

REVIEW OF SAFETY OF CERTAIN ANTIPSYCHOTIC AND ANTIDEPRESSANT MEDICINES**Response:**

- To respond to repeated representations from psychiatrist [REDACTED] concerning the safety of certain psychotropic medications, in August 2008 the TGA established an independent expert advisory panel to review dozens of case reports submitted to the TGA by [REDACTED].
- [REDACTED] is a psychiatrist with a special interest in forensic and medico-legal psychiatry, who has very strong views concerning the safety of SSRI antidepressants and atypical antipsychotic medications
- The TGA's Office of Medicines Safety Monitoring (OMSM) has been in correspondence with [REDACTED] since February 2004.
- [REDACTED]
- In August 2008 the Secretary wrote to [REDACTED] informing her that the TGA had established a special panel to consider and comment on the case reports that she had submitted. It is apparent that [REDACTED] has shared this information with [REDACTED].
- [REDACTED]
- On 20 April 2009 the TGA received a request from [REDACTED] under the *Freedom of Information Act 1982*, requesting further details of the expert panel and its deliberations to date. This request is currently being processed by the TGA in accordance with the FOI Act.
- [REDACTED]
- [REDACTED] continues to correspond with the OMSM about many subjects that she feels the OMSM should be aware of ranging from the safety of psychiatric medicines to the alleged corruption within the pharmaceutical industry and in governments here and overseas.
- Since December 2008, the OMSM has received approximately 400 separate emails from [REDACTED]. It has not been possible to respond to these given the sheer volume of correspondence, in many cases of uncertain relevance to the TGA's role or activities.
- It is anticipated that the expert panel will deliver its findings to the TGA within the next few weeks. The work of the panel has to some degree been delayed by the undertaking given to review the many public representations made earlier in the year.

Background

To respond to concerns raised by repeated representations from psychiatrist [REDACTED] concerning the safety of certain psychotropic medications, in August 2008 the TGA established an independent expert advisory panel to review dozens of case reports submitted to the TGA by [REDACTED]

[REDACTED] is a psychiatrist with a special interest in forensic and medico-legal psychiatry, who has very strong views concerning the safety of SSRI antidepressants and atypical antipsychotic medications. From her frequent correspondence it may be inferred that she believes the risks of the use of these medicines outweigh the potential benefits for many patients, either when used alone or in combination with other psychotropic medications. She has been particularly concerned about a particular side effect known as *akathisia*, a condition of motor restlessness which appears to occur more commonly with SSRIs than other antidepressants, and that akathisia may lead to suicidal behaviour and violence.

[REDACTED]

In August 2008 the Secretary wrote to [REDACTED] noting that the TGA had previously referred case reports submitted by her to ADRAC, but that in order to respond to [REDACTED] persistent concerns, the TGA had established the special panel to consider and comment on the case reports that she had submitted. [REDACTED] was advised the panel would also review the relevant literature and determine the degree to which the adverse effects documented by her were reported in the literature and reflected in the various Product Information documents.

[REDACTED]

Index No:



Division: Therapeutic Goods Administratio

Cleared by:

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Phone: (w) (h) (mob)

Date:

Outcome: 1: POPULATION HEALTH AND SAFETY