STATEMENT OF COMPATIBILITY FOR A LEGISLATIVE INSTRUMENT THAT DOES NOT RAISE ANY HUMAN RIGHTS ISSUES

Statement of Compatibility with Human Rights

Prepared in accordance with Part 3 of the Human Rights (Parliamentary Scrutiny) Act 2011

Therapeutic Goods Information (Joint Adverse Event Notifications System) Specification 2012

This legislative instrument is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

Overview of the Bill/Legislative Instrument

The Therapeutic Goods Information (Joint Adverse Event Notifications System) Specification 2012 is made by the Minister for Health under subsection 61(5D) of the *Therapeutic Goods Act 1989* (the Act). The Specification permits the Secretary of the Department of Health and Ageing to release to the public specified kinds of information relating to adverse events about medicines reported in Australia or New Zealand. The information authorised to be released includes the nature of such adverse events, the medicine reportedly involved, the reported age and gender of the person affected and summarised statistical details such as the number of cases of reported adverse events in Australia and/or New Zealand for a specified period involving a medicine. The information to be released does not include personal information within the meaning of the *Privacy Act 1988*.

Human rights implications

This legislative instrument does not engage any of the applicable rights or freedoms.

Conclusion

This legislative instrument is compatible with human rights as it does not raise any human rights issues.

John Skerritt, delegate of the Minister for Health