

Tough curbs on Prozac prescribed for children

- Antidepressant only to be used with counselling
- Drug manufacturer must continue to monitor safety

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Prozac is to be licensed for treating children over eight with depression, but regulators have imposed an unprecedented restriction on its use, ordering that it may not be prescribed unless talking therapies have failed, and even then a course of the drug must be accompanied by counselling.

The conditions imposed by the European licensing agency (EMA) are likely to result in Prozac being used less to treat children. While neither Prozac nor any of the other antidepressants of its class had a licence, doctors were free to prescribe them as they liked.

Because of shortages of therapists and because they seemed a quick and easy fix, the prescribing of Prozac and other drugs known as SSRIs (selective serotonin reuptake inhibitors) to adults and children soared. The annual number of prescriptions to those under 18 leapt from 13,227 in 1995 to 27,658 in 2003.

While doctors can still theoretically prescribe "off label", they are unlikely to flout the terms of the licence, which will be laid down in the Summary of Product Characteristics and written in the prescribing bible, the British National Formulary.

"Prozac should only be used together with psychological therapy in patients non-responding to such therapy alone after four to six sessions," said the EMA in its recommendation to the European commission, which will formally grant the licence. If the child does not get better in nine weeks, the drug treatment should be reconsidered, it says.

The move is unprecedented, according to Tim Kendall, joint director of the National Collaborating Centre for Mental Health, which formulated the NHS guidelines on the treatment of depression in children. "This is the first time to my knowledge that a drug has been given a licence which includes a period of psychological treatment before and during the drug treatment," he said.

Eli Lilly, manufacturer of Prozac, was specifically asked to apply for a licence by the drug regulator, the Medicines and Healthcare Products Regulatory Authority (MHRA). Prozac is the only antidepressant of the SSRI class the MHRA exempted from its general ban on use in children. Analysis of trial data has shown that the risk children will become suicidal on other SSRIs is greater than the benefit they get from taking the drugs.

With a licence for use on children, Prozac will also be subject to post-licensing surveillance by the MHRA, which will look for reports of troubling side-effects. "I think the MHRA will not take their eye off the ball now," said Dr Kendall.

Eli Lilly has also been instructed by the EMEA to "carry out additional studies to ensure that the safety profile of Prozac remains acceptable". The agency also wants further investigation of findings in the early animal safety studies on "sexual development, emotional behaviour and testicular toxicity".

Meanwhile nearly half the men (46%) questioned for a survey by Men's Health Forum published today said they suffered from stress on a weekly basis and two-thirds admitted to anxiety or depression. But almost a third said they would be too ashamed or embarrassed to ask for help.