DRUG ALERT

Warning: selective serotonin reuptake inhibitors in children and adolescents

The Medicines Control Council (MCC) has resolved that manufacturers of selective serotonin reuptake inhibitors (SSRIs) update the package inserts for their products to include warning statements alerting health care providers to an increased risk of worsening of depression and suicidality (suicidal thinking and behaviour) in patients being treated with these agents, and to include additional information about the use of these medicines in children and adolescents.

The risk of suicidality for these medicines was identified in a combined analysis of short-term (up to 4 months) placebo-controlled trials of antidepressant agents, including the SSRIs and others, in children and adolescents with major depressive disorder (MDD), obsessive-compulsive disorder (OCD) or other psychiatric disorders. A total of 24 trials involving over 4 400 patients were included. The analysis showed a greater risk of suicidality during the first few months of treatment in those receiving antidepressants. The average risk of such events on drug was 4%, twice the placebo risk of 2%. No suicides occurred in these trials.[1]

On the basis of these data, prescribers should be alerted to the following points:

- None of the SSRIs are currently approved in South Africa for any indication in children and adolescents.
- SSRIs have been associated with an increase in the risk of suicidal thinking and behaviour (suicidality) in children and adolescents with MDD and other psychiatric disorders.[2]
- Products containing citalopram, escitalopram, fluvoxamine, paroxetine, sertraline and venlafaxine are contraindicated in children under 18 years of age, as safety and efficacy have not been established in this age group. The package inserts for these products are being updated accordingly.
- Discontinuation of SSRIs, especially abrupt discontinuation, commonly leads to significant withdrawal symptoms.[2] When stopping treatment of an SSRI the dose should be tapered over an appropriate period of time. The package insert for the SSRI should be referred to.

The MCC is currently working with the manufacturers of all approved antidepressant agents to optimise the safe use of these medicines and implement the product package insert changes and other safety communications in a timely manner.

Health professionals are encouraged to report any adverse reactions associated with the use of medicines to the MCC's National Adverse Drug Event Monitoring Centre by telephone (021) 447-1618 or fax (021) 448- 6181.

National Adverse Drug Event Monitoring Centre
Medicines Control Council
Cape Town

1. FDA Public Health Advisory, 15 October 2004. Suicidality in children and adolescents being treated with antidepressants. **www.fda.gov/cder/drug/antidepressants/SSRIPHA200410.htm** (last accessed 15 August 2005).
2. European Medicines Agency/CHMP/128918/2005. Press Release: European Medicines Agency finalises review of antidepressants in children and adolescents. **http://www.emea.eu.int/pdfs/human/press/pr/12891805en.pdf** (last accessed 15 August 2005).