All Wales Medicines Strategy Group

Grŵp Strategaeth Meddyginiaethau Cymru Gyfan

Final Appraisal Recommendation

Advice No: 0214 – January 2014

Atomoxetine (Strattera®) 10 mg, 18 mg, 25 mg, 40 mg, 60 mg, 80 mg and 100 mg hard capsules

Submission by Eli Lilly & Co Ltd

Recommendation of AWMSG

Atomoxetine (Strattera®) is recommended for use within NHS Wales for the initiation of treatment in adults with attention deficit hyperactivity disorder (ADHD). Treatment must be initiated by a specialist in the treatment of ADHD, such as a paediatrician, child/adolescent psychiatrist, or psychiatrist. Diagnosis should be made according to current Diagnostic and Statistical Manual of Mental Disorders (DSM) criteria or the guidelines in International Classification of Mental and Behavioural Disorders (ICD).

In adults, the presence of symptoms of ADHD that were pre-existing in childhood should be confirmed. Third-party corroboration is desirable and atomoxetine should not be initiated when the verification of childhood ADHD symptoms is uncertain. Diagnosis cannot be made solely on the presence of one or more symptoms of ADHD. Based on clinical judgment, patients should have ADHD of at least moderate severity as indicated by at least moderate functional impairment in two or more settings (for example, social, academic, and/or occupational functioning), affecting several aspects of an individual's life.

Additional note:

- Please refer to the Summary of Product Characteristics for the full licensed indication.

In reaching the above recommendation AWMSG has taken account of the appraisal documentation prepared by the AWMSG Secretariat (reference number 1361), which includes the AWMSG Secretariat Assessment Report (ASAR), the Preliminary Appraisal Recommendation (PAR) and the applicant company's response to the PAR, clinical expert opinion (where available), the views of patients/patient carers (where available) and the lay member perspective.

This recommendation has been ratified by Welsh Government and will be considered for review every three years.

Marketing authorisation holder on first issue:	Eli Lilly & Co Ltd
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