



Australian Government

Department of Health
Therapeutic Goods Administration

Therapeutic goods orders

If you intend to rely on any legislation referred to on this website, you should access copies of the official versions on the [Attorney-General's Federal Register of Legislation website](https://www.legislation.gov.au/) (<https://www.legislation.gov.au/>), which incorporates the **Federal Register of Legislation (FRL). Instruments are amended from time to time and may, on occasions, be replaced or new instruments made.**

Therapeutic goods must comply with various standards, which determine the consistency of product quality, including label quality. Many of these standards are international standards. However, sometimes it is necessary to specify an Australian standard, either for a particular type of therapeutic good or to specify particular labelling, packaging or other requirements. In these situations a Therapeutic Goods Order (TGO) is published.

Since 1992, TGOs have been approved by a delegate of the Minister under section 10 of the *Therapeutic Goods Act 1989* after consultation with the Therapeutic Goods Committee. Prior to this the TGOs were approved under various sections of the *Therapeutic Goods Act 1966*.

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Current TGOs

- [Therapeutic Goods Order No. **34** - Standard for Diagnostic Goods of Human Origin](https://www.legislation.gov.au/Details/F2007B00462)
(<https://www.legislation.gov.au/Details/F2007B00462>)
 - [Explanatory notes for TGO 34](https://www.tga.gov.au/explanatory-notes-therapeutic-goods-order-no-34-standard-diagnostic-goods-human-origin) (<https://www.tga.gov.au/explanatory-notes-therapeutic-goods-order-no-34-standard-diagnostic-goods-human-origin>)
- [Therapeutic Goods Order No. **37** - General Requirements for Labels for Therapeutic Devices](https://www.legislation.gov.au/Details/F2008B00074) (<https://www.legislation.gov.au/Details/F2008B00074>)
- [Therapeutic Goods Order No. **46** - Standards for Potassium Chloride, Hydrocortisone Acetate Cream and Hydrocortisone Acetate Ointment](https://www.legislation.gov.au/Details/F2007B00458) (<https://www.legislation.gov.au/Details/F2007B00458>)
- [Therapeutic Goods Order No. **50** - General Standard for Pyrogen and Endotoxin Content](#)

of Therapeutic Goods (<https://www.legislation.gov.au/Details/F2007B01293>)

- [Therapeutic Goods Order No. 54](https://www.legislation.gov.au/Details/F2009C00327) - Standard for Disinfectants and Sterilants (as amended)
- [Therapeutic Goods Order No. 63](https://www.legislation.gov.au/Details/F2007B00464) - Standard for Sterile Therapeutic Goods
- [Therapeutic Goods Order No. 69](https://www.legislation.gov.au/Series/F2007B00719) - General requirements for labels for medicines
 - [Supplementary Notes on TGO 69](https://www.legislation.gov.au/Details/F2007B00719/Supporting%20Material/Text)
- [Therapeutic Goods Order No. 70C](https://www.legislation.gov.au/Details/F2014L00683) - Standards for Export Only Medicine
- [Therapeutic Goods Order No. 75](https://www.legislation.gov.au/Details/F2007L03598) - Standard for Haematopoietic Progenitor Cells Derived from Cord Blood
- [Therapeutic Goods Order No. 77](https://www.legislation.gov.au/Details/F2008L03574) - Microbiological Standards for Medicines
 - [Guidance on TGO 77](https://www.tga.gov.au/guidance-therapeutic-goods-order-no-77-microbiological-standards-medicines)
- [Therapeutic Goods Order No. 78](https://www.legislation.gov.au/Details/F2008L04287) - Standard for Tablets and Capsules
 - [Guidance on TGO 78](https://www.tga.gov.au/guidance-therapeutic-goods-order-no-78-standard-tablets-and-capsules)
- [Therapeutic Goods Order No. 80](https://www.legislation.gov.au/Details/F2014C00067) - Child-Resistant Packaging Requirements for Medicines
 - [Guidance on TGO 80](https://www.tga.gov.au/guidance-therapeutic-goods-order-no-80-child-resistant-packaging-requirements-medicines)
- [Therapeutic Goods Order No. 81](https://www.legislation.gov.au/Details/F2008L04724) - Standards for Blood and Blood Components
- [Therapeutic Goods Order No. 82](https://www.legislation.gov.au/Details/F2009L00756) - Standard for Tampons - Menstrual
- [Therapeutic Goods Order No. 83](https://www.legislation.gov.au/Details/F2011L01489) - Standards for human musculoskeletal tissue
 - [Guidance on TGO 83](https://www.tga.gov.au/publication/australian-regulatory-guidelines-biologicals-argb) is available as an appendix of the [Australian Regulatory Guidelines for Biologicals \(ARGB\)](https://www.tga.gov.au/publication/australian-regulatory-guidelines-biologicals-argb)
- [Therapeutic Goods Order No. 84](https://www.legislation.gov.au/Details/F2011L01490) - Standards for human cardiovascular tissue

- Guidance on TGO 84 is available as an appendix of the [Australian Regulatory Guidelines for Biologicals \(ARGB\)](https://www.tga.gov.au/publication/australian-regulatory-guidelines-biologicals-argb) (<https://www.tga.gov.au/publication/australian-regulatory-guidelines-biologicals-argb>)
- [Therapeutic Goods Order No. 85 - Standards for human ocular tissue](https://www.legislation.gov.au/Details/F2011L01491) (<https://www.legislation.gov.au/Details/F2011L01491>)
 - Guidance on TGO 85 is available as an appendix of the [Australian Regulatory Guidelines for Biologicals \(ARGB\)](https://www.tga.gov.au/publication/australian-regulatory-guidelines-biologicals-argb) (<https://www.tga.gov.au/publication/australian-regulatory-guidelines-biologicals-argb>)
- [Therapeutic Goods Order No. 86 - Standards for human skin](https://www.legislation.gov.au/Details/F2011L01492) (<https://www.legislation.gov.au/Details/F2011L01492>)
 - Guidance on TGO 86 is available as an appendix of the [Australian Regulatory Guidelines for Biologicals \(ARGB\)](https://www.tga.gov.au/publication/australian-regulatory-guidelines-biologicals-argb) (<https://www.tga.gov.au/publication/australian-regulatory-guidelines-biologicals-argb>)
- [Therapeutic Goods Order No. 87 - General requirements for the labelling of biologicals](https://www.legislation.gov.au/Details/F2011L01493) (<https://www.legislation.gov.au/Details/F2011L01493>)
 - Guidance on TGO 87 is available as an appendix of the [Australian Regulatory Guidelines for Biologicals \(ARGB\)](https://www.tga.gov.au/publication/australian-regulatory-guidelines-biologicals-argb) (<https://www.tga.gov.au/publication/australian-regulatory-guidelines-biologicals-argb>)
- [Therapeutic Goods Order No. 88 - Standards for donor selection, testing, and minimising infectious disease transmission via therapeutic goods that are human blood and blood components, human tissues and human cellular therapy products](https://www.legislation.gov.au/Details/F2013L00854) (<https://www.legislation.gov.au/Details/F2013L00854>)
 - Guidance on TGO 88 is available as an appendix of the [Australian Regulatory Guidelines for Biologicals \(ARGB\)](https://www.tga.gov.au/publication/australian-regulatory-guidelines-biologicals-argb) (<https://www.tga.gov.au/publication/australian-regulatory-guidelines-biologicals-argb>)
- [Therapeutic Goods Order No. 89 - Standard for Water for Injections for Parenteral Medicines](https://www.legislation.gov.au/Details/F2011L02128) (<https://www.legislation.gov.au/Details/F2011L02128>)
- [Therapeutic Goods Order No. 90 - Standard for Human Albumin](https://www.legislation.gov.au/Details/F2011L02127) (<https://www.legislation.gov.au/Details/F2011L02127>)
- [Therapeutic Goods Order No. 91 - Standard for labels of prescription and related medicines](https://www.legislation.gov.au/Details/F2016L01285) (<https://www.legislation.gov.au/Details/F2016L01285>)
- [Therapeutic Goods Order No. 92 - Standard for labels of non-prescription medicines](https://www.legislation.gov.au/Details/F2016L01287) (<https://www.legislation.gov.au/Details/F2016L01287>)
 - [Guidance for TGO 91 and TGO 92](https://www.tga.gov.au/medicine-labels-guidance-tgo-91-and-tgo-92) (<https://www.tga.gov.au/medicine-labels-guidance-tgo-91-and-tgo-92>)

Recently spent/repealed instruments

- [Therapeutic Goods Order No. 70B - Standards for Export Only Medicine](https://www.legislation.gov.au/Details/F2007L00555)
(<https://www.legislation.gov.au/Details/F2007L00555>)
Replaced by TGO 70C

The following instruments were repealed by the Health (Spent and Redundant Instruments) Repeal Regulation 2014 ('the Regulation').

The instruments repealed by the Regulation fall into two groups, explained below.

1. Instruments that were amending or revoking instruments and were spent (Schedule 1 of the Regulation)

These instruments amended or revoked principal TGOs and were therefore "spent". The amendments effected by these instruments have been incorporated into subsequent consolidations of their corresponding principal instrument (with the exception of TGO 67, which has itself been repealed - see section 2 below).

The amending instruments are therefore no longer needed. These instruments are as follows:

- [Therapeutic Goods Order No. 54A - Amendment to Therapeutic Goods Order No. 54 - Standard for Disinfectants and Sterilants](https://www.legislation.gov.au/Details/F2008B00738) (<https://www.legislation.gov.au/Details/F2008B00738>)
- [Therapeutic Goods Order No. 54B - Amendment to Therapeutic Goods Order No. 54 - Standard for Disinfectants and Sterilants](https://www.legislation.gov.au/Details/F2008B00739) (<https://www.legislation.gov.au/Details/F2008B00739>)
- [Therapeutic Goods Order No. 67A - Amendment to Therapeutic Goods Order No. 67 - Standard for Dental Materials](https://www.legislation.gov.au/Details/F2007B00466) (<https://www.legislation.gov.au/Details/F2007B00466>)
- [Therapeutic Goods Order No. 69A - Amendment to Therapeutic Goods Order No. 69 - General requirements for labels for medicines](https://www.legislation.gov.au/Details/F2007B00741) (<https://www.legislation.gov.au/Details/F2007B00741>)
- [Therapeutic Goods Order No. 69B - Amendment to Therapeutic Goods Order No. 69 - General requirements for labels for medicines](https://www.legislation.gov.au/Details/F2008L02056) (<https://www.legislation.gov.au/Details/F2008L02056>)
- [Therapeutic Goods Order No. 69C - Amendment to Therapeutic Goods Order No. 69 - General requirements for labels for medicines](https://www.legislation.gov.au/Details/F2009L00985) (<https://www.legislation.gov.au/Details/F2009L00985>)
- [Therapeutic Goods Order No. 70B - Standards for Export Only Medicine](https://www.legislation.gov.au/Details/F2007L00555)
(<https://www.legislation.gov.au/Details/F2007L00555>)
- [Therapeutic Goods Order No. 76 - Revocation of Therapeutic Goods Orders](https://www.legislation.gov.au/Details/F2007L03972)
(<https://www.legislation.gov.au/Details/F2007L03972>)
- [Therapeutic Goods Order No. 80A - Amendments to Therapeutic Goods Order No. 80](https://www.legislation.gov.au)
[Child-Resistant Packaging Requirements for Medicines](https://www.legislation.gov.au) (<https://www.legislation.gov.au>)

[/Details/F2012L01920](#))

2. Instruments that were no longer required (Part 3 of Schedule 4 of the Regulation)

The instruments in this group were redundant and no longer required.

At its 39th meeting, the Therapeutic Goods Committee provided advice on the revocation of the following standards.

These orders (predominantly relating to medical devices) were made before the introduction of Chapter 4 to the *Therapeutic Goods Act 1989*, which set out a specific regulatory regime for medical devices and provided for a transition period for existing medical devices that were then regulated under Chapter 3 of the Act. As that transition period ended in 2007, the repeal of the orders does not alter existing arrangements.

These instruments are as follows:

- [Therapeutic Goods Order No. 28 - Standard for Contraceptive Devices - Diaphragms](https://www.legislation.gov.au/Details/F2008B00084) (<https://www.legislation.gov.au/Details/F2008B00084>)
- [Therapeutic Goods Order No. 41 - Single-use syringes \(sterile\) for the injection of 100 units per millilitre insulin \(U-100\)](https://www.legislation.gov.au/Details/F2007B00457) (<https://www.legislation.gov.au/Details/F2007B00457>)
- [Therapeutic Goods Order No. 49 - General Standard for Sutures](https://www.legislation.gov.au/Details/F2008B00044) (<https://www.legislation.gov.au/Details/F2008B00044>)
- [Therapeutic Goods Order No. 52 - Examination Gloves for General Medical and Dental Use](https://www.legislation.gov.au/Details/F2007B00443) (<https://www.legislation.gov.au/Details/F2007B00443>)
- [Therapeutic Goods Order No. 53 - Single-use Sterile Surgical Rubber Gloves](https://www.legislation.gov.au/Details/F2007B00442) (<https://www.legislation.gov.au/Details/F2007B00442>)
- [Therapeutic Goods Order No. 59 - Polymer Urethral Catheters for General Medical Use](https://www.legislation.gov.au/Details/F2007B00449) (<https://www.legislation.gov.au/Details/F2007B00449>)
- [Therapeutic Goods Order No. 61A - Contraceptive Devices - Rubber Condoms](https://www.legislation.gov.au/Details/F2007B00451) (<https://www.legislation.gov.au/Details/F2007B00451>)
- [Therapeutic Goods Order No. 67 - Standard for Dental Materials](https://www.legislation.gov.au/Details/F2007C00312) (<https://www.legislation.gov.au/Details/F2007C00312>)
- [Therapeutic Goods Order No. 68 - Standard for Plasticized Polyvinyl Chloride \(PVC\) Blood Bags](https://www.legislation.gov.au/Details/F2007B00476) (<https://www.legislation.gov.au/Details/F2007B00476>)

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