About the Therapeutic Goods Administration (TGA)

- The Therapeutic Goods Administration (TGA) is part of the Australian Government Department of Health and Ageing, and is responsible for regulating medicines and medical devices.

- TGA administers the *Therapeutic Goods Act* 1989 (the Act), applying a risk management approach designed to ensure therapeutic goods supplied in Australia meet acceptable standards of quality, safety and efficacy (performance), when necessary.

- The work of the TGA is based on applying scientific and clinical expertise to decision-making, to ensure that the benefits to consumers outweigh any risks associated with the use of medicines and medical devices.

- The TGA relies on the public, healthcare professionals and industry to report problems with medicines or medical devices. TGA investigates reports received by it to determine any necessary regulatory action.

- To report a problem with a medicine or medical device, please see the information on the TGA website <www.tga.gov.au>.
## Version history

<table>
<thead>
<tr>
<th>Version</th>
<th>Description of change</th>
<th>Author</th>
<th>Effective date</th>
</tr>
</thead>
<tbody>
<tr>
<td>V1.0</td>
<td>Original publication</td>
<td>Regulatory Compliance</td>
<td>April 2013</td>
</tr>
</tbody>
</table>
## Contents

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Introduction</td>
<td>5</td>
</tr>
<tr>
<td>Section 42YL—enforceable undertakings</td>
<td>6</td>
</tr>
<tr>
<td>Under what circumstances are s.42YL written undertakings considered appropriate?</td>
<td>8</td>
</tr>
<tr>
<td>Accepting an enforceable undertaking</td>
<td>8</td>
</tr>
<tr>
<td>Terms typically included in a written s.42YL enforceable undertaking</td>
<td>10</td>
</tr>
<tr>
<td>Terms in an s.42YL enforceable undertaking not normally acceptable by the TGA</td>
<td>11</td>
</tr>
<tr>
<td>Variations to an enforceable undertaking</td>
<td>11</td>
</tr>
<tr>
<td>Compliance with enforceable undertakings</td>
<td>12</td>
</tr>
<tr>
<td>Attachment A</td>
<td>14</td>
</tr>
<tr>
<td>Attachment B</td>
<td>18</td>
</tr>
</tbody>
</table>
Introduction

The acceptance by the Secretary of the Department of Health and Ageing of an enforceable undertaking under section 42YL of the *Therapeutic Goods Act 1989* (the Act) is one of a number of options available to secure compliance with the Act and the Therapeutic Goods Regulations 1990 and Therapeutic Goods (Medical Devices) Regulations 2002. For the purposes of this paper, all references to undertakings are a reference to an enforceable undertaking under section 42YL of the Act.

The availability of this form of administrative action enhances the ability of the Secretary to influence behaviour and encourage compliant conduct and provides a mechanism for encouraging and assisting companies and individuals to observe their obligations under the legislation which will help protect public health and consumers. As is the case for other Commonwealth regulators, the availability of enforceable undertakings to the Secretary can offer more effective regulatory outcomes if obligations are not met than might be achieved through other civil or administrative action under the Act.

While not limited to such circumstances, the offer of an enforceable undertaking will be considered where there is reason to believe there has been a contravention of the legislation and it provides an effective regulatory outcome. The advantages it offers is a relatively quick solution that ensures that those potentially affected by the contravening conduct are protected from that conduct in the future and require the company or individual involved in the contravening conduct to implement improved compliance arrangements, restrict the activities that can be undertaken by the company or individual in the future and be a cost-effective alternative to litigation.

Factors that may be relevant to the issue of whether acceptance of the offer of a company or individual to give an enforceable undertaking will produce a more effective regulatory outcome include:

- whether the company or individual is prepared to publicly acknowledge that the Secretary has taken the view that its conduct breached the legislation and corrective action is necessary
- whether the conduct was or may have been inadvertent
- whether the conduct may have been undertaken with the knowledge of senior officers of the company
- the level of cooperation of the company or individual with investigations of the conduct, including by providing full information
- does the individual or company have any history of breaching the legislation or been the subject of complaints about compliance with the legislation
- whether compliance with the undertakings will protect the public from the risk of potentially harmful conduct
- the likelihood of the company or individual complying with the undertakings
- the prospects of a timely resolution of the matter.

Under section 42YL the Secretary of the Australian Department of Health and Ageing can accept a written undertaking from a person \(^1\) in connection with any matter in relation to

---

\(^1\) Person generally includes a body corporate; *Acts Interpretation Act 1901*, s. 2C.
which the Secretary has a power or function under the Act or the Regulations.\textsuperscript{2} This section also allows for enforcement by the Secretary of a breach of the terms of an enforceable undertaking, by seeking certain orders in the Federal Court of Australia.

An enforceable undertaking accepted by the Secretary may subsequently be withdrawn or varied but only with the consent of the Secretary.

Under a delegation from the Secretary, the National Manager of the Therapeutic Goods Administration (for the purposes of this paper called the TGA), has the power to accept an enforceable undertaking, consent to the withdrawal or variation of an enforceable undertaking, or to make an application to the Federal Court in relation to an enforceable undertaking.

The TGA regards enforceable undertakings as an important regulatory tool. For example, they may be used in those situations where there is evidence of a breach, or a potential breach of the regulatory requirements of the Act or the Regulations, that may otherwise justify the TGA taking regulatory action, including enforcement action in the courts against the person.

This guideline outlines the TGA's approach to the use of section 42YL and includes a template for a written undertaking (at Attachment A) and the text of the section (at Attachment B). Persons proposing to offer an enforceable undertaking under section 42YL to the TGA are advised to use the template at Attachment A.

These guidelines are based closely on those adopted by the Australian Competition and Consumer Commission for the purposes of section 87B of the \textit{Competition and Consumer Act 2010} (enforcement of undertakings) which is in very similar terms to section 42YL\textsuperscript{3} and also have been informed by the guidelines of the February 2012 Australian Securities and Investments Commission guidelines on the Commissions acceptance of undertakings under sections 93A and 93AA of the \textit{Australian Securities and Investments Commission Act 2001}.

\section*{Section 42YL—enforceable undertakings}

The giving of 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 taking of other regulatory or administrative action in relation to a company or individual breaching a regulatory requirement.

They can allow those who are required to comply with the Act or Regulations to offer innovative and business efficient alternatives to formal litigation or regulatory action, whilst still allowing the TGA to protect the health of Australians. They can also be used in relation to conduct that may not amount to a breach but where the person or company

\textsuperscript{2} This includes the Therapeutic Goods Regulations 1990 and the Therapeutic Goods (Medical Devices) Regulations 2002.

\textsuperscript{3} The ACCC guidelines \textit{Section 87B of the Trade Practices Act} (September 2009) can be found at \url{http://www.accc.gov.au/content/index.phtml/itemId/263958}.

\textsuperscript{4} The ASIC guidelines Regulatory Guide 100 Enforceable undertakings (February 2012) can be found at \url{http://www.asic.gov.au/asic/pdflib.nsf/LookupByFileName/rg100-published-20-February-2012-1.pdf/$file/rg100-published-20-February-2012-1.pdf}.
and the TGA see some benefit in clarifying their positions in relation to that conduct. An enforceable undertaking is enforceable by the TGA in the Federal Court if the person giving the written undertaking (the Promisor) breaches or fails to comply with any of its terms.

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 are bound by the relevant provisions.

In negotiating an enforceable undertaking, the TGA will seek to achieve desired outcomes such as:

- where relevant, cessation of the particular activity that is alleged to be a breach or potential breach of the legislation \(^5\)
- the taking of various specified actions to ensure compliance with the Act, or remedy the consequences of non-compliance
- in appropriate cases, 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, noting that 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
- where relevant, a commitment to future adherence to the requirements of the *Therapeutic Goods Advertising Code* \(^6\) which might include corrective advertising or notices to rectify misleading conduct, noting that in order to be enforceable, the undertaking has to be sufficiently specific for the Promisor to know exactly what is expected of them and
- in addition to the mandatory publication of the details of the undertaking on the internet, using the publication of written undertakings as a public awareness tool to deter others from breaching legislation or the Code.

---

\(^5\) That is, the Act and the Regulations.

\(^6\) It is an offence under the Act to publish or broadcast an advertisement about therapeutic goods that does not comply with the Code and under the Therapeutic Goods Regulations, an advertisement for therapeutic goods will not be given approval if it does not comply with the Code.
Under what circumstances are s.42YL written undertakings considered appropriate?

The TGA can accept a section 42YL enforceable undertaking in connection with any matter in relation to which the TGA has a power or function under the Act or Regulations. This will include provisions of the Act and Regulations that create statutory obligations or impose requirements in relation to which a civil or criminal penalty is applicable if they are breached, or in relation to which some other form of regulatory sanction or regulatory action (for instance, cancellation or suspension of a product from the Register or the imposition of additional conditions on a product's entry in the Register) available to the TGA.

As part of the decision between taking regulatory action/commencing formal court 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 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 regulatory requirements by the company or individual involved
- the attitude of the company or individual involved (which may be demonstrated by cooperation and/or admissions made)
- the prospect of a speedy and economical resolution of the matter that will fully address any health and safety issues, and
- the size of any company involved (which might suggest that compliance programs should have been in place to prevent a breach).

In consideration of a written 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.

Accepting an enforceable undertaking

The TGA does not consider accepting an offer of written enforceable undertaking lightly, nor does the TGA see such undertakings as an alternative to taking regulatory action or commencing formal enforcement proceedings where the circumstances would otherwise justify such action. The TGA reserves the right to pursue any form of regulatory or administrative action in relation to a person notwithstanding that an enforceable undertaking from the person has been accepted.
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 or formal enforcement proceedings.

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

The TGA has the option, when it engages in any negotiations about the possible acceptance of undertakings arising from conduct in breach of the legislation, to accept the undertakings on the basis that they are:

- in full and final resolution of any action that might otherwise have been taken in relation to that conduct, or
- without prejudice to any other action that the TGA may otherwise decide to take in relation to that conduct.

In any event, the TGA will not normally accept the offer of enforceable undertakings on the basis that the TGA is prevented from taking action in relation to future conduct by the relevant company or individual that represents a breach of those undertakings.

A person wishing to offer an enforceable undertaking under section 42YL should first discuss it with the TGA officer assigned to the investigation. In the course of drafting the undertaking, the TGA will negotiate the terms of the undertaking to arrive at an appropriate regulatory outcome. TGA investigators and other staff are not generally empowered to accept undertakings 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 staff, typically the National Manager, as delegate 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, or
- the TGA will accept an undertaking offered by another person in relation to the same or similar conduct in the future.
Terms typically included in a written s.42YL enforceable undertaking

An enforceable undertaking must be in writing. The undertaking must be written in such a way to ensure that the promises of future behaviour being made are clear, unambiguous and enforceable. The details of the terms of the written undertaking can be the subject of negotiation between the TGA and the party concerned.

Where the matter relates to a breach or possible breach of the Act or Regulations any enforceable undertaking proposed to be given must contain sufficient details for the following to be clear:

- the nature of the breach/es
- how the Promisor will address the breach/es
- the exact nature of the resolution of the breach/es that is proposed.

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

- an acknowledgement or admission that the conduct constituted, 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 for instance, a positive statement that the Promisor will not import, export, manufacture, supply or advertise therapeutic goods in breach of the Act for a specified period of time (usually three years), noting that in order to enforceable the undertaking has to be sufficiently specific that the Promisor knows what is expected of them
- initiating a compliance policy 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 in accordance with the standard for the Handling and Destruction of Drugs AS/NZS 4757:2002 at the Promisor’s expense and to supply a certificate of destruction of those goods to the TGA, and
- an acknowledgement that the TGA will make the undertaking public by publishing it on the TGA’s website in accordance with section 42YL(3) of the Act
- an acknowledgement that the undertaking is given freely
- an acknowledgement that the undertaking in no way derogates from the rights and remedies available to the TGA, the Commonwealth or any other person arising from the conduct alleged to have breached the Act.

---

7 Section 42YL(1).
8 Anything done by the Promisor during the period in which the enforceable undertaking is in effect that amounted to a breach of this commitment would not only be a breach of the undertaking (in relation to which enforcement of the undertaking could be taken in the Federal Court) but may also involve an offence under the Act or other regulatory breach in relation to which enforcement or other regulatory action could be taken under the Act.
In appropriate circumstances, the TGA will also consider the inclusion of terms that will assist in monitoring compliance with the undertaking such as the inclusion of provisions requiring relevant information to be made available to it:

- periodically – for example, a periodic audit of compliance with the undertaking
- in specified circumstances – for example, a requirement to report any conduct that might amount to a default, and the reasons, or
- at the TGA’s request.

**Terms in an s.42YL enforceable undertaking not normally acceptable 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 and Ageing 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 actions\(^9\)
- 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 will allow 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

\(^9\) It is not necessary however for the undertaking to state that it is such an admission.
to address issues that were not foreseen at the time the undertaking was first accepted. However, a 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 as for the acceptance of the undertaking. In cases where the parties agree to a variation, the TGA will publish the varied agreement on its website but the original document will normally remain available on the TGA website.

Compliance with enforceable undertakings

The TGA has many stakeholders in the regulation of therapeutic goods and receives information in relation to activities of concern or allegations of unlawful behaviour, or behaviour that may involve a breach of regulatory requirements.

The TGA's Regulatory Compliance Unit (RCU) will monitor the activities of entities bound by an undertaking accepted by the TGA under section 42YL to ensure its terms are met during the period the enforceable undertaking is in effect. The RCU will also work with its partners in border control agencies and State and Territory Health Departments for this purpose. Monitoring can also involve random unannounced regulatory visits to the Promisor's place of business. The inclusion of provisions in the undertaking requiring relevant information to be provided by the Promisor that will assist the RCU in monitoring compliance.

The TGA will, where it has information that indicates that an enforceable undertaking has 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 its terms. Failure by the Promisor to comply with an 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 as a result of such an application may constitute a contempt of court.

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

If the TGA considers that the person who gave the undertaking has breached any of its terms, the TGA can apply to the Federal Court to make orders to enforce its terms.

If the Court is satisfied that the person 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 directing the person to compensate any other person who has suffered loss or damage because of the breach, and
d. any other order that the Court considers appropriate.

The enforceable undertakings document will remain available on the TGA website as a public record of the acceptance and terms of the undertakings notwithstanding all the undertakings have been complied with and/or the period during which the undertakings are to apply to the relevant company or individual is over.
Attachment A

ENFORCEABLE UNDERTAKING

*Therapeutic Goods Act 1989*

Section 42YL

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

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

ACN: ### ### ###

Persons giving this undertaking

1. This Undertaking is given to the Secretary of the Australian Department of Health and Ageing (DoHA), 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 *Therapeutic Goods Act 1989* (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 company structure or that of directors as required, and the conduct that the TGA investigated].

4. The Therapeutic Goods Administration (TGA) is a division of the Australian Department of Health and Ageing, and is responsible for the national regulation of therapeutic goods including medicines, biologicals and medical devices.

5. The meaning of 'sponsor' in the Act includes a person (including a corporation) who is resident of or carrying on business in Australia, who imports or arranges the importation, exports from or arranges the exportation from, manufactures in or supplies therapeutic goods in Australia.

6. Unless otherwise exempt or excluded, therapeutic goods must be included in the Australian Register of Therapeutic Goods (ARTG) by a sponsor prior to import, export, manufacture or supply. Criminal offences and/or civil penalty provisions may apply if the goods are imported, exported, manufactured or supplied and are not included in the ARTG.

7. [Detail of conduct by the promisor such as importing therapeutic goods not included in the ARTG – further paragraphs may be required for full explanation including a description of the Contravening goods].
8. [Circumstances since breach – example – Since becoming aware of the TGA investigation, XXXXX has ceased the importation into Australia of the Contravening goods].

9. [Full description of why the TGA considers the activity undertaken in relation to the Contravening goods constitutes a criminal offence and/or civil penalty provision of the Act].

10. XXXXX acknowledges that its conduct described at paragraph 8 above, involved the commission or the likely commission of a criminal offence and/or involved a breach or likely breach of the civil penalty provisions as described in paragraph 9 above.

Period of undertaking

11. This undertaking comes into effect when all of the following are satisfied:
   i. the undertaking is executed by [Company name, Business or Individual name]; and
   ii. the Delegate of the Secretary signs the executed undertaking.

12. Upon the commencement of this undertaking, [Company name, Business or Individual name] undertakes to assume the obligations set out in paragraphs [insert numbers] below.

13. This undertaking terminates on the third anniversary of the day on which it comes into effect.

Undertakings

14. [Company name, Business or Individual name] undertakes for the purposes of section 42YL of the Act that within one month from the date of this undertaking it will, at its own expense, engage a qualified compliance professional to advise and assist with the implementation of regulatory procedures to ensure that [Company name, Business or Individual name] does not commit any future breaches of the Act.

15. For the purposes of this Undertaking, a ‘qualified compliance professional’ will be someone with a minimum of 5 years experience in advising on regulatory compliance matters concerning therapeutic goods in Australia.

16. That [Company name, Business or Individual name] further undertakes for the purposes of section 42YL of the Act that it will at its own expense:
   i. establish and implement a Therapeutic Goods Compliance Program, within 3 months of the commencement of this Undertaking in accordance with Australian Standard AS 3806-2006 and the requirements set out in Annexure A to this Undertaking, being a program designed to minimise [Company name, Business or Individual name] and its subsidiaries risk of future breaches of sections (eg) 19B, 19D, 41MI and 41MB of the Act; and
   ii. maintain and continue to implement the Compliance Program for a period of 3 years from the commencement of this Undertaking; and
   iii. provide a copy of any documents required by the TGA in accordance with Annexure A.
17. [Company name, Business or Individual name] also undertakes for the purposes of section 42YL of the Act that it will:

i. at its own expense, within 2 months of the commencement of this Undertaking have caused the Contravening Goods to be collected from the TGA, transported and destroyed in accordance with the standard for the handling and destruction of drugs AS/NZS 4757:2002 and provide the TGA with a Certificate of Destruction and;

ii. pay to the TGA (on behalf of the Commonwealth) an amount as reimbursement for transportation and storage costs incurred by the TGA in connection with the Contravening Goods.

Acknowledgements

18. [Company name, Business or Individual name] acknowledge that:

i. this undertaking was given; and

ii. the Secretary may make this Undertaking publicly available on a public register and is obliged under the Act to publish details of the Undertaking, as in force from time to time, on the internet; and

iii. the Secretary and/or the Commonwealth or officers thereof may from time to time, make publicly refer to this Undertaking including through, but not limited to, news media statements, and in TGA or DoHA publications; and

iv. 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 of [Company name, Business or Individual name]
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 of ....................................20##

OR

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

........................................................
Secretary/Director
........................................................
Director
This ....................day of....................................20##

Accepted by the National Manager of the TGA as delegate of the Secretary under Section 42YL of the Act.

....................................................
Dr John Skerritt
National Manager
Delegate of the Secretary

This .........................day of ................................20##
Attachment B

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 because of the breach;
   d. any other order that the Court considers appropriate.