

A CLINICAL trial by the makers of Prozac has revealed evidence the antidepressant could harm the growth and development of children.

The Sunday Herald has uncovered details of a 19-week trial carried out by Eli Lilly where children aged between eight and 17 years old who were given the drug gained an average of 1cm less in height and 1.1kg less in weight than others treated with a placebo.

The results revealed that treatment with fluoxetine, the generic name for Prozac, was also linked to a decrease in levels of alkaline phosphatase, an enzyme crucial to bone development.

Despite concerns from America's Food and Drug Administration (FDA) in 2001, which requested that Lilly carry out a further one-year trial to ensure the drug was safe to be used by children, no such test has ever been done.

According to FDA documents seen by the Sunday Herald, Lilly refused to carry out a more thorough trial, but was granted a licence to prescribe Prozac to children a year later. In the FDA paper Andrew Mosholder, medical officer for the FDA, writes: "Nineteen weeks of fluoxetine treatment was associated with reduced growth velocity relative to placebo.

"On balance, I believe that this trial provides evidence of reduced growth velocity with fluoxetine treatment, and I believe labelling should reflect the finding. In my opinion, the sponsor has not provided an adequate rationale for declining to do a one-year study as we requested."

British experts on psychiatric drugs last night expressed astonishment about the trial, the results of which have never been highlighted to doctors or printed by Eli Lilly on UK Prozac patient information leaflets.

News about the possible harm to children comes at a time when the Medicines and Healthcare Products Regulatory Authority (MHRA), the UK drug licensing agency, is considering an application by Lilly to have Prozac licensed for use on under-18s.

In the last year, thousands of British children have moved on to Prozac after the MHRA ruled that all antidepressants in the SSRI class, with the exception of Prozac, should be banned from use on children. The change followed a major inquiry by the authority that found the drugs could cause suicide.

Although Prozac does not have a licence for use on children, the decision to ban all other SSRIs has led to a massive rise in the number of doctors and psychiatrists prescribing the drug to children on an "off-licence" basis. Before the MHRA ban, experts say 25,000 children under the age of 18 in the UK were being prescribed antidepressants.

Between 2000 and 2002 the number of antidepressant prescriptions for children soared by

68%.

Dr David Healy, director of the north Wales department of psychological medicine, whose warnings that antidepressants could cause suicide led to the MHRA inquiry, expressed concern at the Prozac trial results. He said: "Very few people will have heard of this. Doctors who are giving Prozac to children and who read the published scientific articles won't see anywhere that clinical trials have indicated that children on Prozac don't grow as well.

"This was flagged up by the FDA two years ago and the FDA asked the company to do further work. It should give people who may be thinking about using the drug, some cause for concern."

He said that in the past, trials on antidepressants had been carried out and been reported by pharmaceutical firms "in very misleading terms".

"In the Prozac children's trials there is evidence that the children didn't grow and put on weight in the same way," he said. "That's the kind of thing you just don't get to hear about. For those who are in the process of development this is potentially a very important issue.

"You'd have thought that in the first instance the company or the MHRA, who are responsible for making sure these drugs are on the market, would ensure that an appropriate label was placed on them so that we would know what the risks are and know what to look out for.

"But when you look at the label for Prozac there is no mention of concerns about the development of children. All it says is that this product is not recommended for children. But the number of children taking Prozac in the UK has increased hugely in the last two years."

Dr Andrew Herxheimer, a clinical pharmacologist and founding editor of the Drug And Therapeutics Bulletin, said: "I think the news about the possible effect on children's growth is serious. The effects of antidepressants in children is a hugely under-researched area.

"When there are doubts the benefit of the doubt has to be given to the patients and not to the drug. But both the MHRA and Eli Lilly are not in the business of admitting doubt."

Dr Iain McClure a child and adolescent psychiatrist and spokesman for the Royal College of Psychiatrists in Scotland, said that despite prescribing Prozac to children for the last five years he had not encountered problems with side-effects. He added: "Over the last few years I've been using fluoxetine with young people and I have not experienced any difficulties with side-effects and I've seen genuine therapeutic results.

"All I can do is speak to my own clinical experience of using fluoxetine with young people. I haven't had such evidence brought to my attention."

Dr Harvey Marcovitch, a consultant paediatrician and associate editor of the BMJ, said: "There is lots of information that is not generally available and pharmaceutical companies have been accused of publishing good news and burying bad news for years. As a journal editor, I believe

that every trial that's ever conducted ought to be published somewhere regardless of whether the results are embarrassing to somebody or not."

Andrew Day, a spokesman for Eli Lilly, said the company was designing a "long-term" study into the effects of Prozac on children's development. He added: "We have a clear and transparent policy. Any and all clinical data that we have is shared with all regulatory authorities."

A spokeswoman for the MHRA said: "Eli Lilly was encouraged to put in a licence application for Prozac and that is being considered at the moment."

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Author: *Liam McDougall*

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