

**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 (Stakeholder Consultation on Database of Adverse Event
Notifications – Medical Devices) Specification 2013**

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 (Stakeholder Consultation on Database of Adverse Event Notifications – Medical Devices) Specification 2013 is made by the Minister for Health under subsection 61(5AB) of the *Therapeutic Goods Act 1989* (the Act). The effect of the making of the instrument is that it will permit the Secretary of the Department of Health and Ageing to release information already held by the Therapeutic Goods Administration (TGA) relating to adverse events reported about medical devices to the bodies (including the Consumer Health Forum of Australia and the Medical Technology Association of Australia) and kinds of persons described in the instrument in order to obtain feedback about the establishment by the TGA of a publicly available database of such information and about the functionality, suitability and presentation of a prototype of that database. The information authorised to be released by the Secretary includes descriptions of such adverse events and the medical device reportedly involved, but 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