



Research warning on drug for kids

Clara Pirani, Medical reporter

AUSTRALIA'S medicines regulator approved Ritalin as a treatment for ADHD in children in 1993 despite drug evaluators warning there was insufficient data about the drug's safety.

A 1993 report by the Australian Drug Evaluation Committee, the Therapeutic Goods Administration's advisory body, found that no clear data on laboratory testing of Ritalin had been provided. "Data on the incidence of adverse reactions was provided in only four of the short-term placebo-controlled trials," the drug committee noted in its report to the TGA.

The documents - obtained under Freedom of Information by the Citizens Committee on Human Rights, a group founded by the Church of Scientology - also reveal that the committee was concerned about the lack of research to support the approval of a long-acting, higher dose of Ritalin, called Ritalin LA, in 2002.

Almost 400 serious adverse reactions to ADHD drugs have been reported to the

TGA, some involving children as young as three. Cases include the sudden death of a seven-year-old, and a five-year-old who suffered a stroke after taking Ritalin.

The evaluator said there was "no safety data on Ritalin LA for longer than 12 weeks" and recommended that its use be limited to children between the ages of six and 12.

West Australian MP Martin Whitely, who has campaigned against the widespread use of ADHD medication, said the TGA had not adequately assessed Ritalin.

"The TGA has approved ADHD drugs despite knowing that the safety data to support the application was seriously deficient," Mr Whitely said.

George Halasz, a senior lecturer in psychological medicine at Monash Medical Centre, said there was a need for better research into long-term use of both forms of Ritalin.

"Ritalin is commonly used in children younger than six and older than 12," Dr

Halasz said. "Given the concern by a committee at such an official level at the absence of such long-term studies, I would have thought that the first action would be to launch such studies."

The TGA will be asked about the safety data for Ritalin at the Senate estimates hearings today. A spokeswoman for the TGA said that in its evaluation of Ritalin and Ritalin LA, the agency took into consideration that the drug had been available in Australia since the 1960s as a treatment for several disorders.

She said Ritalin LA was not recommended for children under the age of six.

The TGA disputes there was a lack of data about the long-term use of Ritalin.

"Long-term efficacy was documented in two studies with approximately 180 subjects," the spokeswoman said.

privacy terms © The Australian