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 (System for Australian Recall Actions) 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 Legislative Instrument

The Therapeutic Goods Information (System for Australian Recall Actions) 2013 (the Specification) is made by the Minister for Health under subsection 61(5D) of the *Therapeutic Goods Act 1989* (the Act). It has the effect of permitting the Secretary of the Department of Health and Ageing to release to the public specified kinds of information relating to Australian recall actions being information kept by the Therapeutic Goods Administration in its System for Australian Recall Actions database.

Recall action is described in the Specification as action taken by a person to resolve a problem with therapeutic goods supplied in the Australian market that have, or may potentially have, deficiencies relating to safety, quality, efficacy or presentation. The kinds of information that will be released include, for example, the name and a description of the goods, the person undertaking the recall and its date of commencement, the nature of the recall action (e.g., permanent removal of the goods from the Australian market), recall instructions and relevant contact information for obtaining more information about the goods.

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.

Dr John Skerritt, delegate of the Minister for Health