not extensively used in the UK and Ritalin® (methylphenidate) is the main drug used in the treatment of ADHD.
3. On 15 September 2005, the manufacturer (Lilly) submitted further analyses of their clinical trial data which do identify an increased risk of suicidal thoughts in those receiving Strattera® compared with those receiving placebo.
4. The Yellow Card Scheme enables healthcare professionals and patients to report any suspected adverse drug reaction to the MHRA.
5. The MHRA is the government Agency which is responsible for ensuring that medicines and medical devices work, and are acceptably safe. We keep watch over medicines and devices, and we take any necessary action to protect the public promptly if there is a problem. No product is risk-free. Underpinning all our work lie robust and fact-based judgements to ensure that the benefits to patients and the public justify the risks.