

**STRATTERA**  
**(atomoxetine hydrochloride)**

**MUTUAL RECOGNITION PROCEDURE**  
**UK/H/0686/001-006**

**8<sup>th</sup> PERIODIC SAFETY UPDATE REPORT**

**REFERENCE MEMBER STATE'S FINAL ASSESSMENT**  
**REPORT**

**04 December 2007**

<b>Pharmaceutical form(s)</b>	<b>5 mg, 10 mg, 18 mg, 25 mg, 40 mg, 60 mg HARD CAPSULES</b>
<b>MAH</b>	<b>Eli Lilly and Company</b>
<b>IBD/EBD</b>	<b>26/11/2002 (U.S.) / 26/05/2004 (E.U.)</b>
<b>PSUR covered period</b>	<b>27/11/2006 – 26/05/2007</b>
<b>RMS</b>	<b>United Kingdom</b>
<b>CMS</b>	<b>AT, BE, CY, CZ, DE, DK, EE,EL, ES, FI, HU, IE, IS, It, LI, LT, LU, LV, MT, NL, NO,PL, SE, SI, SK</b>
<b>Assessor</b>	<b>XXXXX</b>
<b>Contact point</b>	<b>XXXXX</b>

Four cases related to depression or depressive symptoms.

Three cases were reports of hallucinations.

Three cases were reports of tics.

There was one report of homicidal ideation and aggression, one report of mania with abnormal behaviour, one report of restlessness with sleep disorder and impulse-control disorder, one report of impulsive behaviour with fatigue and educational problem, and one report of pyromania with aggression, convulsions and somnolence

*Assessor's comments:*

*Suicidal behaviour is a listed reaction and this issue is being kept under review.*

*With regards to the reports of depression, emotional lability and mood swings are listed reactions. This is an area that should be kept under review*

*With regards to the reports of tics, in two of these cases the patients had an underlying tic disorder and in the third it was unclear if the patient experienced a tic or dystonia. The MAH has recently been requested to provide a further cumulative evaluation of all serious and non-serious cases of tic with atomoxetine, as the previous review was too restricted to allow a meaningful assessment of the signal.*

*The MAH has recently been asked to perform a cumulative review of all spontaneously reported cases of 1) mania, 2) psychotic disorders and 3) hallucinations.*

*The MAH has also been asked to provide a cumulative review of homicidal ideation and/or behaviour (all serious and non-serious cases) in the next PSUR.*

### 3.5.19 Renal and Urinary Disorders

There have been a total of 21 case reports where the primary reaction categorised in this SOC. None of the cases had a fatal outcome and none were serious unlisted reactions.

### 3.5.20 Reproductive System and Breast Disorders

There have been a total of 42 case reports where the primary reaction was categorised in this SOC. None of the cases had a fatal outcome and none were serious unlisted reactions.

### 3.5.21 Respiratory, Thoracic and Medistinal Disorders

There have been a total of 12 case reports where the primary reaction was categorised in this SOC. None of the cases had a fatal outcome. There were 2 serious, non-fatal case reports with an unlisted ADR as a primary reaction in this SOC:

Case 1 - **XXXXXX** who experienced a pneumothorax after approximately two years of atomoxetine treatment. The patient experienced another pneumothorax approximately 8 months later. The reporter felt that the patient was predisposed to this type of event as his was **XXXXXX**.

Case 2 – involved a 15 year old male who was hospitalised with acute alcohol, unknown drug intoxication and respiratory failure 7 days after starting atomoxetine. The patient had consumed 4-6 dL of 60% ethanol and had taken 4 tablets of an unknown drug by crushing them and sniffing the powder. The patient recovered from respiratory failure.

### 3.5.22 Skin and Subcutaneous Tissue Disorders

There have been a total of 55 case reports where the primary reaction as categorised in this SOC. None of the cases had a fatal outcome. There were 4 serious, non-fatal case reports with an unlisted ADR as a primary reaction in this SOC. One was a case of cold sweat and the other three were reports of skin discoloration, which are suggestive of possible Raynaud's phenomenon or peripheral vascular instability.