

[REDACTED]  
Review of Complaint

Background

Between January 2004 and July 2005, [REDACTED] submitted to the Adverse drug Reactions Advisory Committee the case details of more than 250 patients who m she claimed had experienced adverse reactions to medicines used in psychiatric practice.

All these case reports were individually assessed by professional staff (pharmacist and in many cases medical officer) within the Adverse Drug Reactions Unit, Therapeutic Goods Administration (TGA) in accordance with the standard practices and procedures of the Unit, as are applied to all Australia adverse drug reaction reports.

There has been some disagreement between [REDACTED] and the TGA about the significance of those reports and the regulatory stance taken by the TGA.

On 30 January 2008, [REDACTED] wrote to the Secretary of the Department of Health and Ageing (Ms J Halton) submitting two folders which contain 88 case histories, each apparently extracted from her specialist opinion letters and each of which is said to describe an adverse reaction to a medicine used.

