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Probe into anti-depressants being conducted 'in secret'

Julie-Anne Davies | *November 01, 2008*

THE Therapeutic Goods Administration is investigating the adverse effects of SSRI anti-depressants, a widely prescribed group of drugs that includes the well-known brands Prozac and Zoloft.

The TGA confirmed in a statement to The Weekend Australian that it had established a special expert panel of psychiatrists and epidemiologists to review a number of cases involving patients who had had adverse reactions to these drugs. It is believed hundreds of cases will be reviewed.

"Although there has not been a jump in adverse events from SSRIs, there has been community concern about potential overuse," the TGA said.

Medicare figures show that, since 1990, when Prozac first appeared on pharmacy shelves, there have been almost 10,000 reports of suspected adverse reactions to SSRIs received by the TGA's Australian Adverse Drug Reactions Advisory Committee.

More than 12 million SSRI antidepressant scripts were subsidised by the Pharmaceutical Benefits Scheme last year.

Sydney psychiatrist Yolande Lucire, who has reported between 300 and 400 cases to the TGA in which she claims patients have had serious reactions to the anti-depressants, including some who had committed suicide, said the inquiry must be made public.

"This is being done in secret," Dr Lucire said. "We have no terms of reference, no opportunity for people to make submissions; it's a scandal."

Federal Health Department secretary Jane Halton wrote to Dr Lucire recently, informing her the inquiry was under way and the panel would report back at the end of this year.

"This only happened after," Dr Lucire said. "In frustration at being fobbed off by the TGA, I personally sent the head of the department 100 cases detailing what had actually happened to people who went from being fully functioning members of the

community to patients with serious mental health problems and some who in fact killed themselves after being put on these drugs for stress-related disorders."

The TGA has also asked all drug companies that market SSRI anti-depressants in Australia to update the wording of their suicide warnings concerning children and young people under 24 years in the information provided to patients.

"The TGA is working with other sponsors to ensure that the wording in the CMI clearly reflects the issues contained in the product information for their products," it said.

The move comes after an investigation by The Weekend Australian revealed several hundred thousand scripts for anti-depressants such as Zoloft and Prozac were last year prescribed to children and subsidised through the Pharmaceutical Benefits Scheme, despite the TGA and Pfizer, the company that markets Zoloft in Australia, recommending they not be prescribed to anyone under the age of 24 for the treatment of depression.

Significant discrepancies in the information given to parents about the potential dangers of the drugs to children were also uncovered.

Two weeks ago, Melbourne mother Nicola Mulcahey reached a confidential court settlement with her 16-year-old daughter's GP, who she had sued for prescribing Zoloft to the teenager for depression.

Ms Mulcahey claimed the drug made her daughter suicidal and said she was not advised of the risks associated with the drug.

In another case detailed in The Australian and now being followed up by Pfizer, a 14-year-old girl became suicidal after taking Zoloft. Her parents said they were not warned this might happen nor told to monitor her for symptoms of suicidal thoughts or self-harm.

David Kitching, from the Royal Australian and New Zealand College of Psychiatrists, said his organisation was unaware of the inquiry and had not been approached by the TGA to contribute.

"But in the general setting I would say that nothing new in the literature suggests we need to be any more vigilant than we already have been when it comes to documenting the side effects of this class of drug," Dr Kitching said.

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