Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Draft TGA approach to disclosure of commercially confidential information (CCI)

Version 1.0 (draft), June 2013

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 Ageing, 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>.

Confidentiality
All submissions received will be placed on the TGA's Internet site, unless marked confidential. Any confidential material contained within your submission should be provided under a separate cover and clearly marked "IN CONFIDENCE". Reasons for a claim to confidentiality must be included in the space provided on the TGA submission coversheet. For submission made by individuals, all personal details, other than your name, will be removed from your submission before it is published on the TGA's Internet site. In addition, a list of parties making submissions will be published. If you do not wish to be identified with your submission you must specifically request this in the space provided on the submission coversheet.

Version history

Version	Description of change	Author	Effective date
V1.0 (draft)	Original publication	Therapeutic Goods Administration	27/06/2013

Contents

Draft TGA approach to disclosure of commercially confidential information (CCI)

1. Introduction

The Therapeutic Goods Administration becomes the repository of a large amount of information as part of its functions of assessing and monitoring the safety, quality, and effectiveness of therapeutic goods. This information has a regulatory value to the TGA; however it may also have value to those from whom it has been obtained, to their competitors and to those who use the therapeutic goods to which it relates.

As a division within an agency of the Commonwealth (the Department of Health and Ageing) 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. The mandatory requirements as set out in the PSPF core policy are based on the three elements of information security: confidentiality - ensuring that information is accessible only to those authorised to have access; integrity - safeguarding the accuracy and completeness of information and processing methods; and availability - ensuring that authorised users have access to information and associated assets when required.[2]

The TGA, like other national therapeutic goods regulators:

- receives substantial amounts of commercially 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 the therapeutic goods they regulate
- may hold a limited amount of sensitive personal information about individuals, in particular about their health status or history

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>. 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*>.

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.

- operates in an environment where there is an increasing demand for transparency in government regulation and accountability, and
- has commitments to be more efficient through information and work sharing with international counterparts.

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

Recommendation 11 of the Transparency Review

In November 2011, the Australian Government announced acceptance of a series of recommendations arising from the 2011 *Review to improve the transparency of the Therapeutic Goods Administration* (the Transparency Review).[3] These recommendations were designed to increase the public's understanding of the TGA's role and functions, and to better inform stakeholders on the issues that are of concern to them.

Recommendation 11 of the Transparency Review was that:

> The TGA develop and publish a policy on the disclosure of commercially confidential information, noting significant issues for each therapeutic product type. The policy should take into account the practices followed by comparable international regulators.[4]

The Panel commented that it was important to develop a policy that:

- enables sponsors to have a high degree of certainty about what is recognised by the TGA as commercially sensitive information
- is broadly consistent between different product types while recognising that there are differences between product types[5]
- includes guidance on the timing of the release of information, and
- is consistent with overseas regulatory practice.[6]

The Panel noted that the consultations it conducted highlighted the sensitivities and constraints about the release of information by the TGA and the methods and timing of such release.[7] In formulating Recommendation 11, the Review panel referred to suggestions that if information is "deemed to be in the public's interest" it should be in the public domain but that this gives rise to questions about how this is to be done, who should determine its sensitivity and what the "public's interest" might mean in this

---

3 See *Review to improve the transparency of the Therapeutic Goods Administration, Final Report*, June 2011 at <http://www.tga.gov.au/newsroom/review-tga-transparency-1101.htm>.

4 See Review to improve the transparency of the Therapeutic Goods Administration, Final Report, June 2011, page 5 at <http://www.tga.gov.au/newsroom/review-tga-transparency-1101.htm>.

5 'Product types' is a reference to the different types of therapeutic goods regulated by the TGA – medicines (prescription, over the counter and complementary), medical devices (including in vitro diagnostic medical devices), biological and therapeutic devices.

6 See Review to improve the transparency of the Therapeutic Goods Administration, Final Report, June 2011, page 42 at <http://www.tga.gov.au/newsroom/review-tga-transparency-1101.htm>.

7 See *Review to improve the transparency of the Therapeutic Goods Administration, Final Report*, June 2011, page 23 at <http://www.tga.gov.au/newsroom/review-tga-transparency-1101.htm>.

context. Industry members of the panel were concerned about the release of information that is currently treated as commercially confidential.[8]

What is meant by "commercially confidential information"?

This document is about the TGA's approach to the release of "commercially confidential information". The definition used by the European Medicines Agency (EMA) 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.[9]

A useful reference point for a definition can be found in section 185 of the *Gene Technology Act 2000*. This section gives the Gene Technology Regulator power to declare specified information to be "confidential commercial information" if it satisfies the following criteria:

- it is a trade secret; or
- it has a commercial or other value that would be, or could reasonably be expected to be, destroyed or diminished if it were disclosed; or
- it 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. [10]

Similar criteria can be found in the exemption from disclosure under the *Freedom of Information Act 1982* in paragraphs 47(1)(a) (trade secrets) and 47(1)(b) (information with a commercial value) and in the conditional exemption in paragraph 47G(1)(a) (release would unreasonably affect business, financial affairs etc) except in relation to the latter, the exemption will not apply unless disclosure would be contrary to the public interest.[11]

---

8 See *Review to improve the transparency of the Therapeutic Goods Administration, Final Report*, June 2011, page 42 at <http://www.tga.gov.au/newsroom/review-tga-transparency-1101.htm>.

9 See *HMA/EMA recommendations on transparency* – EMA/484118/2010 dated November 2010, page 2 at <http://www.ema.europa.eu/docs/en_GB/document_library/Other/2010/12/WC500099536.pdf> and see also discussion in *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*, dated 27 March 2012 at <http://www.ema.europa.eu/docs/en_GB/document_library/Other/2012/03/WC500124536.pdf>.

10 The effect of such a declaration is that the requirements in section 187 of the Act about how such information can be dealt with are applicable. Section 3 of the Agriculture and Veterinary Chemicals Code Act 1994 contains a definition of "confidential commercial information" which is in similar terms. Section 162 of the Code sets out how Australian Pesticides and Veterinary Medicines Authority must deal with such information. See also the definition of "confidential commercial information" in section 4 of the Food Standards Australia and New Zealand Act 1991 and section 114 of that Act which sets out how FSANZ must deal with such information.

11 See subsection 11A(5) of the FOI Act.

Common to these definitions is the reference to potential commercial or financial damage from release of the information rather than on the circumstances in which the information was obtained or made available.[12]

The elements considered necessary for information to be regarded by the TGA as commercially confidential are as follows:

the information must be specifically identified

- the information must have the necessary quality of confidence ie it must be secret or only known to a limited number of people – if it is in the public domain, it cannot be commercially confidential
- 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), 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).

Commercially confidential information held by the TGA may include information of the following kinds:

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 of the active ingredient, and methods of extraction and manufacture, certain information about clinical trials, testing methods and validation of manufacturing processes, "trade secrets"[13], design information, the outcome of testing of a product or investigations into its performance, information about the

---

12 One of the essential elements of a 'trade secret' is the harm that can result if the relevant information is released. See footnote following. The TGA does not regard commercially confidential information as being synonymous with information in relation to which obligations of confidentiality may arise under, and be recognised by, the law ie information of a kind, the unauthorised release of which would give rise to an action for breach of confidence in law.

13 In its section 9CA FOI Act Guideline the Information Commissioner quotes the Federal Court in *Lansing Linde Ltd v Kerr* [1990] 21 IPR 529 per Staughton LJ at 536, cited in *Searle Australia Pty Ltd and Public Interest Advocacy Centre and Department of Community Services and Health* [1992] 108 ALR 163 as referring to the following test in considering whether information amounts to a trade secret - the information is used in a trade or business, the owner must limit the dissemination of it or at least not encourage or permit widespread publication and if disclosed to a competitor, the information would be liable to cause real or significant harm to the owner of the secret. Factors that the Information Commissioner regards as 'useful guidance but not an exhaustive list' of matters to be considered include:

- the extent to which the information is known outside the business of the owner of that information
- the extent to which the information is known by persons engaged in the owner's business
- measures taken by the owner to guard the secrecy of the information
- the value of the information to the owner and to his or her competitor
- the effort and money spent by the owner in developing the information
- the ease or difficulty with which others might acquire or duplicate the secret.

The guidelines go on to say that Information of a non-technical character may also amount to a trade secret but to be a trade secret, information must be capable of being put to advantageous use by someone involved in an identifiable trade. See paragraphs 5.180 to 5.183 (inclusive) at <http://www.oaic.gov.au/publications/guidelines/guidelines-s93a-foi-act_part5_exemptions.html#_ftnref114>.

manufacture of particular batches, information about the manufacturing processes applied to batches, including document names and numbers, aspects of adverse event reports and related information, information provided as part of a recall, post-market studies/performance/safety information about the products,

2. certain kinds of information about a manufacturer or supplier – this might include information provided for the purpose of being obtaining a 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.[14]

"Commercially confidential information" for the purposes of the approach outlined in this paper is, consistent with the definition used by EMA as described above, limited to information that is provided **to the TGA**.[15] Thus it does **not** cover potentially sensitive commercial information held by the TGA that was either generated by the TGA or provided by other regulators and agencies or from elsewhere, for instance about a company's product or a company's business.[16]

What this document is about

The purpose of this document is to describe a proposed approach to the release of commercially confidential information held by the TGA for the purposes of carrying out its regulatory functions.

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.[17]

This approach about the release of commercially confidential information **to the public** so does **not** cover the following matters:

---

14 It may also include information provided to the TGA by a person or a company about another company's products or circumstances, the release of which could, in certain circumstances, be damaging to the provider of the information. This would be commercially confidential information for the purposes of this document in relation to the provider, not the company about which the information relates.

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

16 This of course does not mean that the TGA releases such information (unless the public interest required it). If a request was made under the FOI Act for this information, the same kind of considerations would apply as apply to commercially confidential information covered by this document.

17 For instance, 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.

- 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[18]
- the use by the Secretary, subject to section 25A of the Therapeutic Goods Act[19], of information provided by a sponsor as part of the Secretary's regulatory functions under the TG Act[20], 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, to the courts or in relation to legal proceedings.[21]

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

The principle of promoting community access to government information is the basis for the objects of the Commonwealth access to information legislation[22], 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.[23]

---

18 These general principles are not intended to impact upon any collaborative arrangements/confidentiality arrangements between therapeutic goods regulators, nor on the exchange of confidential regulatory information that regularly takes place under these arrangements.

19 This section implements Australia's WTO Agreement on Trade-Related Aspects of Intellectual Property (TRIPs) and Australia United States Free Trade Agreement obligations in relation to data protection.

20 Subsection 61(8) of the Act makes it clear that, subject to section 25A, "therapeutic goods information" (defined in subsection 61(1) of the Therapeutic Goods Act as information in relation to therapeutic goods held by the Department of Health and Ageing that relates to the performance of the Department's functions) can be used by the Department in consideration of any other matter within its functions relating to therapeutic goods and be provided to a committee appointed to advise the Minister or the Secretary on matters relating to therapeutic goods including a committee of the National Health and Medical Research Council.

21 Such as in response to a subpoena.

22 *Freedom of Information Act 1982.*

23 See section 3 of the Freedom of Information Act.

PRINCIPLE 2: Regulator's obligation to provide timely information to the public about the quality, safety and effectiveness 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 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.

Trade secrets and commercial confidences will not normally be released for so long as they retain their quality of confidentiality unless there is an overriding public interest reason for doing so.

PRINCIPLE 4: Ensuring the future timely provision of information to the regulator

The timely, free flow of information to the TGA from sponsors and manufacturers 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 whether the release of any information would discourage the timely provision of information in the future.[24]

PRINCIPLE 5: Relevance of timing

Whether information has the necessary quality of confidentiality must be judged at the time the release to the public is being considered. Depending on its nature, the commercial sensitivity of information can diminish over time. In determining whether it is appropriate to release information, its sensitivity must be considered as at the time that is proposed to be released, not the time at which it may have been provided.[25]

---

24 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 recently 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.

25 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

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 *Freedom of Information Act 1982* on the basis of potential damage to the company from which it was obtained.[26] 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.

PRINCIPLE 6: Consultation

Consultation with the provider of commercially confidential 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 to the public information and it is not possible to provide that information without disclosing commercially confidential information, all reasonable efforts should be made to consult the provider of the information prior to its release. In particular circumstances, however, such consultation may be impractical or unwarranted where there is an overriding requirement for timely publication of relevant information.

The adoption of any practice that may involve the release of information (potentially containing commercially confidential information) on a systemic basis should be preceded by consultation with stakeholders.[27]

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) may be contained within 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 individual and is consistent with its obligations as set out in the Information Privacy Principles in section 14 of the *Privacy Act 1988*. Privacy Principle 11 sets out the circumstances in which personal information can be disclosed. The TGA is obliged to consult the relevant person in relation to any proposed release of personal information under the FOI 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.

commercially confidential information may become a matter of public knowledge through later external review or publication.

26 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).

27 The release of information to the public which is potentially commercially sensitive (whether or not it is also commercially confidential) is authorised under section 61 of the Therapeutic Goods Act. Where that is done by means of the making of a legislative instrument under subsection 61(5D). Section 17 of the *Legislative Instruments Act 2003* requires a description of the consultation undertaken in relation to the making of the instrument to be included in the explanatory statement accompanying the instrument.

PRINCIPLE 8: Release to be authorised by or under law

It is important that the release to the public by the TGA of commercially confidential information that by definition has the capacity to cause commercial detriment to a company is authorised by or under the law.[28] This will most typically be because it is released under the FOI Act or under section 61 of the Therapeutic Goods Act.

Summary

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 sponsors etc 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 have to be made at the time that consideration is being given to release of the information.

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

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 is provided by the TGA in response to an ad hoc request by an individual, most usually under the FOI Act[29]

28 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>.

29 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 that contain information about a person's

2. where information is provided by the TGA on a pro-active ad hoc basis for transparency and public health reasons, and

3. where information is provided by the TGA on a pro-active regular basis for transparency and public health reasons.

4. They are dealt with further in Part 7 below .

The TGA's approach to the release of information

The TGA's approach to the release of commercially confidential information is informed by, and referable to, the principles described above.

1. The TGA takes all reasonable steps to ensure that information provided to it by a company is protected (ie is not released to a third party or to the public)[30] as long as it is commercially confidential (as defined in this document) noting that this is subject to:

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

    b. the TGA's obligations under the FOI Act and other relevant Commonwealth legislation, and

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

2. The TGA will 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 would only be released to the extent that it was necessary to do so in the circumstances.

3. In determining what commercially confidential information is, the TGA considers the circumstances in which the information was provided to the TGA and the inherent nature of the information. A request for confidentiality by a company in relation to information provided to the TGA will be regarded as indicative of what is regarded by the company as commercially confidential but:

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

    b. 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:

        i. for instance, information which would satisfy the test of being a trade secret, information about formulations, manufacturing processes, identity of

commercial, business, financial or professional affairs or personal information unless it is "unreasonable" to do so (see subsection 11C(1) of the FOI Act).

30 See for instance the obligations of the TGA as part of a Commonwealth agency under the Protective Security Policy Framework (see footnote 1).

suppliers, manufacturers, financial and sales information etc will, depending on the circumstances, be regarded as confidential but not information that is in the public domain or is otherwise readily ascertainable

ii. information may have the quality of confidentiality at the time it is accepted by the TGA (for instance when it is part of an application for registration of a medicine or the grant of conformity assessment certificate) but may no longer have that 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 Register based on the grant of that certificate).

4. While whether or not particular information is commercially confidential is informed by the circumstance in which it was provided to the TGA and the nature of the information itself, it is determined at the time at which consideration is being given to public release. As noted above, 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.

5. The release by the TGA of information that could be commercially confidential will be appropriately authorised under the relevant legislation, usually either the TG Act or the FOI Act.

6. The TGA complies with the consultation requirements of the FOI Act in relation to requests for commercially confidential information made under that FOI Act. In other circumstances the TGA will consult with the relevant company about the release of information involving that company, its business or any of its products to the extent that it is reasonably able and practicable to do so in the circumstances.

7. Any decision to release information to the public on a regular or systematic basis about any aspect of its regulatory functions that could involve the release of commercially confidential information will be preceded by consultation with affected stakeholders and the release appropriately authorised under legislation.

8. The TGA will review its application forms, guidance documents and material on its website to ensure that the circumstances in which particular kinds of information is accepted from a company on the basis that it is or may be commercially confidential, the circumstances in which it may lawfully be released at any later time and the processes that apply in relation to any such release (eg consultation/authorised by law etc) is clear.

4. Regulatory context

The transparency review

In June 2011 the report of the Panel established by the then Parliamentary Secretary for Health and Ageing, the Hon Catherine King MP, to conduct a review to improve the transparency of the TGA was published. It contained recommendations designed to assist the Government and the TGA adopt more effective practices to ensure the public is better informed about the TGA's regulatory processes, and the benefits and risks of therapeutic goods.

In the Panel's view the TGA was required to:

> ...establish a pro-disclosure culture that will give the public confidence in the performance of its regulatory role. It should communicate openly with stakeholders and should, **where possible**, make the information it holds accessible and usable. TGA should solicit public feedback on a regular basis to identify information of greatest use to stakeholders, improve its communication, and offer stakeholders increased opportunities to participate in policymaking and to provide the benefits of their collective expertise and information.[31] (emphasis added).

A copy of the report of the review containing 21 recommendations is available on the TGA's website.

In its report the Panel mentioned in particular the National Medicines Policy, the Government's Declaration of Open Government and the global nature of the regulation of therapeutic goods as of particular relevance to issues of transparency.

National medicines policy

The central objectives of the National Medicines Policy[32] (NMP) are:

- timely access to the medicines that Australians need, at a cost individuals and the community can afford
- medicines meeting appropriate standards of quality, safety and efficacy
- quality use of medicines, and
- maintaining a responsible and viable medicines industry.

It is regarded as necessary for this purpose that industry policy and health policy be coordinated, providing a consistent and supportive environment for industry, and appropriate returns for the research and development, manufacture, and supply of medicines.

The relevance of the NMP is the argument that disclosure of commercially confidential information in the absence of an overriding public health benefit may discourage future investment and innovation in the therapeutic goods industry. If this were to have an impact on the development of new and innovative products for existing and emerging health issues it could have long term effects on public health.

The Transparency Review Panel took the view that the TGA has a critical role to play in giving effect to the objectives of the Policy and quoted statements in the NMP it believed are relevant to the issue of the transparency of the TGA's activities:

- consumers and health practitioners should have timely access to accurate information and education about medicines and their use
- issues relating to use of medicines should be reported accurately and responsibly by the media

31 See *Review to improve the transparency of the Therapeutic Goods Administration, Final Report*, June 2011, page 11 at <http://www.tga.gov.au/newsroom/review-tga-transparency-1101.htm>.

32 The National Health Policy is a partnership based framework between the Commonwealth and State and Territory government, health educators, health practitioners, and other healthcare providers and suppliers, the medicines industry, healthcare consumers and the media.

- to the extent possible, the NMP partners must recognise the primary position of the consumer
- regulatory agencies should promote quality use of medicines by encouraging use of modern communication principles in provision of Consumer Medicines Information (CMI), label information, etc, and
- governments should do likewise by coordinating and funding efforts to promote quality use of medicines, including public information campaigns.[33]

Open government

On 16 July 2010, the Australian Government made a declaration that it was committed to open government in order to promote greater participation in Australia's democracy. This commitment is based on a culture of engagement, built on better access to, and use of, government held information, and sustained by the innovative use of technology.

The Australian Government's support for openness and transparency in Government has three key principles:

> **Informing:** strengthening citizen's rights of access to information, establishing a pro-disclosure culture across Australian Government agencies, including through online innovation, and making government information more accessible and usable;
>
> **Engaging:** collaborating with citizens on policy and service delivery to enhance the processes of government and improve the outcomes sought; and
>
> **Participating:** making government more consultative and participative.

As an Australian Government regulator, this commitment applies to the actions of TGA, and provides a basis for the adoption of a culture of openness in its decision-making. These principles are also reflected in the 2010 changes that were made to the *Freedom of Information Act 1982*, which came into effect in 2011.[34]

However, it should be noted that it does not provide for any 'open' availability of commercially confidential information. While the 2011 amendments to the FOI Act made some changes to relevant exemptions, there are grounds on which agencies can seek to exempt information release of which would be damaging to a company or business (see further below in Part 6 and **Attachment A**).

Global regulation of therapeutic goods

As noted by the Transparency Review Panel the world-wide trend towards greater openness in governmental decision-making has resulted in overseas regulators against

---

33 See *Review to improve the transparency of the Therapeutic Goods Administration, Final Report*, June 2011, page 10 at <http://www.tga.gov.au/newsroom/review-tga-transparency-1101.htm>.

34 See in particular the objects at sections 3 and 3A of the FOI Act. See also the comments on the Panel which commented that this commitment applies to the actions of TGA, and provides a basis for the adoption of a culture of openness in its decision-making. See *Review to improve the transparency of the Therapeutic Goods Administration, Final Report*, June 2011, page 10 at <http://www.tga.gov.au/newsroom/review-tga-transparency-1101.htm>.

which TGA benchmarks its activities[35] reviewing, or indicating an intention to review, the transparency of their decision-making. Australia could not afford to be left behind in this worldwide approach to the regulation of therapeutic goods.[36]

Trade Related aspects of Intellectual Property rights (TRIPS agreement)

Most of the value to the developers of new medicines, and other high technology medical products, lies in the amount of invention, innovation, research, design and testing involved in their development and production. The protection of intellectual property seeks to encourage inventors and creators of new technologies, because they can expect to earn some future benefits from their creativity. This, in turn, brings about social benefits in the form of new and innovative medical products that can treat existing and emerging medical conditions.

Australia has international obligations under the World Trade Organization (WTO) Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), which attempts to strike a balance between the long term social objective of providing incentives for future inventions and creation and the short term objective of allowing people to use existing inventions and creations.

The TGA is bound by the provisions of section 25A of the *Therapeutic Goods Act 1989* (the TG Act) which implements Australia's obligations under the TRIPS agreement.[37] It describes the circumstances when "protected information" cannot be used when evaluating therapeutic goods for registration under the TG Act.

Australia's obligations to the TRIPS agreement do not provide for an absolute protection of intellectual property. In relation to the evaluation of new medicines, Article 39.3 of the TRIPS agreement provides for certain exceptions to that protection, including the ability to disclose such information where necessary to protect the public.[38]

5. How does the TGA come to hold commercially confidential information?

The TGA holds commercially confidential information as part of the performance of its statutory functions. This will usually be information and data provided to the TGA for the purpose of determining market authorisation or access or in the context of the monitoring of therapeutic goods in the market.

---

35 The United Kingdom Medicines and Healthcare Products Regulatory Agency (MHRA), the European Medicines Agency (EMA), the United States Food and Drug Administration (FDA) and Health Canada.

36 See *Review to improve the transparency of the Therapeutic Goods Administration, Final Report*, June 2011, page 11 at <http://www.tga.gov.au/newsroom/review-tga-transparency-1101.htm>.

37 Therapeutic Goods Legislation Amendment Bill 1997, second reading speech.

38 Article 39.3 says as follows: "Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, **except where necessary to protect the public**, or unless steps are taken to ensure that the data are protected against unfair commercial use." (emphasis added)

The main source of such information will be in the "pre-market" area where companies supply information and data to the TGA as part of an application for:

- the registration of a medicine or therapeutic device, or inclusion of a biological or medical device, in the Australian Register of Therapeutic Goods (the Register) where evaluation of the product is required[39]
- the listing in the Register of "export only" therapeutic goods
- an exemption from regulatory standards that would otherwise apply to therapeutic goods
- the variation of an entry in the Register of a product (for instance where some aspect of a registered medicine is proposed to be varied or modified)
- a licence to manufacture medicines or biologicals in Australia
- a conformity assessment certificate in relation to the manufacture of medical devices
- an export certificate
- approval for a new ingredient for use in listed medicines
- a new proprietary ingredient
- the importation or supply of unauthorised therapeutic goods (for instance under the Special Access Scheme, where approved therapeutic goods are in short supply, for the purposes of clinical trials etc)
- the inclusion of substances in the Standard for the Uniform Scheduling of Drugs and Poisons (the Poisons Standard) and amendments to the Standard.

Such information may also be provided in correspondence and discussions with applicants in the course of consideration of such applications and in the responses to requests from the TGA for information during the evaluation process. The fact of the making of the application itself may also be commercially confidential information.[40]

Commercially confidential information is provided to the TGA as part of its functions of monitoring and compliance in relation to therapeutic goods and their manufacture, for instance:

- by sponsors of therapeutic goods on the Register in response to requests for information from the TGA to determine whether all regulatory requirements were complied with when the goods were included on the Register or whether the goods should remain on the Register
- by the holders of licences or other approvals under the TG Act in response to requests to provide information about therapeutic goods relating to those approvals
- as part of the sponsor's statutory obligations to report to the TGA about adverse events

39 Some low risk therapeutic goods such as listed complementary medicines, Class 1 medical devices and biological and higher level medical devices that are not selected for audit are included in the Register based on certifications made by the sponsor at the time the application is made. Such products can be suspended or cancelled from the Register if it becomes apparent that any of those certifications was incorrect.

40 See discussion in **Attachment A**.

- as part of a sponsor's obligations to comply with conditions of registration eg providing regular Periodic Safety Update Reports, information and data as part of a Risk Management Plan
- by a sponsor or supplier when therapeutic goods are recalled (including information about to whom the goods were supplied or their performance)
- the provision by a company, hospital or other institution of information in relation to therapeutic goods as part of an exemption from a requirement to include those goods in the Register or that the TGA receives in relation to the ongoing application of such an exemption[41]
- from licensed manufacturers or the holders of conformity assessment certificates (or applicants for manufacturing licences or conformity assessment certificates) in the course of inspections or collected from overseas manufacturers in the course of GMP clearance
- by sponsors, suppliers or manufacturers as part of the monitoring by the TGA of therapeutic goods supplied in Australia or provided by sponsors as part of their compliance activities including pharmacovigilance studies etc
- as a result of work done by the TGA on the release of vaccine batches and testing of therapeutic goods
- as a result of inquiries undertaken in relation to breaches of advertising requirements.

Sponsors also provide commercially sensitive financial and business information to support applications for exemption from the payment of annual charges, for "orphan status" for an application for registration (and thus an exemption from application and evaluation fees), to pay a fee by instalments, or for a waiver or reduction in a fee that would otherwise be payable.

Commercially confidential information may also be provided in correspondence on regulatory matters, complaints, confidential submissions made as part of public consultations, applications for review of TGA regulatory decisions, and letters written to the Minister or Parliamentary Secretary.[42]

6. Relevant legislation

Restrictions on disclosure by TGA staff

As members of the Australian Public Service, officers of the Department of Health and Ageing (including staff of the TGA) are subject to rules about the disclosure of information, including commercially confidential information.

While the Therapeutic Goods Act does not make it an offence to disclose information that comes to the knowledge of a person by reason of his or her functions under the

41 For instance, the exemption in item 5 of Schedule 5A of the Therapeutic Goods Regulations for medicines under contract to a hospital or public institution requires the provision of certain information to the TGA on a quarterly basis about the goods and party to the contract.

42 As noted earlier in this document, the TGA receives commercially confidential information as part of procurement processes. The management of that information is governed by the Commonwealth Procurement Rules.

Therapeutic Goods Act, 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[43] which states that an employee must not make improper use of "inside information" in order to gain or seek to gain a benefit of 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.

The Therapeutic Goods Act

The absence of an offence under the *Therapeutic Goods Act 1989* (TG Act) of releasing information that the TGA has obtained as part of its regulatory functions reflects the fact that release of information in appropriate circumstances is part of the functions of a therapeutic goods regulator.

Section 61 of the TG Act sets out the circumstances in which the Secretary or her delegate can release specified kinds of "therapeutic goods information"[44] to:

- the World Health Organisation
- other Commonwealth agencies and of States and Territories that have functions in relation to therapeutic goods or in relation to health or law enforcement
- State and Territory bodies that have responsibility for the registration of medical practitioners and pharmacists
- national regulatory authorities for therapeutic goods, health or law enforcement of other countries
- individuals on application and payment of a fee
- persons or authorities identified in a legislative instrument made by the Minister under subsection 61(5AA), and
- the public.
- The Secretary can release therapeutic goods information to the public under section 61:
  - where it relates to any decision or action taken under the TG Act or the regulations made under the TG Act[45]
  - 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 TG Act[46], and

43 See subsection 13(10) of the *Public Service Act 1999*.

44 This is information about therapeutic goods that is held by the Department of Health and Ageing (of which the TGA is a division) and relates to the performance of the Department's functions (see subsection 61(1) of the Therapeutic Goods Act).

45 See subsection 61(5A) of the Therapeutic Goods Act.

46 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

- 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[47].

As noted above, it is not an offence under the TG 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.[48] 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'.[49] 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 provider of the information.

Thus the Secretary (and her delegates in the TGA) can under section 61 of the TG 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[50]
  - regulatory action taken by the TGA to cancel products from the Register,[51] or
  - information about the evaluation of a prescription medicine and the considerations that led the TGA to approve or not approve an application[52] and the future publication of similar documents in relation to other types of therapeutic goods.[53]

---

the Act – see *Therapeutic Goods Information Specification 2009* at <http://www.comlaw.gov.au/Details/F2009L04131>.

47 See subsection 61(7) of the Therapeutic Goods Act.

48 For instance, the Secretary must publish in the Gazette particulars of cancellations of medical devices and biologicals from the Register and revocations of conformity assessments certificates and manufacturing licences.

49 See section 61A(2) of the Therapeutic Goods Act.

50 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.

51 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>.

52 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>.

53 Such publication is the subject of Recommendation 12 of the Transparency Review (see footnote 72).

The Freedom of Information Act

Under the *Freedom of Information Act 1982* (the FOI Act) any person has a statutory right to seek access to documents[54] held by the Commonwealth, irrespective of the reasons the person gives for seeking access to or the agency's belief as to those reasons.[55] Agencies holding documents, 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 they are "exempt" under one of the provisions of the FOI Act.

Thus a competitor of a sponsor of therapeutic goods that has provided commercially confidential information to the TGA or any patient proposing to sue that company has a right to seek any information that the TGA holds and the TGA is required to deal with such a request in accordance with the provisions of the FOI Act.[56]

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 agency believes that the organisation or undertaking would wish to argue that it makes the document exempt under particular provisions of the FOI Act, the agency **is obliged** to give the organisation or undertaking the opportunity to make submissions and take them into account when considering giving access to the documents.[57]

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 the organisation or undertaking 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 of 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[58] but agencies are not required to consult third parties under section 27 about the application of this exemption. There is a degree of overlap between the "breach of confidence" exemption and the exemptions referred to above, particularly the issue of whether material is in the public domain.[59]

54 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.

55 See section 11 of the FOI Act.

56 The information being sought has to be sufficiently identifiable for the TGA to determine whether or not the relevant document is in its possession.

57 See section 27 of the FOI Act.

58 See section 45 of the FOI Act.

59 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

An agency is not bound by the arguments 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 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,[60] 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.[61] 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.[62] The decision by an agency to publish on its website documents made available to the FOI applicant is not subject to review.[63]

7. Current TGA practices

Current practices

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

1. where information is provided by the TGA in response to an ad hoc request by an individual, most usually under the FOI Act[64]

2. where information is provided by the TGA on a pro-active ad hoc basis for transparency and public health reasons, and

---

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>.

60 There is no obligation under the FOI Act to consult a 3rd party about whether section 45 (confidential information) might apply to might apply to documents coming with the scope of a request but 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).

61 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>.

62 See subsection 11C(1) of the FOI Act.

63 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.

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

3. where information is provided by the TGA on a pro-active regular basis for transparency and public health reasons.

1. Release of information in response to ad hoc requests

The TGA is bound by the procedures set out in the FOI Act as described in Part 6 above 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. The TGA can ensure the lawfulness of the release of commercially confidential information to a third party or to the public if it is processed and released in accordance with the provisions of the FOI Act[65] or under section 61 of the TG Act.[66]

Release under the FOI Act – general approach

Details about how commercially confidential information is dealt with by the TGA when a request is made under the FOI Act is set out at **Attachment A**.

2. Pro-active release of information to the public on an ad hoc basis

The TGA will not release commercially confidential information on a pro-active ad hoc basis except where it is judged to be a necessary in order to inform the public about the quality, safety or effectiveness/performance of therapeutic goods or it is otherwise justifiable in the public interest.

In the great majority of cases, the information released (for instance on the TGA website) about the safety of therapeutic goods may well be commercially sensitive to a sponsor company but it will not necessarily include commercially confidential information provided by the company.

However, to the extent it is necessary to properly inform the public, information provided to the TGA by the company for the purposes of an investigation about the goods or otherwise as part of post-market monitoring by the TGA may be included. In such a case, consistent with Principle 5, the release of the information will be appropriately authorised under the TG Act by a delegate of the Secretary, usually under subsection 61(7).[67]

Any such information would need to be related and relevant to the subject matter ie the therapeutic goods themselves. Thus, information about a company's financial or commercial position or status, sales or marketing information, financial information about its suppliers or distributors or manufacturers would not be released except, in the very unlikely situation that the information was relevant to a safety matter to do with therapeutic goods. In accordance with Principle 6, the TGA would consult the relevant company to the extent that it was practicable to do so.

The TGA does not currently release commercially confidential information on a pro-active ad hoc basis about the making of applications (the fact of the application being made, by

---

65 See sections 90, 91 and 92 of the FOI Act.

66 See discussion in Part 6 above. The Secretary can release information on the application of an individual under subsection 61(6) of the TG Act for the payment of a fee (calculated as if the application were made under the FOI Act). The information that can be sought under this subsection is limited to information about therapeutic goods in the Register as described in regulation 46 of the Therapeutic Goods Regulations 1990 and does not extend to commercially confidential information.

67 Under subsection 61(7) of the TG Act the Secretary can release information to the public the release of which is necessary to ensure the safe use of particular therapeutic goods or relating to the reasons for the withdrawal of therapeutic goods from supply in Australia.

whom and when) or about the ongoing evaluation of applications. The fact that an application has been made will usually only become apparent to the public (as a result of TGA processes[68]) where the outcome of consideration by the TGA results in for instance:

- the inclusion of therapeutic goods in the Register
- a change to the approved product information for a registered medicine
- the publication of an AusPAR in relation to an application for registration of a medicine where the application was rejected or withdrawn (see **Attachment B**)
- the inclusion of a company's name in an entry in the Register (for instance as the holder of a conformity assessment certificate) or on the TGA website as a designated orphan drug
- the inclusion of a company name and information in the list of Australian manufacturers
- a new entry in the list of proprietary ingredients or in a Therapeutic Goods (Listing) Notice[69]
- the inclusion in, or change to, the schedules in the Poisons Standard.[70]

The outcome of other kinds of applications is not explicitly made known to the public by the TGA though it may result in a change to the product information for a medicine or change to a label. The TGA also does not make public the outcome of applications for exemptions or reductions or waivers in fees or charges or applications to pay by instalments etc.

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. Any change to the practice would be preceded by consultation with stakeholders.

3. Pro-active release of information on a systemic basis

The TGA does not normally release commercially confidential information to the public unless there is an overriding public interest reason for doing so. For instance, the ad hoc release of information about the safety of a particular product may involve release of what the sponsor of the product may regard as commercially confidential information.

However, in the interests of transparency about decision making and informing the public about how regulatory decisions about therapeutic goods approved for marketing in

---

68 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. It may be that the company chooses to make information known to the public itself and may have obligations under other regulatory regimes to inform its shareholders or the stock exchange about an application. The fact of the application having been made prior to a decision being made may also become known by reason of the company for instance, making an application for the inclusion of the medicine on the PBS. If asked, the TGA would normally still regard the fact of the application having been made as not for comment by the TGA.

69 By means of a notice under subsection 9A(5) of the Therapeutic Goods Act the Minister can declare new ingredients that can be used in listed medicines.

70 The Standard for the Uniform Scheduling of Drugs and Poisons at <http://www.tga.gov.au/industry/scheduling-poisons-standard.htm#electronic>.

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.

As noted above the only circumstances in which the TGA currently makes available to the public information that may include commercially confidential information is in AusPARs. Information about the publication by the TGA of AusPARs is at **Attachment B**.

Release of information about adverse events and recalls

A number of other recommendations from the Transparency Review as well as various 'Business-to-Business' (B2B) projects underway in anticipation of the formation of the Australia New Zealand Therapeutic Products Agency (ANZTPA), directly relate to the ongoing establishment of a pro-disclosure culture within the TGA.

It should be emphasised that while a number of these involve, or potentially involve, the release of information that may be commercially sensitive to some companies (for instance the making available to the public the database of adverse events reported in relation to medicines and medical devices), it is most unlikely that any involve the publication of commercially confidential information to which the approach as set out in this document applies.

However, consistent with Principle 8, the release of information about recalls of therapeutic goods and about adverse events is authorised under section 61 of the TG Act.[71] Consistently with Principle 7, the databases do not contain personal information. Moreover, in the case of the publicly searchable databases and the early warning system, the detail of the information to be published was subject to consultation with industry and stakeholders and 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 a result of the implementation of Recommendation 20 of the Transparency Review, the Database of Adverse Event Notifications (DAEN) was launched on 1 August 2012. It is a publicly searchable database of adverse events reported about medicines (including vaccines) and (since 19 June 2013) about medical devices, supplied in Australia. This is the "Australia-only" version and can be found on the TGA website.

The Joint Adverse Event Notification System (JAENS) which contains information from adverse event reports that the TGA and Medsafe (New Zealand) have received in relation to medicines, including vaccines used in Australia and New Zealand can about found on the ANZTPA website. From 27 June 2013 it will also contain information about adverse event reports about medical devices.

A publicly searchable database of Australian recall actions (System for Australian Recall Actions (SARA)) on the TGA website contains information about all recall actions undertaken by the TGA for therapeutic goods since 1 July 2012. A publicly searchable database of recall actions occurring in Australia and New Zealand since 1 July 2012 (The Recall Portal) can be now be found on the ANZTPA website.

71 See for instance, the Therapeutic Goods Information (Database of Adverse Event Notifications) Specification 2012; the Therapeutic Goods Information (Joint Adverse Event Notifications System) Specification 2012 and the Therapeutic Goods Information (System for Australian Recall Actions) Specification 2013.

The establishment of a trans-Tasman early warning system for advising the public about potential safety concerns associated with medicines and medical devices is proposed. The Australian portal has been available on TGA's website since 4 June 2013.

The implementation of these recommendations is subject to extensive stakeholder consultation. Information about implementation can be found on TGA's website.

Implementation of recommendation 12 of the Transparency Review is likely to involve publication by the TGA of material similar to an AusPAR in relation to other kinds of therapeutic goods including medical devices.[72] The TGA will consult stakeholders prior to implementation.

What does the TGA tell the public and sponsors about the release of commercially confidential Information?

Applicants and sponsors not infrequently request that information provided (particularly as part of an application) remain confidential. It flows from what is said above that the TGA is not in a position to give any undertakings to companies providing what they regard as commercially confidential information that the information will never be released.

In some cases, the TGA has indicated in the relevant guidance document that certain information provided will be treated as 'commercial-in-confidence' and not released unless in accordance with the TG Act or as otherwise required or permitted by law.[73] More recently, the TGA has informed applicants/sponsors in guidance documents in relation to so-called 'confidentiality statements'[74], it should be understood that the TGA does not accept these as binding and will be treated only as indicative of what was regarded by sponsors as confidential.[75]

The guidelines published on the TGA website for the use of industry and for the information of the public and health care professionals are not necessarily all consistent in the information provided about the TGA's legal obligations in relation to the disclosure of commercially confidential information and the TGA's approach as outlined in this document.

Some TGA forms that are available for use by applicants (for instance for a clinical trials notification and for notification for a new proprietary ingredient) are marked 'commercial-in-confidence'.[76] Because this may suggest that the TGA is able to ensure that any information provided on this form is not released, more information needs to be provided to the applicant about the TGA's legal obligations in relation to such information. These forms are being reviewed for that purpose.

---

72 Recommendation 12 of the Transparency Review is that "The TGA explore mechanisms for providing explanations in its various regulatory processes, and the TGA adopt publication principles on the outcomes of application assessments using as an exemplar the Australian Public Assessment Reports (AusPAR)."

73 See for instance *Guide to the Completion of the 'Notification of a New Proprietary Ingredient' form*.

74 This may be a statement by a company that is included in an application made to the TGA that claims that all or specific parts of the information provided are confidential.

75 See for instance, the draft document *Module 1 Administrative Information and Prescribing Information for Australia, Notice to Applicants CTD-Module 1 January 2011*, Applicable to submissions received by the TGA from 1 March 2011, at pages 92 and 93 at <http://www.tga.gov.au/pdf/pm-ctd-module1-1101.pdf>.

76 This is a designation for classifying information held by Commonwealth Government agencies that was applicable under the Commonwealth's previous information security policy which has now been replaced by the PSPF. Such references in TGA forms will be updated.

As described under Part 3 above, the TGA will being reviewing its application forms, guidance documents and other material on the TGA website to ensure consistency with the approach set out in this document.

8. Overseas regulatory practice

It is apparent that the national regulatory agencies with which the TGA normally is compared (the United Kingdom Medicines and Healthcare Products Regulatory Agency; the European Medicines Agency; the United States Food and Drug Administration; and Health Canada) there are a variety of practices in relation to the release of information about their regulatory activities.

Differences of approach are also reflected in the release of commercially confidential information. The legislation governing the release of information by government agencies differs and is complicated in Europe by the inter-relationship between European and national laws.

While consistency in approach between regulators is important given the global nature of the regulation of therapeutic goods, any injunction that the TGA approach to the release of commercially confidential information "be consistent with overseas regulatory practice may presuppose a level of commonality of approach between regulators that has yet to be achieved.

Even so, there has been general endorsement by heads of agencies about the applicability and relevance of principles only the lines of those referred to in Part 2 above as a basis for a common approach to the issue.

The TGA, through its constant contact with its counterparts, informs itself of practices and developments in this regard and any changes or modifications to the approach as outlined in this document will be considered in light of those practices and developments.

Attachment A

Ad hoc release of information under the FOI Act

Where a request for documents made under the FOI Act covers information about which a company is likely to want to argue that any of the relevant exemptions apply (see discussion in Part 6), the TGA follows all the statutory requirements in consulting that company.

It is only where either:

- the company agrees to 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,

will the TGA release the relevant documents to the FOI applicant.

The TGA will not normally publish documents released to the FOI applicant on the TGA website if the company objects.[77]

Where documents coming within the scope of an FOI request include information or documents provided by a third party[78] and contain what appears to be commercially confidential information, the TGA will always consult that third party under section 27 of the FOI Act where it is proposing to release the documents and will often do so even if it is not proposing to release the documents. 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 affected if the information were released, whether (in the case of section 47G) release would be contrary to the public interest etc.

This third party may also be consulted about documents that contain commercially sensitive information (for instance, information from hospitals/health care professionals about adverse events involving its product). Such documents are not considered as coming within the scope of the TGA's approach to the release of commercially confidential information as the third party did not provide that information to the TGA.

Even though not required to by the FOI Act, the TGA will also:

- ask the views of the third party about the application of the "breach of confidence" exemption in section 45 on the basis that it is in the best position to provide information about the matters that would satisfy the criteria
- consider any views that the third party may have about any personal information contained in the documents, and
- seek the view of the third party about publication on the disclosure of any documents provided to the FOI applicant (for instance, the party may not object to release to the FOI applicant but may object to publication to the public).

77 See subsection 11C(1) of the FOI Act.

78 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 sections 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 under that subsection 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.[79] 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 affect 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 a recent cases 'Q' and the Department of Health and Ageing [2013] AICmr 29 (22 March 2013)[80] 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[81] 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.[82]

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.

---

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

80 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.

81 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".

82 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" 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.

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.

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 following:

- whether the information could constitute a trade secret (section 47(1)(a)),
- whether release of the information would diminish its commercial value (section 47(1)(b)) or
- whether release of the information could unreasonably adversely affect the third party in its business, commercial or financial affairs).

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 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. The TGA is barred under subsection 27(7) of the FOI Act from releasing information the subject of an objection by a 3rd party unless and until any time to seek of the decision to release has run out or the decision has been confirmed or otherwise still stands.

Attachment B

Pro-active release of information – AusPARs

The introduction of the AusPAR in late 2009 followed extensive industry consultation over a number of years and is consistent with similar transparency measures introduced by the European Medicines Agency[83] and the practice of the US Food and Drug Administration (FDA), which publishes extensive information about its evaluation of prescription medicines.

The AusPAR provides information about the evaluation of a prescription medicine and the considerations that led the TGA to approve or not approve an application for registration of a prescription medicine. They are currently published in relation to applications for new chemical entities, major variations, and extensions of indications and for some generics.

The intention has always been to publish AusPARs in relation to all applications for generic medicines and this is expected to happen in the future.

An AusPAR is prepared for rejected applications as well as successful, and also for applications that are withdrawn beyond a certain point in the evaluation process.[84] Where the application is approved, the TGA aims to publish the AusPAR within 4 weeks of the inclusion of the medicine on the Australian Register of Therapeutic Goods. Where an application is rejected it won't be published pending expiration of the 90-day internal review period or the outcome that review. AusPARs are published on the TGA website.[85]

The content of an AusPAR typically includes detailed information about the product and the views of the delegate (and where relevant the TGA's expert advisory committee) on quality, non-clinical, clinical and pharmacovigilance, and the overall conclusion and risk/benefit assessment. It contains material from the submission dossier but the great majority of the information is not commercially confidential. Any confidentiality about the fact of an application having been made can only be relevant to those applications that were rejected or withdrawn.[86]

The TGA provides the sponsor with an opportunity to review the content of an AusPAR (allowing 14 calendar days) with the purpose of ensuring the document does not contain commercially confidential information, or where it may do, whether its publication is justified. In the event of a disagreement about the proposed inclusion of content, an internal review process is applied by the TGA. The sponsor is able to provide a justification for the removal of the content in writing to the TGA, which will be referred for advice (as needed) prior to making a decision about its exclusion.

83 The European Public Assessment Report (EPAR).

84 If the application is withdrawn after acceptance but prior to the sponsor being sent the delegate's overview, the policy is to publish notification of the withdrawal in lieu of an AusPAR.

85 The AusPAR includes the assessment summaries for each evaluation stream (module 3 – quality, module 4 – safety and module 5 – efficacy), pharmacovigilance requirements, the conclusion/risk benefits which are based on the delegate's overview and refer to the views (where relevant) of the expert advisory committee.

86 The AusPAR is only published after details about a successful application are included in the Register and thus published on the TGA website.

The guidance document for AusPARs[87] makes it clear that the TGA recognises the potential impact that disclosure of significant commercially confidential information may have. The fundamental rule is described as follows:

> Openness and transparency of the regulatory process is important in the promotion of public health. However, unless there is an overriding public interest in disclosure, **the TGA will refrain from disclosing commercially confidential information when it might hurt the interest or prejudice to an unreasonable degree the commercial interests, of individuals or companies concerned.** (emphasis added)[88]

Guidance is provided on the classification of commercially confidential information in the appendix to the document and guiding principles and procedural direction to assist the TGA and a sponsor to identify what information could be identified for consideration for removal by the TGA from a draft AusPAR.[89] Information already in the public domain is not considered as commercially confidential. The appendix of the guidance documents (which was based on the EMA approach, now under reconsideration) then sets out the kinds of information the TGA would regard as 'commercial in confidence'.[90]

In line with Principle 8, publication of information in all AusPARs is authorised by a delegate of the Secretary under subsection 61(5C) of the TG Act as contemplated in the legislative instrument made by a delegate of the Minister under subsection 61(5D) of the TG Act as set out in the *Therapeutic Goods Specification 2009*.[91]

Since the start of the publication of AusPARs by the TGA in December 2009 there have only been a handful of occasions on which a sponsor has objected to release of what it regarded as commercially confidential information and in each case the issue has been resolved.

Consideration is being given to publication by the TGA of material similar to an AusPAR in relation to other kinds of therapeutic goods including medical devices.[92] The TGA will consult stakeholders prior to implementation of any such proposal.

87 See *Australian Public Assessment Report (AusPAR) for prescription medicines: guidance document* Version 1.2 at <http://www.tga.gov.au/industry/pm-auspar-guidance.htm>.

88 See Australian Public Assessment Report (AusPAR) for prescription medicines: guidance document Version 1.2, Appendix 1 (Principles to be Applied for the Deletion of Commercially Confidential Information), page 11, at <http://www.tga.gov.au/industry/pm-auspar-guidance.htm>.

89 See Appendix 1 (Principles to be Applied for the Deletion of Commercially Confidential Information) of Australian Public Assessment Report (AusPAR) for prescription medicines: guidance document Version 1.2 at <http://www.tga.gov.au/industry/pm-auspar-guidance.htm>.

90 It should be noted that the designation 'commercial in confidence' has now been replaced under the Commonwealth Protective Security Policy Framework.

91 At <http://www.comlaw.gov.au/Details/F2009L04131>.

92 See recommendation 12 of the Transparency Review referred to at footnote 72.

Therapeutic Goods Administration

PO Box 100 Woden ACT 2606 Australia
Email: info@tga.gov.au Phone: 1800 020 653 Fax: 02 6232 8605
http://www.tga.gov.au