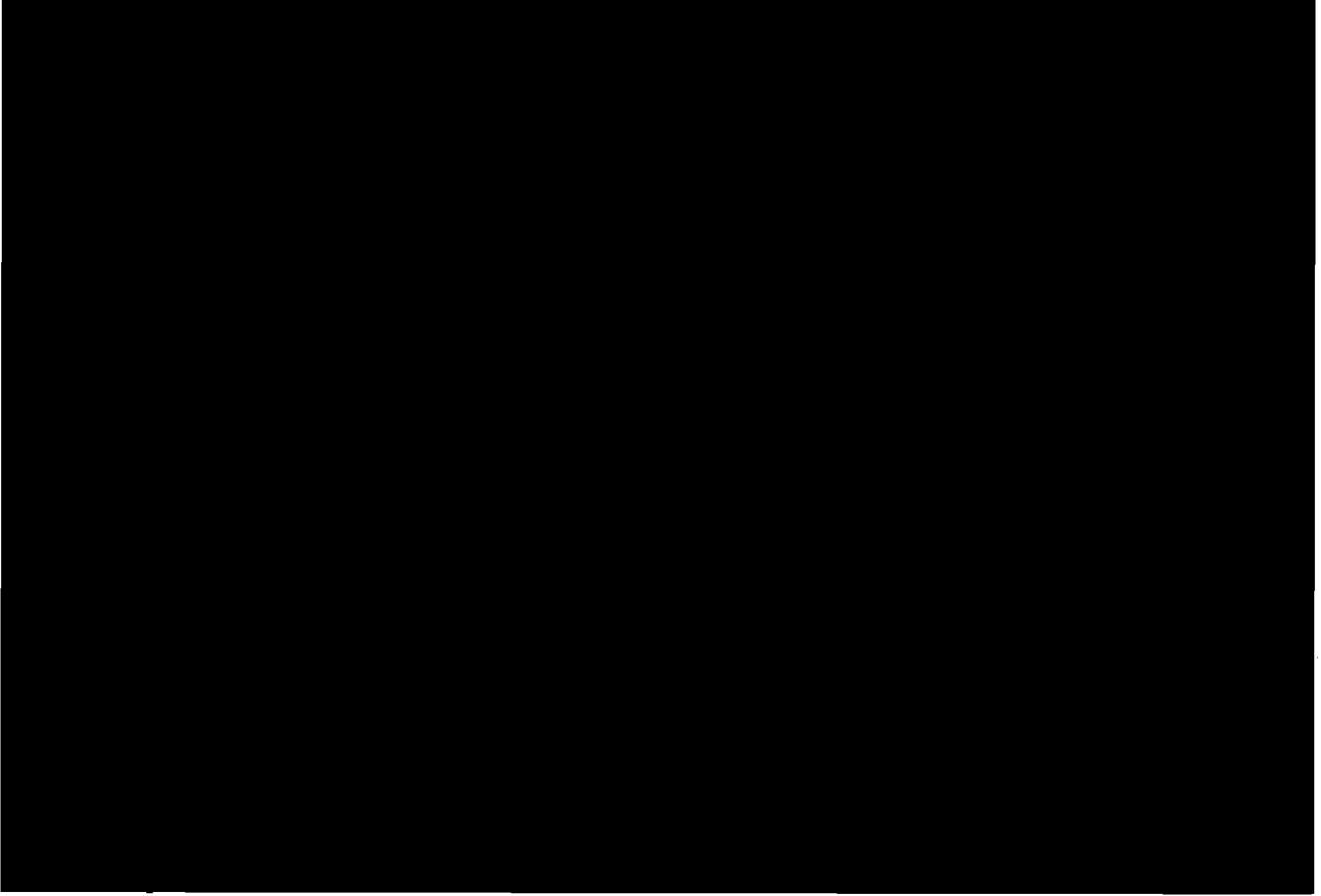


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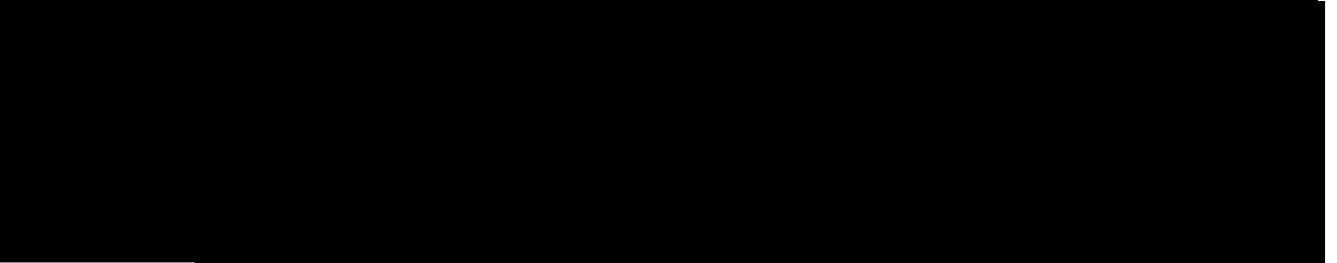
BACKGROUND

To respond to concerns raised by repeated representations from psychiatrist [REDACTED] concerning the safety of certain psychotropic medications, in August this year 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.

The TGA Office of Medicines Safety Monitoring has been in correspondence with [REDACTED] since February 2004.



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]