



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

Therapeutic Goods Act 1989

I, JOHN SKERRITT, a delegate of the Minister for Health, make this Specification under subsection 61(5AB) of the *Therapeutic Goods Act 1989*.

Dated

22nd January 2015

(Signed by)

JOHN SKERRITT

Delegate of the Minister for Health

1 Name of Specification

This Specification is the *Therapeutic Goods Information (Sharing of Information about Prescription Medicines) Specification 2015*.

2 Commencement

This Specification commences on the day after it is registered.

3 Definitions

In this Specification:

Act means the *Therapeutic Goods Act 1989*.

Australian Prescriber means the journal published by NPS MedicineWise containing information for health professionals and health professional students, including comments on newly marketed drugs in Australia.

Australian Public Assessment Report, means, in relation to a registered prescription medicine, the document prepared by the TGA in relation to the medicine that provides information about its evaluation and the considerations that resulted in the application for the medicine being approved.

NPS MedicineWise means the independent organisation of that name funded by the Department of Health.

Product information, in relation to a registered prescription medicine, means information relating to the safe and effective use of the medicine, including information regarding the usefulness and limitations of the medicine, approved by the Secretary under the Act.

Registered prescription medicine means a medicine that is registered in the Australian Register of Therapeutic Goods that either requires a prescription from a health professional or is supplied in a hospital by a health professional.

TGA means the Therapeutic Goods Administration, which is part of the Department of Health.

4 Therapeutic goods information, persons and purposes

The kinds of therapeutic goods information, bodies and purposes, mentioned in Schedule 1 are specified under subsection 61(5AB) of the Act, for the purposes of subsection 61(5AA) of the Act.

Schedule 1 Specified kinds of therapeutic goods information, persons, bodies and purposes

(section 4)

The following kinds of therapeutic goods information, persons, bodies and purposes:

Note: The following specified kinds of therapeutic goods information may be released by the Secretary under subsection 61(5AA) of the Act to the following specified body, for the following specified purpose.

1. Therapeutic goods information:

The following kinds of therapeutic goods information in relation to a registered prescription medicine, being information that is held by the TGA:

- a) information in the Australian Public Assessment Report (AusPAR) for the medicine that is proposed to be published on the TGA website;
- b) information in the Product Information approved by the TGA in relation to the medicine, proposed to be published on the TGA website as an attachment to the AusPAR for the medicine; and
- c) information in the document titled “Extract from the Clinical Evaluation Report”, proposed to be published on the TGA website as an attachment to the AusPAR for the medicine.

2. Body:

NPS MedicineWise.

3. Purpose:

To facilitate the publication by NPS MedicineWise in the *Australian Prescriber* of information about a registered prescription medicine as soon as reasonably possible after its registration in the Australian Register of Therapeutic Goods.

Note

1. All legislative instruments and compilations are registered on the Federal Register of Legislative Instruments kept under the *Legislative Instruments Act 2003*. See <http://www.frli.gov>