



Australian Government

Department of Health

Therapeutic Goods Administration

Therapeutic Goods Information (Medicine Shortages Information Initiative) Specification 2014

Therapeutic Goods Act 1989

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

Dated 19 May 2014

(Signed by)

JOHN SKERRITT

Delegate of the Minister for Health

1 Name of Specification

This Specification is the *Therapeutic Goods Information (Medicine Shortages Information Initiative) Specification 2014*.

2 Commencement

This Specification commences on the day after it is registered.

3 Definitions

In this Specification:

Act means the *Therapeutic Goods Act 1989*.

Active ingredient has the same meaning as in the Regulations.

Anticipated shortage, in relation to a medicine, means a shortage of the medicine that is anticipated to commence at a future date.

ARTG means the Australian Register of Therapeutic Goods.

Consumer demand, in relation to a medicine, means the overall volume and timing needs of the consumer to access the medicine. For the purpose of medicine shortages, the assessment of the demand is limited to the availability to the overall Australian market and not the separate points of distribution.

Current shortage, in relation to a medicine, means a shortage of the medicine that has commenced and is ongoing.

Discontinuation, in relation to a medicine, means that the sponsor has decided to cease supply of the medicine to the Australian market.

Medicine (other than where it is a substitute medicine) means a registered therapeutic good included in the ARTG that:

- is a medicine within the meaning of the Act;
- contains a substance mentioned in Schedule 4 or 8 to the Standard for Uniform Scheduling of Medicines and Poisons; and
- is normally available for supply in Australia.

Regulations means the *Therapeutic Goods Regulations 1990*.

Resolved shortage, in relation to a medicine that has been the subject of an anticipated or current shortage, means:

- in relation to a medicine which has been the subject of an anticipated shortage – a shortage is no longer anticipated to commence in the future other than by reason that there is a current shortage of the medicine; and
- in relation to a medicine which has been the subject of a current shortage – that the supply of the medicine is now meeting normal consumer demand.

Sponsor, in relation to a medicine, means the person in relation to whom the medicine is included in the ARTG.

Shortage, in relation to a medicine, means that the supply of the medicine is not reasonably likely to meet the normal or projected consumer demand for the medicine within Australia for a period of time.

Substitute medicine, in relation to a medicine which is subject to a shortage, means a medicine that has the same active ingredient as the medicine subject to the shortage, but may have a different strength, dosage form or route of administration.

Supply, in relation to a medicine, means the overall arrangements for the meeting of consumer demand.

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

Therapeutic alternative, in relation to a medicine which is subject to a shortage, means other therapeutic options that a health professional may consider as an alternative treatment for a patient who may be affected by a shortage of the medicine.

4 Therapeutic goods information

The kinds of therapeutic goods information mentioned in Schedule 1 are specified under subsection 61(5D) of the Act for the purposes of subsection 61(5C) of the Act.

Schedule 1 Specified kinds of therapeutic goods information

(section 4)

The following kinds of therapeutic goods information:

Note: The following specified kinds of therapeutic goods information may be released by the Secretary to the public under subsection 61(5C) of the Act.

Kinds of therapeutic goods information relating to a medicine in relation to which there is, or was, an anticipated shortage or current shortage, or which is a discontinuation

Item	Information	Description
(a)	Sponsor name	The name of the sponsor.
(b)	Sponsor's nominated public contact details	An Australian telephone number and / or email address nominated by the sponsor for the purposes of responding to enquiries from the public seeking additional information about the medicine.
(c)	Sponsor's nominated website details	The website address (URL) nominated by the sponsor for the purposes of providing the public with additional information about the medicine.
(d)	Active ingredient(s)	The active ingredient(s) of the medicine.
(e)	ARTG number	The ARTG number of the medicine.
(f)	Name of medicine	The trade or brand name of the medicine.
(g)	Strength	The strength of the medicine.
(h)	Dosage form	The dosage form of the medicine.
(i)	Pack size(s)	The pack size(s) of the medicine.
(j)	Therapeutic Class description	The therapeutic classification of the medicine.
(k)	Status of the shortage	Whether the medicine is the subject of an anticipated shortage, a current shortage or a resolved shortage, or a discontinuation.

Item	Information	Description
(l)	Reason for the shortage	<p>The sponsor's advice, in relation to an anticipated or current shortage of the medicine, about the general reason for the shortage, as described as follows:</p> <ul style="list-style-type: none"> (i) a product recall; (ii) a manufacturing site problem; (iii) an unexpected increase in demand (for instance because of the shortage of another medicine); (iv) commercial reasons; or (v) other.
(m)	Estimated shortage dates for anticipated shortage	<p>For an anticipated shortage of the medicine, the sponsor's advice as to:</p> <ul style="list-style-type: none"> • the date from which the shortage is anticipated to be a current shortage; and • if the shortage becomes a current shortage, the date at which the shortage is anticipated to be a resolved shortage, current at the date of publication.
(n)	Estimated shortage dates for current shortage	<p>For a current shortage of the medicine, the sponsor's advice as to:</p> <ul style="list-style-type: none"> • the date at which the shortage commenced; and • the date at which the shortage is anticipated to be a resolved shortage, current at the date of publication.
(o)	Market deletion date	<p>For a discontinuation of the medicine, the sponsor's advice as to the date from which the sponsor will cease, or has ceased, supply of the medicine to the Australian market.</p>
(p)	Supply details and other information	<p>Any information, or links to any information, in relation to:</p> <ul style="list-style-type: none"> • the supply arrangements for the medicine; • substitute medicines for the medicine including supply arrangements and use; • therapeutic alternatives to the medicine, including supply arrangements and use; and • where there is an anticipated shortage of the medicine: <ul style="list-style-type: none"> • the likely date from which the shortage is anticipated to be a current shortage; and • the date at which the shortage is anticipated to be a resolved shortage; • in relation to a current shortage of the medicine: <ul style="list-style-type: none"> • the date at which the shortage commenced; and

Item	Information	Description
		<ul style="list-style-type: none"> the date at which the shortage is anticipated to be a resolved shortage; and in relation to a discontinuation of the medicine – the estimated date from which the medicine will cease, or has ceased, to be supplied to the Australian market by the sponsor.
(q)	Last updated date	The most recent date that information relating to the medicine was updated on the TGA website.

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.au>