Australian Government
Department of Health
Therapeutic Goods Administration

TGA approach to disclosure of commercially confidential information (CCI)

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TGA Health Safety Regulation

About the Therapeutic Goods Administration (TGA)

- The Therapeutic Goods Administration (TGA) is part of the Australian Government Department of Health, and is responsible for regulating medicines and medical devices.
- The 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 <http://www.tga.gov.au>.

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Therapeutic Goods Administration approach to disclosure of commercially confidential information (CCI)

1. Introduction

The TGA becomes the repository of a large amount of information as part of its functions of assessing and monitoring the safety, quality, and effectiveness/performance of therapeutic goods. This information has a regulatory value to the TGA and will often have value to those who provide it.

As a part of the Department of Health and the Commonwealth, the TGA has obligations under the Protective Security Policy Framework (PSPF)[1] to ensure that the TGA develops, documents, implements and reviews appropriate security measures to protect information from unauthorised use or accidental modification, loss or release.

When information is provided to the TGA, such as personal, business or commercially confidential information, it is treated as *official information*. As such, the TGA is required to take measures to protect this information under the PSPF. [2] This means the TGA is required to classify the information using the Australian Government Classification System.[3]

There are five (5) Disseminating Limiting Markers (DLMs) that indicate how access to official information is to be limited:

- For Official Use Only (FOUO) - for use only on unclassified information (see below) when its compromise may cause limited damage to, amongst other things, commercial entities or members of the public
- SENSITIVE – for use where secrecy provisions of legislation apply, and/or disclosure may be limited or prohibited under legislation
- SENSITIVE: Legal – information that may be subject to legal professional privilege
- SENSITIVE: Cabinet
- SENSITIVE: Personal – for use only for "sensitive information" as defined in s.6 of the Commonwealth *Privacy Act 1988* (the Privacy Act) (particular types of personal information including health information about a person).

The four (4) SENSITIVE DLMs can be used with four (4) security classifications: Top Secret, Secret, Confidential and Protected.

Information provided to the TGA will be subject to the Australian Government information security management protocol. Once the information has been identified as requiring a protective marking, the protection and special handling requirements for the specific marking is

[1] The Protective Security Policy Framework (PSPF) provides the appropriate controls for the Australian Government to protect its people, information and assets, at home and overseas. The PSPF can be found at <http://www.protectivesecurity.gov.au/pspf/Pages/default.aspx>.
[2] Under the PSPF, individual agencies are responsible for determining the appropriate protections to be applied to information, including information of the kind described in this document.
[3] Information about the controls to be applied in relation to information can be found in the document *Information security management guidelines - Australian Government security classification system* at <http://www.protectivesecurity.gov.au/informationsecurity/Documents/Australian%20Government%20classification%20system.pdf>.

applied. This is to protect official information from unauthorised use or accidental modification, loss or release.

Sensitive personal, business or commercially confidential information is likely to attract the "For Official Use Only" DLM.

The TGA, like other therapeutic goods regulators:

- receives substantial amounts of commercially sensitive information from companies engaged in a highly competitive industry
- has obligations to the public, consumers, patients, healthcare professionals and to government to provide information about the quality, safety and efficacy/performance of regulated goods
- may hold a limited amount of sensitive personal information about individuals, in particular about their health status or history
- operates in an environment where there is an increasing demand for transparency in government regulation and accountability, and
- is committed to being more efficient through information and work sharing with international counterparts.

The TGA holds information provided for the purpose of determining market authorisation or access, authorising the manufacture of therapeutic goods or in the context of monitoring regulatory compliance of therapeutic goods in the market. Commercially sensitive financial and business information is also provided in relation to the payment of fees and charges and in correspondence on regulatory matters, complaints, confidential submissions, applications for review of TGA regulatory decisions, and letters written to the Minister or Assistant Minister.

The TGA needs to balance various factors, interests, and obligations when considering how this information is dealt with.

This document is about the TGA's approach to the release to the public of "commercially confidential information". Consultation on a draft version of this paper[4] (published on TGA's website on 27 June 2013) closed on 29 August 2013. The paper has been revised taking into account submissions made in response. They can be viewed on the TGA website.

What is "commercially confidential information"?

The TGA has adopted the definition used by the European Medicines Agency (EMA) which is as follows:

> Any information which is not in the public domain or publicly available, and where disclosure may undermine the economic interest or competitive position of the owner of the information.[5]

The definition picks up the following:

- trade secrets;

[4] See <http://www.tga.gov.au/pdf/consult/consult-disclosure-cci-130627.pdf>.

[5] See *HMA/EMA Guidance document on the identification of commercially confidential information and personal data within the structure of the marketing authorisation (MA) application – release of information after the granting of a marketing authorisation*, adopted on 9 March 2012 at <http://www.ema.europa.eu/docs/en_GB/document_library/Other/2012/03/WC500124536.pdf> at page 2.

- information that has a commercial or other value that would be, or could reasonably be expected to be, destroyed or diminished if it were disclosed;
- information that concerns the lawful commercial or financial affairs of a person, organisation or undertaking and if it were disclosed, could unreasonably affect the person, organisation or undertaking.

Common to these definitions is the reference to potential damage from release of the information rather than the circumstances in which the information was obtained or made available.

The elements considered as pre-conditions for information to be regarded by the TGA as commercially confidential information at a particular time by the TGA are as follows:

- the information must be specifically identified as of value when it was provided to the TGA
- it has been identified when provided to the TGA as being confidential in nature or is of such a kind that it is generally accepted to be confidential (for instance a trade secret, details of a medicine's formulation or manufacturing details etc)
- the information must have the necessary quality of confidence ie it must be secret or known only to a limited number of people – if it is in the public domain (ie the information, not necessarily in the form in which it was provided to the TGA), it cannot be commercially confidential, and
- the information is of such a nature that release of the information in the circumstances proposed would diminish the value of that information or otherwise cause damage to the company that provided it (usually commercial or financial loss or damage).

A request for confidentiality by a company in relation to information provided to the TGA is indicative of what is regarded by the company as commercially confidential but is not determinative of its status at any particular time (see discussion on page 10 below).

The following information is of a kind that, depending on the circumstances, is likely to be commercially confidential information:

1. certain kinds of information about therapeutic goods - depending on the nature of the product, this might include (but is not limited to), information or data about the formulation or the active ingredient, methods of extraction and manufacture, certain information about clinical trials, testing methods and validation of manufacturing processes, "trade secrets", design information, the outcome of testing of a product or investigations into its performance, information about the manufacture of particular batches, information about the manufacturing processes applied to batches, aspects of adverse event reports and related information, information provided as part of a recall, post-market studies/performance/safety information about the product.
2. certain kinds of information about a manufacturer or supplier – this might include information provided for the purpose of obtaining a manufacturing licence or conformity assessment certificate, information about manufacturing and product processes obtained in the course of, or for the purposes of, Australian or overseas inspections and clearances, site master files etc, and
3. financial or commercial information including about a sponsor or manufacturer and its business (provided for instance in an application to pay by instalments or for an exemption from annual charges, or evaluation or assessment fees), the identity of suppliers, marketing information and business strategies etc, information provided as part of a procurement process including for instance, about the financial viability of a company, pricing structure and profit margin.

Commercially confidential information for the purposes of the approach outlined in this paper is limited to information that is provided **to the TGA**.[6] Thus it does **not** cover potentially sensitive commercial information held by the TGA that was either generated by the TGA or provided to the TGA by other regulators and agencies or from elsewhere, for instance about a company's product or a company's business. This does not mean that the TGA releases such information to the public. **The same kinds of considerations and principles would apply to the release of such information by the TGA as apply to commercially confidential information.**

What this document is about

The purpose of this document is to describe the criteria applied by the TGA in determining whether information it holds for the purposes of carrying out its functions is commercially confidential and the TGA's approach to the release to the public of that information.

The document does not purport to describe all the specific kinds of information provided to the TGA that could be regarded as commercially confidential information but describes the criteria that are applicable in determining whether information can be regarded as commercially confidential for the purposes of the approach so described.[7]

This document is about the release of commercially confidential information **to the public**. It does **not** cover the following matters where release of information will be lawful:

- the disclosure by the TGA of information to 3rd parties such as health care professionals, other government agencies, other national regulators or international agencies or health organisations;
- the use by the Secretary, subject to section 25A of the Therapeutic Goods Act of information provided by a sponsor as part of the Secretary's regulatory functions under the Therapeutic Goods Act; or
- the disclosure by the TGA of information as required by or under law, to the Parliament or any of its committees, or to the Auditor-General, the Ombudsman, the Australian Information Commissioner, the Privacy Commissioner or the Freedom of Information Commissioner, to the courts or in relation to legal proceedings.[8]

2. Principles

The following eight (8) principles are relevant to the consideration of whether, and if so when and how, information that might be regarded as commercially confidential could be released to the public:

- PRINCIPLE 1: Open access to information held by government and transparency about government decision making
- PRINCIPLE 2: Regulator's obligation to provide timely information to the public about the quality, safety and effectiveness/performance of therapeutic goods
- PRINCIPLE 3: Appropriate protection of trade secrets and intellectual property rights

[6] It is therefore narrower than information that may come within the exemptions in sections 47 and 47G of the FOI Act.

[7] In relation to information provided to the TGA as part of a procurement process, the TGA applies the Commonwealth policy which is governed by the Commonwealth Procurement Rules – see <http://www.finance.gov.au/procurement/docs/cpr_commonwealth_procurement_rules_july_2012.pdf>. This document does **not** cover such information.

[8] Such as release in response to a subpoena.

- PRINCIPLE 4: Timely provision of information to the regulator
- PRINCIPLE 5: Relevance of timing and circumstances to status of information
- PRINCIPLE 6: Consultation
- PRINCIPLE 7: Excision of personal information
- PRINCIPLE 8: Release authorised by or under law

More details about each of these principles are at Attachment A**.**

Principles 1 and 2 reflect the public interest in open government, access by the public to relevant information and transparency about government decision-making. Principles 3 and 4 reflect another aspect of the public interest that is, the need to ensure that investment and innovation is not jeopardised and that individuals, organisations or companies that have information about the safety, quality or effectiveness/performance of therapeutic goods are not discouraged from volunteering information in a timely way to the regulator in order to ensure it can undertake its statutory functions effectively and efficiently.

Principles 6, 7 and 8 not only reflect "good practice" but promote the public interest by ensuring that those potentially affected have confidence in the process.

Principle 5 is a recognition that the commercial sensitivity of information will change over time and that judgements about its status are made at the time that consideration is being given to release of the information.

No one principle determines the circumstances in which particular information might be released to the public. Consideration of these principles may well produce different outcomes depending on various factors, such as:

- the particular circumstances and the degree to which public health considerations are relevant
- the nature of the information
- whether the consideration is of a one-off release of particular information, or a proposal that certain kinds of information be released as a matter of course, and
- the age and currency of the information.

3. TGA's approach to release of commercially confidential information

Basic rule

The TGA does not release information provided to it by an individual, organisation or company to the public as long as it is commercially confidential (as defined in this document) noting that this is subject to:

1. legal and other requirements to which the TGA, as part of the Commonwealth and the Department of Health, is subject including obligations to provide information to the Minister, to the Parliament and its committees, and to Commonwealth agencies that have powers to scrutinise the TGA's activities such as the Ombudsman, the Australian Information Commissioner, the Privacy Commissioner and the Freedom of Information Commissioner and the Australian National Audit Office, as well as to the courts and in relation to legal proceedings

2. the TGA's obligations under the *Freedom of Information Act 1982* (the FOI Act) and other relevant Commonwealth legislation, and

3. the obligation on the TGA to keep the public informed about the safety and safe use of therapeutic goods and more generally early warning of a potential safety, quality or efficacy/performance issue, or otherwise in the public interest.

The TGA does not release commercially confidential information (as defined in this document) except in particular circumstances where the TGA can justify the release in the public interest and it is lawful to do so. It will only be released to the extent that it is judged necessary to do so in the circumstances. (See further below about consultation.)

Who determines the status of information

As noted above, in determining whether information is commercially confidential, the TGA considers the circumstances in which the information was provided to the TGA, the inherent nature of the information, any potential damage to the owner if the information were released and the circumstances in existence at the time the issue of its proposed release.

A request for confidentiality by a company in relation to information provided to the TGA may be indicative of what is regarded by the company as commercially confidential but is not determinative of its status at any particular time:

1. because of the TGA's obligations under the law (as described above), it cannot be regarded as binding on the TGA

2. the information itself must be inherently capable of being confidential and release of which could undermine the economic interest or competitive position of the company.

For instance (and consistently with relevant exemptions in the FOI Act), information which would satisfy the test of being a trade secret, information about formulations, manufacturing processes, identity of suppliers, manufacturers, financial and sales information etc will, depending on the circumstances, normally be regarded as confidential, but information that is in the public domain or is otherwise readily ascertainable will not be so regarded.

When status of information is determined

The time at which a determination is made whether information is commercially confidential is when consideration is being given to its release. Information that might have been commercially confidential at the time it was provided to the TGA may, at the time consideration is being given to its release, no longer have that characteristic, for instance where it is now in the public domain.

For instance, information that is part of an application for registration of a medicine or the grant of conformity assessment certificate may no longer have a confidential quality once a decision on the application is a matter of public record (for instance by the inclusion of the medicine on the Register or inclusion of medical devices on the Australian Register of Therapeutic Goods based on the grant of that certificate). This approach has been endorsed by the Office of the Australian Information Commissioner.

Lawfulness of release

Any release by the TGA of information that could be commercially confidential is appropriately authorised under the relevant legislation, usually either the Therapeutic Goods Act or the FOI Act (see further below).

Consultation

The TGA consults the owner of commercial information provided to the TGA in relation to requests made under that FOI Act in accordance with that Act. The owner of the information has the opportunity to make submissions about whether relevant exemptions apply. The owner also has the opportunity to seek a review of any decision by the TGA (see further at Attachment B).

Where it is proposed in the interests of public health to release to the public information and it is not possible to provide that information without disclosing commercially confidential information, all reasonable efforts will be made to consult the owner of the information prior to its release. It is unlikely that consultation would not be undertaken other than in exceptional public health circumstances.

Affected stakeholders will be consulted before any decision is made by the TGA to adopt any practice of releasing potentially sensitive information (which may include commercially confidential information) to the public on a regular or systematic basis.

4. Current TGA practices

When does the TGA release information?

There are 3 distinct situations in which the issue of the release of commercially confidential information may arise:

1. where information about a company or a product is requested by a person, most usually under the FOI Act[9]
2. where information is published by the TGA on an ad hoc basis for transparency and public health reasons, and
3. where information is published by the TGA on a regular basis for transparency and public health reasons.

Release of information in response to ad hoc requests

The TGA is bound by the procedures in the FOI Act in responding to requests for information made under that Act. Generally, the TGA will suggest to a person seeking information that may include commercially confidential information of a third party, that they apply under the FOI Act so as to ensure that the third party has the opportunity to object to its release and have any decision reviewed. Details about the treatment by the TGA of information that may be commercially confidential under the FOI Act is set out at Attachment B.

Release to the public of information on an ad hoc basis

The TGA releases information about particular therapeutic goods to ensure their safe use. In particular cases, this may include information about a product that is commercially sensitive for a sponsor. However, it will not involve release to the public of commercially confidential information unless the TGA is of the view that it is necessary to do so in order to inform the public about the safe use of therapeutic goods. Such release would be authorised under law (section 61 of the Therapeutic Goods Act). The TGA does not release information about the making of applications (the fact of the application being made, by whom and when) or about the

[9] This is considered as release to the public because the FOI applicant is not constrained in what it can do with the information and the TGA is under an obligation under section 11C of the FOI Act to publish copies of documents provided to an FOI applicant that contain information about a person's commercial, business, financial or professional affairs or personal information unless it is "unreasonable" to do so (see subsection 11C(1) of the FOI Act).

ongoing evaluation of applications.[10] The fact that an application has been made will usually only become apparent to the public where the outcome of consideration by the TGA results in for instance, the inclusion of therapeutic goods in the Register.

Apart from the publication of AusPARs (which can extend to unsuccessful applications for the registration of certain types of prescription medicines and applications for the registration of prescription medicines that are withdrawn after a particular time in the evaluation process) the TGA also does not make public information about unsuccessful applications for marketing approval for therapeutic goods on a pro-active basis. Any change to the practice would be preceded by consultation with stakeholders.

Apart from the publication of AusPARs (which can extend to unsuccessful applications for the registration of certain types of prescription medicines and applications for the registration of prescription medicines that are withdrawn after a particular time in the evaluation process) the TGA also does not make public information about unsuccessful applications for marketing approval for therapeutic goods on a pro-active basis.[11] Any change to the practice would be preceded by consultation with stakeholders.[12]

Release of information on a systematic basis

In the interests of transparency about decision making and informing the public about how regulatory decisions about therapeutic goods approved for marketing in Australia are made, and in order to provide more information about those goods to inform health care professionals, consumers and the public, consideration is increasingly being given to the provision of more information to the public about those matters on a systemic basis.

Information is made available to the public about the safe use of medicines through the publication of approved Product Information and of Consumer Medicine Information on the TGA website. The TGA also makes available information about certain registered medicines through the publication of AusPARs (see <http://www.tga.gov.au/industry/pm-auspar.htm>).

Release of information about adverse events, recalls and early warning notifications

The TGA has implemented a number of initiatives involving the release to the public of information about adverse events[13], recalls[14] and early warnings about potential safety concerns with medicines and medical devices[15]. While a number of these involve, or potentially involve, the release of information that may be commercially sensitive to some companies, the TGA has taken care to ensure that the information that is accessible on the databases does not include either personal information or commercially confidential information as defined in this document. In each case, the proposals were subject to consultation with industry and stakeholders before implementation and the release of information is authorised under section 61 of the Therapeutic Goods Act.

[10] It is of course open for a sponsor to make public at any time information about an application that it has made to the TGA. If asked, the TGA would normally still regard the fact of the application having been made as not for comment by the TGA.

[11] If such information is sought under the FOI Act, the TGA would consult the relevant company about whether information is exempt under that Act.

[12] On the other hand, the Secretary is, under the Act, obliged to publish particulars about certain kinds of regulatory decisions (such as the cancellation of medical devices and medicines) in the Commonwealth Gazette or on the TGA's website.

[13] See Database of Adverse Event Notifications (DAEN) <http://www.tga.gov.au/safety/daen.htm> and The Joint Adverse Event Notification System (JAENS) <http://www.anztpa.org/aen/landing.aspx>.

[14] See System for Australian Recall Actions (SARA) <http://www.tga.gov.au/safety/sara.htm>.

[15] See Early warning system <http://www.tga.gov.au/safety/ews.htm>.

5. Relevant legislation

Restrictions on disclosure by TGA staff

As members of the Australian Public Service, officers of the Department of Health (including staff of the TGA) are subject to rules about the disclosure of information, including commercially confidential information. It is an offence under section 70 of the *Crimes Act 1914* for TGA staff to disclose information that they are under a duty not to disclose. As public servants, TGA staff are also bound by the Australian Public Service Code of Conduct[16] which states that an employee must not make improper use of "inside information" in order to gain or seek to gain a benefit or advantage.

There is a public interest in ensuring that TGA officers can carry out their statutory functions under the Therapeutic Goods Act without fear of being subject to civil action in the courts. This is reflected in section 61A of the Therapeutic Goods Act which protects them from civil actions (including for instance, breach of confidence) that could arise from the release of information alleged to have resulted in commercial damage, provided the officer did not release the information in bad faith.

Therapeutic Goods Act

The Secretary of the Department of Health or her TGA delegate can release therapeutic goods information to the public under section 61 of the Therapeutic Goods Act:

- where it relates to any decision or action taken under the Therapeutic Goods Act or the regulations made under the Therapeutic Goods Act[17]
- where it is information of a kind that has been specified in a legislative instrument made by the Minister under subsection 61(5D) of the Therapeutic Goods Act,[18] or
- where its release is necessary to ensure the safe use of particular therapeutic goods or it relates to the reasons for the withdrawal of therapeutic goods from supply in Australia.[19]

It is not an offence under the Therapeutic Goods Act to release information to the public in other circumstances – indeed the Secretary is required to publish information about a variety of regulatory decisions that may be commercially sensitive.[20]

The effect of a decision to release information under one of the provisions of section 61 is that it protects the Secretary and the TGA officers exercising her power as delegates from any civil liability for any loss, damage or injury of any kind resulting from the release of the information, provided the decision was not done in 'bad faith'.[21] This is likely to include any liability arising from release of information in breach of confidence, or which otherwise resulted in financial damage to the owner of the information.

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[16] See subsection 13(10) of the *Public Service Act 1999*.

[17] See subsection 61(5A) of the Therapeutic Goods Act.

[18] See subsection 61(5C) of the Therapeutic Goods Act. The release of information in an AusPAR is supported by a determination made by the Minister under subsection 61(5D) of the Act – see *Therapeutic Goods Information Specification 2009* at <http://www.comlaw.gov.au/Details/F2009L04131>.

[19] See subsection 61(7) of the Therapeutic Goods Act.

[20] For instance, the Secretary must publish in the Gazette or on the TGA website particulars of cancellations of registered and listed therapeutic goods (including prescription, over-the-counter and complementary medicines), medical devices and biologicals from the Register, and revocations of conformity assessment certificates and manufacturing licences. Particulars of the giving of a consent by the Secretary under section 14 or 14A of the Act to the importing, exporting or supply of a product that does not comply with an applicable standard is also required to be published.

[21] See section 61A(2) of the Therapeutic Goods Act.

Thus the Secretary (and her delegates in the TGA) can under section 61 of the Therapeutic Goods Act authorise the release of information to the public:

- on an ad hoc basis, for instance to authorise the publication of a safety warning on the TGA website about particular therapeutic goods, or
- more generally, for instance to authorise the release of information on the TGA website about:
  - recalls of therapeutic goods or information about adverse events reports in relation to medicines or medical devices[22]
  - regulatory action taken by the TGA to cancel products from the Register,[23] or
  - the evaluation of a prescription medicine and the considerations that led the TGA to approve or not approve an application[24] and the future publication of similar documents in relation to other types of therapeutic goods.

Freedom of Information Act

Under the FOI Act any person has a statutory right to seek access to documents[25] held by the Commonwealth, irrespective of the reasons the person gives for seeking access to or the agency's belief as to those reasons.[26] Agencies holding information, whether generated by the agency or another Commonwealth agency, or provided to that agency by a third party, are required to identify any documents that are within the scope of a request made under the FOI Act and to release them to the person making the request except to the extent any information in the documents is "exempt" under one of the provisions of the FOI Act. See further at Attachment B.

[22] For instance in the publicly searchable database of Australian recall actions (System for Australian Recall Actions (SARA)) at <http://www.tga.gov.au/safety/sara.htm> which contains information about all recall actions undertaken by the TGA for therapeutic goods since 1 July 2012 and in the publicly searchable database of adverse event notifications (DAEN) at <http://www.tga.gov.au/safety/daen.htm> which contains information about adverse events reported in relation to medicines and vaccines. A publicly searchable database of adverse events involving medical devices has been available on the TGA website since 19 June 2013.

[23] See, for instance the publication of information about complementary medicines cancelled from the Register by the Secretary because of a failure to comply with regulatory requirements at <http://www.tga.gov.au/industry/cm-cancellations-cr.htm>.

[24] See, for instance, the publication of the Australian Public Assessment Reports for prescription medicines (AusPARs) at <http://www.tga.gov.au/industry/pm-auspar.htm>.

[25] The definition of "document" under the Freedom of Information Act is very wide and includes information stored electronically from which sounds, images or writing are capable of being reproduced.

[26] See section 11 of the FOI Act.

Attachment A

Principles

PRINCIPLE 1: Open access to information held by government and transparency about government decision making

The principle of promoting community access to government information is one of the objects of the *Freedom of Information Act 1982* which requires agencies to publish information and provide a right of access to documents. Its purpose is to increase:

- public participation in Government processes, with a view to promoting better informed decision making
- scrutiny, discussion, comment and review of the Government's activities, and
- recognition that information held by the Government is a national resource, and is to be managed for public purposes.[27]

PRINCIPLE 2: Regulator's obligation to provide timely information to the public about the quality, safety and effectiveness/performance of therapeutic goods

The TGA has an obligation to the public, health care professionals and consumers to provide timely and accurate information about the quality, safety, and effectiveness/performance of therapeutic goods to health care professionals, consumers, and the general public.

PRINCIPLE 3: Appropriate protection of trade secrets and intellectual property rights

Therapeutic goods regulators hold information that has a significant commercial value that may have involved a considerable investment in resources and effort to compile. Disclosure of information that would discourage future investment and innovation in the therapeutic goods industry without clear public health benefits could have long term effects on investment in public health.

PRINCIPLE 4: Timely provision of information to the regulator

The timely, free flow of information to the TGA is essential to effective regulation. The therapeutics industry, health professionals, and the general public, will often freely provide regulators with advanced notice of safety and compliance issues without the need for the TGA to exercise its statutory powers to collect information.

This voluntary sharing of information can greatly assist government regulation, enabling the mitigation of potential risks to public health and safety. It is therefore important to consider

[27] See section 3 of the FOI Act.

whether the release of any information would discourage the timely provision of information in the future.[28]

PRINCIPLE 5: Relevance of timing and circumstances to status of information

Depending on its nature, the commercial sensitivity of information can diminish over time. The circumstances in which information was provided, and its commercial sensitivity at that time, is relevant to how it is stored and handled by the TGA. However, its status as commercially confidential information need only be finally determined at the time that consideration is being given to its release.[29]

The fact that material is in the public domain is a well-recognised basis for rejecting claims that information should not be released under the FOI Act on the basis of potential damage to the company from which it was obtained or that release will reduce the value of the information.[30] What is now common knowledge, or in the public domain, will no longer have the necessary quality of 'confidentiality' and it would be difficult to establish that its release could cause any damage. If so, it will no longer satisfy the definition of commercially confidential information.

PRINCIPLE 6: Consultation

Consultation with the provider of information is a statutory requirement where a request for that information is made under the FOI Act.

Where it is proposed in the public interest to release information to the public in other circumstances and it is not possible to provide that information without disclosing commercially confidential information, every reasonable effort will be made to consult the owner of the information prior to its release.

The adoption of any practice that may involve the release of information (potentially containing commercially confidential information) on a systematic basis will be preceded by consultation with stakeholders. Consultation about any such proposal, seeking views about the exact nature of the information to be released and the timing of any implementation will ensure relevant members of the therapeutic goods industry have an input and also time to prepare.

PRINCIPLE 7: Excision of personal information

'Personal' information (ie information from which the identity of an individual is apparent or can be ascertained) is sometimes included in what is also considered commercially confidential information.

As a Commonwealth government agency, the TGA is obliged to ensure that personal information is collected, held, used and disclosed in such a way that provides appropriate protection for that

[28] This principle is recognised in an exemption in paragraph 47G(1)(b) of the FOI Act if a 3rd party can demonstrate that release could reasonably be expected to prejudice the future supply of information for the purpose of the administration of a law of the Commonwealth or the administration of matters administered by an agency. The Information Commissioner has confirmed that the test is whether the release will result in a reduction in the quantity and quality of information given to the TGA by sponsors such that the TGA's ability to perform its statutory functions will be prejudiced. See *'Q' and Department of Health and Ageing* [2013] AICmr 29 (22 March 2013) at paragraphs 34 to 41 and *'AC' and Department of Health and Ageing* [2013] AICmr 50 (24 April 2013) at paragraphs 55 to 62.

[29] For instance, the fact that marketing authorisation is being sought for a therapeutic product will lose its commercial sensitivity once approval has been given; otherwise commercially confidential information may become a matter of public knowledge through later external review or publication.

[30] See for instance *'Q' and Department of Health and Ageing* [2013] AICmr 29 (22 March 2013) *'AC' and Department of Health and Ageing* [2013] AICmr 50 (24 April 2013).

individual and is consistent with its obligations as set out in the Privacy Act. Such information will normally be excised from documents released under the FOI Act. It is very unlikely that any release of information by the TGA in the public interest would warrant release of personal information.

PRINCIPLE 8: Release authorised by or under law

It is important that where the TGA comes to the view that it is necessary to release commercially confidential information to the public such release is authorised by or under the law.[31] This will most typically be because it is released under the FOI Act or is authorised under section 61 of the Therapeutic Goods Act.

[31] Thus to the extent that any AusPAR contains commercially confidential information, its release is authorised by a delegate of the Secretary under subsection 61(5C) of the Act relying on the legislative instrument made under subsection 61(5D) of the Act: *Therapeutic Goods Information Specification 2009* at <http://www.comlaw.gov.au/Details/F2009L04131>.

Attachment B

Background information on the Freedom of Information Act

Under the FOI Act any person has a statutory right to seek access to documents[32] held by the Commonwealth, irrespective of the reasons the person gives for seeking access to or the agency's belief as to those reasons.[33] Agencies holding information, whether generated by the agency or another Commonwealth agency, or provided to that agency by a third party, are required to identify any documents that are within the scope of a request made under the FOI Act and to release them to the person making the request except to the extent any information in the documents is "exempt" under one of the provisions of the FOI Act.[34] The motivations of the person seeking access cannot be taken into account in determining whether documents should be released.[35]

Where documents identified as coming within the scope of the request contain information about the business, commercial or financial affairs of an organisation or undertaking and the TGA believes that the organisation or undertaking would wish to argue that it makes the document exempt under particular provisions of the FOI Act, the TGA **is obliged** to give the organisation or the proprietor of the undertaking the opportunity to make submissions and take them into account when considering giving access to the documents.[36]

Those exemptions are under:

- section 47(1)(a) (trade secrets)
- section 47(1)(b) (information having a commercial value that would, or could reasonably be expected to be, destroyed or diminished if disclosed)
- section 47G(1)(a) (information, release of which would, or could reasonably be expected to, unreasonably affect that person adversely in respect of his or her lawful business or professional affairs or the organisation or undertaking adversely in respect of its lawful business, commercial or financial affairs and would be contrary to the public interest)
- section 47G(1)(b) (information, release of which could reasonably be expected to prejudice the future supply of information to the Commonwealth or an agency for the purpose or the administration of a Commonwealth law or the administration of matters administered by an agency and would be contrary to the public interest).

The FOI Act also contains an exemption for documents release of which would found an action for breach of confidence[37] but agencies are not required to consult third parties about the application of this exemption.[38] There is a degree of overlap between the "breach of confidence"

[32] The definition of "document" under the Freedom of Information Act is very wide and includes information stored electronically from which sounds, images or writing are capable of being reproduced.
[33] See section 11 of the FOI Act.
[34] The information being sought has to be sufficiently identifiable for the TGA to determine whether or not the relevant document is in its possession.
[35] Subsection 11(2) of the FOI Act.
[36] See section 27 of the FOI Act.
[37] See section 45 of the FOI Act.
[38] The TGA has a practice of seeking the views of the 3rd party on that issue as part of any consultation as the 3rd party will be in the best position to inform the TGA whether essential elements of the exemption can be made out, for instance, whether or not the information is now in the public domain. The TGA decision maker will consider whether section 45 might apply to information in appropriate cases. Because the FOI Act does not require consultation about the application of section 45, a 3rd party cannot seek internal review on the basis of the TGA's failure to apply that exemption: *'Q' and Department of Health and Ageing* [2013] AICmr 29 (22 March 2013).

exemption and the exemptions referred to above, particularly whether information is in the public domain.[39]

An agency is not bound by the submissions of a third party in relation to the application of any of those exemptions. However, if the agency is proposing to release any such documents notwithstanding the submissions made, the agency must not do so unless and until the organisation or the proprietor of the undertaking has had the opportunity to seek internal review and/or review by the Australian Information Commissioner (the AIC) and the Administrative Appeals Tribunal (the AAT).

An FOI applicant also has a right to an internal review and/or review by the AIC and the AAT in relation to any decision to exempt documents under any provision of the FOI Act, including sections 45, 47 and 47G.

An agency is required under the FOI Act to publish any documents made available to the FOI applicant in a "disclosure log" on its website.[40] The agency is not required to publish any information about the business, commercial, financial or professional affairs of any person, or personal information about any person, if it would be "unreasonable" to publish the information.[41] The decision by an agency to publish on its website documents made available to the FOI applicant is not subject to review.[42] The TGA will not normally publish documents released to the FOI applicant on the TGA website if the relevant third party objects.[43]

Where a request for documents made under the FOI Act covers information about which a third party is likely to want to argue that any of the relevant commercial exemptions apply, the TGA follows all the statutory requirements in consulting that company. It is only where either:

- the company agrees to the release of the information in the document to the applicant, or
- where as a result of a review (whether internal, Information Commissioner or AAT) in relation to which the appeal period has expired, a decision has been made to release the information in the document on the basis that any potentially relevant exemptions do not apply,

that the TGA would release the relevant documents to the FOI applicant.

Where documents coming within the scope of an FOI request include information or documents provided by a third party[44] and contain what appears to be commercially confidential information, the TGA will always consult that third party under section 27 of the FOI Act, even if it is not proposing to release the information. This is because the third party will be in the best position to provide information about the criteria that must be satisfied in order to apply the exemptions in sections 47 and 47G such as the commercial value of the information, how many people know about the content, how the business might be adversely affected if the information were released, whether (in the case of section 47G) release would be contrary to the public interest etc.

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[39] The guidelines made by the Information Commissioner under section 93A of the FOI Act set out the kinds of matters agencies should take into account in determining whether the exemption in section 45 might apply. These can be found at paragraphs 5.135 to 5.153 at <http://www.oaic.gov.au/publications/guidelines/guidelines-s93a-foi-act_part5_exemptions.html#_Toc286409265>.

[40] See section 11C of the FOI Act. Documents released by the TGA under the FOI Act can be found at <http://www.tga.gov.au/about/foi-documents-released.htm>.

[41] See subsection 11C(1) of the FOI Act.

[42] Even if the decision is made by an agency not to publish documents on its website because it would be "unreasonable" to do so under subsection 11C(1) of the FOI Act, there is nothing in that Act that would prevent the FOI applicant making that information available to the public.

[43] See subsection 11C(1) of the FOI Act.

[44] Where a company seeks access to its own commercially confidential information it will normally be provided as a matter of course.

As required by the FOI Act, if the decision maker proposes to release any information to which the third party has argued an exemption in section 47 or 47G applies, the third party is informed of its rights to internal and external review, and both the FOI applicant and third party are informed that the material will not be released until that process has been completed.

The Australian Information Commissioner has, under subsection 93A(2) of the FOI Act, published comprehensive guidelines to which agencies are required to have regard in making decisions under the Act. Those guidelines contain extensive material on the application of the exemptions in sections 45, 47 and 47G of the FOI Act.[45] Third parties consulted under section 27 of the FOI Act are encouraged to consider the guidelines in formulating submissions on the application of exemptions under the FOI Act.

The approach of the TGA to the application of the section 47(1)(b) (diminution of commercial value of information) and 47G (unreasonable adverse effect on business, commercial or financial affairs) where it appeared that the information in relation to which the third party objected to release was already in the public domain, was upheld by the Information Commissioner in the cases 'Q' and the Department of Health and Ageing [2013] AICmr 29 (22 March 2013)[46] and 'AC' and Department of Health and Ageing[2013] AICmr 50 (24 April 2013).

'Neither confirm nor deny'

One exception to this practice of consulting 3rd parties is where it appears that the effect of responding to the FOI request in the usual fashion[47] could make the response to the applicant an exempt document. In such a case, the TGA will not consult any third party that may have made such an application but will rely on section 26(2) of the FOI Act to neither confirm nor deny the existence of any documents that may come within the scope of the FOI Act. This approach was upheld by the Federal Court in December 2010 in the judgment *Secretary, Department of Health and Ageing v iNova Pharmaceuticals (Australia) Pty Limited* [2010] FCA 1442.[48]

Whether or not any of the exemptions apply to particular information provided to the TGA by a third party will be influenced, and in some cases, determined by when the FOI application is made. As noted above, if it is made when an application is under consideration by the TGA, then in order to ensure that information about the application can be exempt, it may be necessary for the TGA to neither confirm nor deny whether any documents coming within its scope do or do not exist.

On the other hand, once the existence of an application has become publicly known through the inclusion of a product on the Register or the publication of an AusPAR then the response to a request for information or data contained in the application will be determined by the application of relevant exemptions to the information or data itself after consultation with the applicant.

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[45] The guidelines made under section 93A of the FOI Act can be found at <http://www.oaic.gov.au/publications/guidelines.html#foi_guidelines>.

[46] The information in this case was in a TGA letter to the third party rather than information provided by the third party to the TGA but the issues of whether the exemptions can apply where it is in the public domain would be equally applicable.

[47] Either (where no application has been made), "no, there are no documents" or, where an application has been made and there is commercially confidential information that comes within the scope of the request "yes there are documents but they are exempt under section 47 and/or section 47G".

[48] The background to the adoption of this approach was a succession of requests to the TGA by sponsors of registered medicines asking for documents which would disclose whether an application had been made for a generic version of the registered medicine. A response to a request which changed from "no documents" to "yes there are now documents but they are exempt" or "I am required to consult a third party about your application" would clearly convey the existence and timing of any such application. The decision by the TGA to respond to such requests using the "neither confirm nor deny" formulation was upheld by the Federal Court.

Where information has been provided to the TGA in the post-market context (for instance where safety issues about a product have arisen), whether the material or knowledge of the safety issues is in the public domain will be relevant to the application of the exemptions. It may be that the TGA itself has published information about potential safety issues concerning the product as part of its obligations to inform the public about the safe use of therapeutic goods.

Review of FOI decisions

Both the person making the FOI request and the 3rd party consulted about release of information that may be commercially confidential have a right under the FOI Act to request internal review of the initial decision (not to release or to release information, respectively) and/or review by the Australian Information Commissioner and then the Administrative Appeals Tribunal.

Under subsection 27(7) of the FOI Act, TGA cannot release information that is the subject of an objection by a 3rd party unless and until the time for the 3rd party to seek a review of the decision to release has run out, or the decision has been confirmed or otherwise still stands.

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