



Australian Government

Department of Health

Therapeutic Goods Administration

Enforceable undertakings

Guidelines for making an offer of enforceable undertaking to the TGA

Version 2.0, September 2019

TGA Health Safety
Regulation

A decorative graphic at the bottom of the page consisting of several overlapping, wavy lines in shades of blue and green, creating a modern, flowing design.

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Introduction

Under section 42YL of the *Therapeutic Goods Act 1989* (the Act), the Secretary of the Department of Health can accept an offer of an enforceable undertaking.

An enforceable undertaking is a court-enforceable commitment by an individual or a company to carry out certain activities.

An enforceable undertaking is relatively quick compliance solution. It may include encouraging entities (individuals or companies) to improve their compliance arrangements or restrict the activities they can undertake. This can help entities meet their obligations under the Act and other regulations into the future, which in turn helps protect consumers and public health.

The Therapeutic Goods Administration (TGA) regards the enforceable undertaking as an important compliance tool in situations where there is evidence of a breach of the Act or regulations, but where it may not be in the public interest to take civil or criminal compliance action. Generally, enforceable undertakings are not used in cases involving deliberate misconduct, fraud, or conduct involving a high level of recklessness.

For an individual or company in potential breach of the Act or regulations, entering into an enforceable undertaking can be a cost-effective alternative to criminal or civil compliance action.

Factors that may be relevant to the TGA accepting an offer of enforceable undertaking can include:

- whether the individual or company is prepared to publicly acknowledge that their conduct has breached the legislation and corrective action is necessary
- whether the conduct was inadvertent
- whether the conduct was undertaken with the knowledge of senior officers of a company
- the entity's level of cooperation with the TGA's investigations of the conduct
- whether the entity has any history of breaching the legislation or regulations or been the subject of complaints
- whether compliance with the enforceable undertaking will protect the public from the risk of potentially harmful conduct
- the likelihood or ability of the individual or company to comply with the enforceable undertaking
- the prospect of a timely resolution of the matter.

Under delegation from the Secretary, the TGA has the power to accept an enforceable undertaking, consent to the withdrawal or variation of an enforceable undertaking, or make an application to the Federal Court to seek orders in relation to a breach of the terms of an enforceable undertaking.

These guidelines are based on those adopted by the Australian Competition and Consumer Commission (ACCC) for the purposes of section 87B of the *Competition and Consumer Act 2010* (enforcement of undertakings) which uses very similar terms to section 42YL.¹

¹ The Australian Competition and Consumer Commission, (Section 87B of the Competition and Consumer Act, Guidelines on the use of enforceable undertakings by the ACCC), April 2014, [https://www.accc.gov.au/system/files/Guide to Section 87B.pdf](https://www.accc.gov.au/system/files/Guide%20to%20Section%2087B.pdf)

What is an enforceable undertaking?

An enforceable undertaking is one of a number of options available to secure compliance with the Act, the *Therapeutic Goods Regulations 1990* and *Therapeutic Goods (Medical Devices) Regulations 2002*. For the purposes of these guidelines, the Act and the two sets of Regulations are collectively referred to as 'the legislation'.

The availability of this option enhances the ability of the Secretary of the Department of Health to influence behaviour and encourage compliant conduct, providing a mechanism for encouraging and assisting entities to observe their obligations under the legislation.

Offering a written enforceable undertaking to the TGA under section 42YL of the Act can provide an alternative to potentially lengthy and expensive court proceedings, or the TGA taking other regulatory or administrative action.

An example of a typical enforceable undertaking is provided in Attachment A, while Section 42YL of the ACT is outlined in [Attachment B](#).

An enforceable undertaking can allow those in breach of the legislation to offer innovative and business-efficient alternatives to formal litigation or regulatory action while protecting the health of Australians. An enforceable undertaking can also be used in relation to conduct that may not amount to a breach but where the person and the TGA see some benefit in clarifying their positions in relation to that conduct.

Where a person who has given an enforceable undertaking (the promisor) breaches or fails to comply with any of its terms, the TGA can seek orders from the Federal Court. The Federal Court may make any or all of the orders specified in subsection 42YL(5) of the Act.

In appropriate cases (for instance involving small companies, or where individuals are directors of a number of small companies), the TGA may accept an enforceable undertaking from both the company itself and from the director/s to ensure that all those likely to be involved in future activities involving therapeutic goods are bound by the relevant provisions.

In order to be enforceable, the undertaking has to be sufficiently specific for the promisor to know exactly what is expected of them and so that any failure to comply will be readily apparent. Noting this, when settling an enforceable undertaking the TGA will seek to achieve our desired regulatory outcomes such as:

- cessation of the particular conduct, act or omission that is alleged to be a breach or potential breach of the legislation
- destruction of the goods concerned at the promisor's expense and providing the TGA with a certificate of destruction of those goods
- a commitment to future compliance with the requirements of the legislation, or particular requirements of the legislation, whether or not supported by the promisor's use of expert assistance to formulate robust standard operating procedures when dealing with therapeutic goods, or any other means specified by the person in breach
- a commitment to future adherence to the requirements of the current Therapeutic Goods Advertising Code (No.2) 2018 which might include corrective advertising or notices to rectify misleading conduct
- in addition to the mandatory publication of the details of the undertaking, the TGA will use the publication of an enforceable undertaking as a public awareness tool to deter others from breaching the legislation or the Advertising Code.

When is an enforceable undertaking appropriate?

The TGA can accept an enforceable undertaking in connection with any matter in relation to which the TGA has a power or function under the legislation including provisions that create statutory obligations or impose requirements in relation to which a civil or criminal penalty is applicable if they are breached. This also includes other forms of regulatory sanction or regulatory action (for instance, cancellation or suspension of a product from the Australian Register of Therapeutic Goods (the Register) or the imposition of additional conditions on a product's entry in the Register) that are available to the TGA.

As part of the decision on whether to commence court or other regulatory action, and the acceptance of an enforceable undertaking, the TGA will consider an outcome that ensures sustained future regulatory compliance.

Factors that may influence the TGA in accepting an enforceable undertaking in a particular instance include (but are not limited to):

- any deliberate measures used by the person such as falsifying documents to mask activities in breach of the legislation
- any likely impact on public health and safety in relation to the activity concerned
- the seriousness of the alleged conduct involved
- any history of complaints and/or non-compliance with the legislation by the person involved
- the attitude towards compliance by the person involved (which may be demonstrated by co-operation and/or admissions made)
- the prospect of a speedy and economical resolution of the matter that will fully address any actual or potential health and safety issues
- the size of any company involved (which might suggest that compliance programs should have been in place to prevent a breach).

When considering an enforceable undertaking, the TGA may have regard to all of the circumstances surrounding an alleged breach of the legislation. The list above is not exhaustive for these purposes.

Entering into an enforceable undertaking

The TGA does not consider accepting an offer of an enforceable undertaking lightly. The TGA will not accept an enforceable undertaking as an alternative to taking regulatory action or commencing formal enforcement proceedings where the circumstances justify these actions, particularly where it is in the public interest to do so.

The TGA reserves the right to pursue any form of administrative, compliance or enforcement action in relation to a person notwithstanding that an enforceable undertaking from the person has been accepted and is in force.

Any company or individual, in particular those who have, or believe they may have breached the legislation, can voluntarily make an offer of an enforceable undertaking to the TGA at any time, including in circumstances where they may be the subject of regulatory action by the TGA including court-based enforcement proceedings.

The TGA does not have the power to demand or compel a person to enter into an enforceable undertaking; the TGA may however in appropriate circumstances, raise this as an option and let the person consider whether they want to make such an offer.

The TGA will not normally accept the offer of an enforceable undertaking on the basis that the TGA is prevented from taking action in relation to conduct by the relevant company or individual that represents a breach of any terms of the enforceable undertaking.

A person wishing to offer an enforceable undertaking should first discuss it with the TGA officer assigned to the investigation. In the course of drafting the undertaking, the TGA will settle the terms of the undertaking to arrive at an appropriate regulatory outcome. TGA investigators and other staff are not generally empowered to accept an enforceable undertaking on behalf of the Secretary. The final decision on whether to accept an offer of a written enforceable undertaking will be made by a senior member of the TGA Executive, including the Deputy Secretary HPRG, as delegates of the Secretary.

Acceptance of an undertaking in particular circumstances cannot be regarded as a binding precedent for future action. In other words, if the TGA accepts an undertaking from a person in respect of particular conduct, this does not mean that:

- the TGA will not take any or any specific kind of regulatory or administrative action in relation to the person
- the TGA will accept an undertaking offered by the person in relation to the same or similar conduct in the future
- the TGA will accept an undertaking offered by another person in relation to the same or similar conduct in the future.

Common terms in an enforceable undertaking

An enforceable undertaking must be in writing. The undertaking must be written in such a way as to ensure that the promises of future behaviour being made by the entity are clear, unambiguous and enforceable.

Where an entity's conduct relates to non-compliance with the legislation, any enforceable undertaking proposed to be given must contain sufficient details for the following to be clear:

- the nature of the alleged non-compliance
- how the person will address the alleged non-compliance in a way that is sustainable
- the exact nature of the resolution of the alleged non-compliance that is proposed.

The undertaking should directly address the activity that has given rise to the matters in relation to which the undertaking is being given. In the case of a breach or alleged breach of the legislation, the enforceable undertaking would usually include such terms as:

- an acknowledgement or admission that the conduct constituted, was or was likely to have constituted, a breach of the legislation
- a positive commitment to cease the conduct, and not to recommence the conduct for a specified period of time
- the promisor initiating a compliance policy² with responsibility to adhere to that policy designated to a particular senior person
- where appropriate, an undertaking to destroy therapeutic goods in relation to which the breach of the legislation occurred, at the promisor's expense, and to supply a certificate of destruction of those goods to the TGA
- an acknowledgement that the TGA will make the undertaking public by publishing it on the TGA's website in accordance with subsection 42YL(3) of the legislation, or make references to the undertaking in media releases or on social media
- an acknowledgement that the undertaking is given freely
- an acknowledgement that the undertaking in no way deviates from the rights and remedies available to the TGA, the Commonwealth or any other person arising from the conduct alleged to have breached the legislation.

In appropriate circumstances the TGA will also consider the inclusion of terms that will assist in the TGA monitoring compliance with the undertaking such as the inclusion of provisions requiring the promisor to make available relevant information to the TGA:

- a periodic audit of compliance with the undertaking
- a requirement to report any conduct that might amount to a default or breach of the terms
- the reasons for the conduct and measures put in place to address future conduct of the same or similar nature.

² See for example see, ISO 19600:2014, Compliance management systems – guidelines - for establishing, developing, implementing, evaluating, maintaining and improving an effective and responsive compliance management system within an organization, <https://www.iso.org/standard/62342.html>

Terms not normally accepted by the TGA

The following terms will not normally be acceptable to the TGA for inclusion in an enforceable undertaking:

- denials that the relevant conduct breached, or was likely to have constituted a breach of the legislation
- any terms purporting to impose conditions on the TGA or the Department of Health generally
- any requirement that the TGA will not instigate future proceedings in the particular matter
- terms purporting to set up defences for possible non-compliance
- any statement that the relevant conduct was inadvertent
- any statement that purports to impose conditions on third parties
- any statement that the undertaking is not an admission for the purposes of third party actions³
- any statement which is “self-serving”, in that it seeks to minimise the possible consequences due to the conduct or for public relations or promotional purposes.

Variations to an enforceable undertaking

Section 42YL(2) of the Act allows the promisor to withdraw or vary the enforceable undertaking at any time, but only with consent of the TGA.

This provision allows negotiation between the parties where, for instance, circumstances have changed such that the original terms of the enforceable undertaking have become impracticable or may no longer be relevant, or where it would be appropriate to address issues that were not foreseen at the time the undertaking was first accepted. However, any proposed variation which alters the spirit of the original undertaking will not be accepted.

The TGA will consider requests for variation of an enforceable undertaking applying, the same criteria when accepting the undertaking. In cases where the parties agree to a variation, the TGA will publish the varied agreement on its website but the original undertaking document will normally remain available on the TGA website.

³ It is not necessary however for the undertaking to state that it is an admission.

Compliance with an enforceable undertaking

The TGA has many stakeholders in the regulation of therapeutic goods and receives information about activities of concern, allegations of unlawful behaviour, or acts or omissions by entities that may be in breach of the legislation.

The TGA will monitor the activities of entities bound by an enforceable undertaking to ensure its terms and reporting requirements are met during the period the enforceable undertaking is in effect. The TGA will also work with its partners including border control agencies and Commonwealth, state and territory agencies with responsibilities for health or law enforcement for these purposes.

Monitoring of an undertaking in force can involve random unannounced regulatory visits to the promisor's place of business. The undertaking will include terms requiring the promisor to provide relevant information that will assist the TGA in monitoring compliance with the undertaking.

The TGA may, where it has information that indicates that terms of an enforceable undertaking have been breached, seek to resolve the matter through consultation in appropriate cases. Where it is not appropriate or where no resolution is possible, the TGA will consider all available regulatory responses, including applying to the Federal Court to make appropriate orders to enforce the terms of the undertaking.

If the Federal Court is satisfied that the promisor has breached a term of the enforceable undertaking, the Court may make all or any of the following orders:

- (a) an order directing the person to comply with that term of the undertaking
- (b) an order directing the person to pay to the Commonwealth an amount up to the amount of any financial benefit that the person has obtained directly or indirectly and that is reasonably attributable to the breach
- (c) any order that the Court considers appropriate, including directing the person to compensate any other person who has suffered loss or damage because of the breach

Failure by the promisor to comply with the terms of an enforceable undertaking cannot itself be the subject of contempt proceedings in court – it is necessary for the TGA to apply to the court for orders to enforce the undertaking. However, any breach of an order made by the Federal Court as a result of such an application by the TGA may constitute a contempt of court.

The TGA will reserve the right to make our taking of any such action public, and to seek legal costs from the promisor.

The enforceable undertaking will remain available on the TGA website as a public record of the acceptance and terms of the undertaking notwithstanding all the terms of the undertaking have been complied with and/or the period during which the undertaking is to apply to the person has expired.

Attachment A: example of an enforceable undertaking

ENFORCEABLE UNDERTAKING

Therapeutic Goods Act 1989

Section 42YL

The commitments in this undertaking are offered to the Secretary of the Australian Department of Health given for the purposes of section 42YL of the *Therapeutic Goods Act 1989* (the Act) by

[Full name of company] or [Name of business or individual]

ACN: ### ### ###

Definitions

The following definitions are used in this undertaking:

- the Department means the Commonwealth Department of Health
- the Act means the *Therapeutic Goods Act 1989* (Cth)
- the Promisor means the person giving the undertaking
- the Regulations means the Therapeutic Goods Regulations 1990, and or the Therapeutic Goods (Medical Devices) Regulations 2002
- the Secretary means the Secretary of the Australian Department of Health
- TGA means the Therapeutic Goods Administration, part of the Department

Persons giving this undertaking

- (1) This undertaking is given to the Secretary by [full name of company (including ACN) (abbreviation of company name-use this throughout the undertaking)] of [company address] [or full name and address of an individual] for the purposes of section 42YL of the Act.

Background

- (2) [Description of company's business, trading such as import, export, manufacture and supply areas in general terms].
- (3) [Description of the conduct that the TGA investigated].
- (4) [Brief details of TGA inquiries].
- (5) [Where appropriate – a statement by the company that the conduct has ceased and any action already taken by the company to redress the effects of that conduct].

The Secretary's conclusion as to breach/contravention of the Act

- (6) [Explanation of why the Secretary considers the conduct to be in contravention of the Act].

Acknowledgement of breach

- (7) [Company name, Business or Individual name] [acknowledges OR admits] that the conduct described at paragraphs [insert numbers] above [contravened, OR was likely to contravene the Act].

Period of undertaking

- (8) This undertaking comes into effect when both the following are satisfied:
- (a) the undertaking is executed by [Company name, Business or Individual name]; and
 - (b) the Secretary accepts the undertaking so executed.
- (9) Upon the commencement of this undertaking, [Company name, Business or Individual name] undertakes to assume the obligations set out in paragraphs [insert numbers] below.
- (10) This undertaking terminates on [date]/the third anniversary of the day on which it comes into effect.

Undertakings

- (11) Under section 42YL of the Act [Company name, Business or Individual name] has offered, and the Secretary has agreed to accept the following undertakings:

- (a) that it will not, and will ensure that its subsidiaries will not, for the period that this undertaking is in effect, in trade or commerce:
 - (i)
 - (ii)

[for instance, import, export, manufacture, supply or advertise therapeutic goods in any way, which is in breach with the regulatory requirements of the Act].

- (b) that for the period that this undertaking is in effect it will:
 - (i)
 - (ii)
 - (iii)

[for instance, takes steps to rectify the harm caused by the alleged breach (including by publishing corrective advertising etc.), to remedy the deficiencies in the company's compliance systems by taking specified action]

- (c) that for the period that this undertaking is in effect, it will monitor and report on the implementation of this undertaking by:
 - (i)
 - (ii)
 - (iii)

[for instance, when and how reports will be made, monitoring and reporting mechanisms the Promisor will adopt, any external assessment of the changes that are to be put in place, the name of the person who is responsible for monitoring compliance with the undertaking etc.]

- (d) that it will pay the costs of its compliance with this enforceable undertaking
- (e) that it will provide all documents and information requested by the Secretary from time to time for the purposes of assessing its compliance with the terms of this enforceable undertaking.

Acknowledgements

(12) [Company name, Business or Individual name] acknowledges that:

- (a) this undertaking was given voluntarily by [Company name, Business or Individual name];
- (b) the Secretary may make this undertaking and information about this undertaking publicly available including by publishing it on the TGA's website;
- (c) the Secretary may, from time to time, make public reference to this undertaking including in news media statements and in publications by the TGA or the Department including on various forms of social media;
- (d) this undertaking in no way derogates from the rights and remedies available to the Secretary, the Commonwealth or to any other person arising from the conduct referred to in paragraph 3.
- (e) the Secretary's acceptance of this enforceable undertaking does not affect the power of the Secretary to investigate or pursue a criminal prosecution, to seek a pecuniary civil penalty or use any other power available to the Secretary under the Act in relation to any contravention or breach, or possible contravention or possible breach of the Act (not referred to in the Background section of this enforceable undertaking) arising from future conduct.
- (f) this undertaking has no operative force until accepted by the Secretary.

(13) [Company name, Business or Individual name] and the Secretary acknowledge that the date of the enforceable undertaking is the date on which it is accepted by the Secretary.

Executed by

[Full name of individual or full name of company and ACN] and by its authorised officers pursuant to section 127(1) of the Corporations Act 2001.

.....

Name or Secretary/Director

.....

Director

This.....day of20##

OR

The common seal of [Full company name and ACN] was affixed in the presence of:

.....

Secretary/Director

.....

Director

Thisday of.....20##

**ACCEPTED BY THE DEPUTY SECRETARY OF THE HEALTH PRODUCTS REGULATION GROUP
(INCORPORATING THE TGA AND THE OFFICE OF DRUG CONTROL) AS DELEGATE OF THE
SECRETARY UNDER SECTION 42YL OF THE ACT.**

.....

**Adjunct Professor John Skerritt
Deputy Secretary HPRG
Delegate of the Secretary**

Thisday of20##

Attachment B: enforceable undertaking legislation

THERAPEUTIC GOODS ACT 1989 - SECTION 42YL

Enforcement of undertakings

- (1) The Secretary may accept a written undertaking given by a person in connection with a matter in relation to which the Secretary has a power or function under this Act or the regulations.
- (2) The person may withdraw or vary the undertaking at any time, but only with the consent of the Secretary.
- (3) The Secretary must publish details of the undertaking, as in force from time to time, on the internet.
- (4) If the Secretary considers that the person who gave the undertaking has breached any of its terms, the Secretary may apply to the Federal Court for an order under subsection (5).
- (5) If the Court is satisfied that the person has breached a term of the undertaking, the Court may make all or any of the following orders:
 - (a) an order directing the person to comply with that term of the undertaking;
 - (b) an order directing the person to pay to the Commonwealth an amount up to the amount of any financial benefit that the person has obtained directly or indirectly and that is reasonably attributable to the breach;
 - (c) any order that the Court considers appropriate directing the person to compensate any other person who has suffered loss or damage as a result of the breach;
 - (d) any other order that the Court considers appropriate.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Regulatory Compliance	April 2013
V2.0	Updated enforceable undertakings guidelines	Regulatory Legal Services Branch (RLSB)	September 2019

Therapeutic Goods Administration

PO Box 100 Woden ACT 2606 Australia

Email: info@tga.gov.au Phone: 1800 020 653 Fax: 02 6203 1605

<https://www.tga.gov.au>

Reference/Publication #