

Poisons and Drugs Amendment Regulation 2006 (No 1)

Subordinate Law SL2006–40

made under the

Poisons and Drugs Act 1978

EXPLANATORY STATEMENT

Clozapine is an anti-psychotic medication. It is a prescription only medicine, and is also listed in Appendix D of the Standard for the Uniform Scheduling of Drugs and Poisons (the Standard). This means that the national standard for regulating prescription of this medicine is that it may only be prescribed by someone who has received an authorisation to do so. This reflects the need to ensure that doctors prescribing clozapine are properly qualified and aware of the monitoring that must be done in order to minimise the risk of an adverse incident for patients who are taking this medication.

This part of the Standard has been implemented under the *Poisons and Drugs Act 1933* (the Act) and the *Poisons and Drug Regulation 1993* (the Regulation). The Appendix D medicines, including clozapine, are listed in as “restricted substances” in the Regulation. This means that only specialists may prescribe it, and then only after seeking written permission from the Chief Health Officer (the CHO). At the time this was done, it was considered prudent to restrict the right to prescribe this (and other Appendix D medicines) to specialists, even though the Standard does not require this for all Appendix D medicines, and in particular does not require it for clozapine. Other Australian jurisdictions allow clozapine to be prescribed by GPs who have the relevant approval (a requirement which more closely reflects the Standard).

The removal of clozapine from the list of “restricted substances” in the *Poisons and Drug Regulation 1993* will enable clozapine to be regulated by other means. As this amendment is made, a declaration will be made under the *Public Health Act 1997* to make the prescribing of clozapine a licensable public health risk activity. The net result of this is that individual doctors who want to prescribe clozapine will need to apply under the *Public Health Act 1997* for approval to do so rather than the *Poisons and Drugs Act 1933*. However, such applications will not be restricted to specialists, and, importantly, such approvals will be able to be granted to the doctors on staff at Mental Health who are appropriately qualified to prescribe and handle the drug properly even though they are not specialists as defined in the *Poisons and Drugs Act 1933*.

No regulatory impact statement has been prepared for this amendment. The instrument being made under the *Public Health Act 1997* maintains a level of regulatory control over prescribing of clozapine very similar to that imposed by the *Poisons and Drugs Regulation 1993*, and in fact relaxes the restrictions to allow more doctors to be given permission to prescribe clozapine.