EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods Information (Sharing of Information about Prescription Medicines) Specification 2015

The *Therapeutic Goods Act 1989* (the Act) provides for the establishment and maintenance of a national system of controls for the quality, safety, efficacy/ performance and timely availability of therapeutic goods that are used in, or exported from, Australia. The Therapeutic Goods Administration (the TGA), which is part of the Department of Health, is responsible for administering the Act.

Section 61 of the Act lists a number of persons or organisations, such as the World Health Organisation and state and territory authorities that have functions relating to therapeutic goods, to which the Secretary of the Department of Health can release specified kinds of therapeutic goods information. Section 61 also allows the Minister for Health to make a legislative instrument setting out other circumstances in which the Secretary can release therapeutic goods information under that section.

The *Therapeutic Goods Information (Sharing of Information about Prescription Medicines) Specification 2015* (the Specification) is made by a delegate of the Minister under subsection 61(5AB) of the Act, and specifies kinds of therapeutic goods information that can be released, bodies and kinds of persons to whom that information can be released, and the purposes for which it can be released, by the Secretary under subsection 61(5AA) of the Act.

The making of the Specification has the effect of permitting the Secretary to release therapeutic goods information of a kind mentioned in the Specification to the body mentioned in the Specification, for the purposes set out in the Specification.

Therapeutic goods information in this context is defined in subsection 61(1) of the Act as, relevantly, information in relation to therapeutic goods that is held by the Department and that relates to the performance of the Department's functions.

The Specification commenced on the day after it was registered on the Federal Register of Legislative Instruments.

BACKGROUND

NPS MedicineWise, which was established in 1998, is an independent non-profit organisation funded by the Department of Health to undertake work in the quality use of medicines, with the philosophy of providing health professionals and consumers with access to a range of information and other supports for good prescribing and informed decisions about medicines and medical tests. The website is at http://www.nps.org.au/.

NPS MedicineWise publishes the independent journal *Australian Prescriber*, which contains articles, features and information about medicines and therapeutics, and includes the Medicines Safety Updates, the medicine safety bulletin of the TGA. The purpose of this journal is to help health professionals to make informed choices when prescribing by making available independent, reliable and accessible information about drugs and therapeutics. This journal is published six times a year, and is available free

of charge online at http://www.australianprescriber.com. Health professionals are entitled to a free subscription of the paper copy.

Each edition of *Australian Prescriber* contains a section providing information on prescription medicines recently approved by the TGA by registration on the Australian Register of Therapeutic Goods (the Register). The comments usually contain a description of the medicine, its indications, pharmacology, the outcome of relevant clinical trials, contraindications and precautions and a summary of its overall likely benefit for the intended patient group.

Where available, these comments take into account the material published by the TGA about the medicine in the form of an Australian Public Assessment Report (AusPAR). An AusPAR contains information about the evaluation of a prescription medicine and the considerations that led the TGA to approve or not approve the application for the medicine's registration (see http://www.tga.gov.au/industry/pm-auspar.htm).

An AusPAR is generally published for new chemical entities, a new salt/ester of a previously approved active ingredient, bio-similar medicines, and new combinations of previously approved active ingredients and extensions of indications. AusPARs are not normally published for new versions of existing medicines where the change is a new product strength, new dosage form or route of administration, a change in patient group (for instance, involving a reduction in indications), change in dosage, or for generic versions of existing medicines.

However, where a prescription medicine is approved for registration, the AusPAR may not always have been published on the TGA's website at the time the newly approved medicine becomes available for prescribing by health professionals and when the publication of information about it in the *Australian Prescriber* would potentially be warranted. This means that NPS MedicineWise will not have available information about the basis on which the TGA approved the medicine for use in Australia to include in the *Australian Prescriber*.

The purpose of the Specification is therefore to allow the Secretary to provide information set out in an AusPAR for a medicine that is approved for registration to NPS MedicineWise before the finalised AusPAR is published on the TGA's website.

The AusPAR will be used by the NPS MedicineWise only for the purpose of assisting in the preparation of comments on medicines for publication in *Australian Prescriber* and extracts from the AusPAR will not be published before the AusPAR is published by the TGA.

The TGA undertakes consultation with the sponsor of a medicine during preparation of an AusPAR for the medicine. Issues or comments the sponsor has relating to any aspect of the information in the AusPAR are addressed prior to its publication on the TGA website. An AusPAR for a medicine will not be provided to NPS MedicineWise until it is in the form in which it will be published on the TGA website. Sponsors will be informed that the AusPAR will be provided to NPS MedicineWise following its finalisation.

CONSULTATION

Medicines Australia is the peak industry body representing sponsors of prescription medicines in Australia of the kind, information about which will be released by the

Secretary under this Specification. The TGA has consulted with Medicines Australia about its intention to provide copies of finalised AusPARs to NPS MedicineWise as described above. Medicines Australia has indicated that its members are comfortable with the TGA providing the finalised AusPAR and its attachments to NPS MedicineWise, provided TGA also notifies the sponsor at the same time an AusPAR is provided to NPS MedicineWise.

The Specification is a legislative instrument for the purposes of the *Legislative Instruments Act 2003*.

Statement of Compatibility with Human Rights for a legislative instrument that does not raise any human rights issues

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

Therapeutic Goods Information (Sharing of Information about Prescription Medicines) Specification 2015

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 (Sharing of Information about Prescription Medicines) Specification 2015* (the Specification) is made by a delegate of the Minister for Health under subsection 61(5AB) of the *Therapeutic Goods Act 1989* (the Act). The effect of making the Specification is that it will permit the Secretary of the Department of Health to release information in the AusPAR about a registered prescription medicine to the body specified in the instrument, being NPS MedicineWise, for the purpose of publishing information about the medicine in its publication *Australian Prescriber*.

Human rights implications

As this instrument does not include any measures other than providing for the release to NPS MedicineWise of the information outlined above, it 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.

Professor John Skerritt, delegate of the Minister for Health