Australian Government
Office of the Australian Information Commissioner

'Q' and Department of Health and Ageing [2013] AICmr 29 (22 March 2013)

Decision and reasons for decision of
Acting Freedom of Information Commissioner, Toni Pirani

Applicant:	**'Q'**
Respondent:	**Department of Health and Ageing**
Other parties:	**Anonymous**
Decision date:	**22 March 2013**
Application number:	**MR11/00316**
Catchwords:	**Freedom of Information — Public interest conditional exemption — Business — Whether documents conditionally exempt from release — (CTH) *Freedom of Information Act 1982* ss 11A(5), 47G**

Contents

Summary

1. I affirm the decision of the Department of Health and Ageing (the **Department**) of 2 September 2011 to grant access to documents requested under the *Freedom of Information Act 1982* (the **FOI Act**).

Background

2. The Therapeutic Goods Administration (the **TGA**), a division of the Department, is responsible for regulating therapeutic goods, such as medical devices, in Australia. Before a medical device can lawfully be supplied in Australia it must be included on the Australian Register of Therapeutic Goods (the **Register**). The TGA is responsible for assessing therapeutic goods for inclusion on the Register, as well as the post-market monitoring and enforcement of standards for these goods.

3. On 11 April 2011, a person (the **FOI applicant**) applied to the Department for access to documents relating to a medical device sponsored by the applicant for IC review (the **applicant**, 'Q').

4. On 11 May 2011, the Department wrote to the applicant to advise it had received an FOI request. The Department said it had identified 10 documents falling within the scope of the request and offered the applicant the opportunity to make submissions that the documents were exempt documents under ss 45, 47 or 47G of the FOI Act.

5. On 24 May 2011, the applicant said it did not object to release of nine of the 10 documents. However it made submissions that one document was exempt under ss 45 and 47G.

6. On 9 June 2011, the Department wrote to the applicant to advise that it had located two further documents falling within the scope of the request filed on 11 April 2011, and invited the applicant to make submissions that these documents were exempt documents under ss 45, 47 or 47G.

7. On 17 June 2011, the applicant wrote to the Department advising that it objected to release of both of the additional documents and made submissions that they were exempt under ss 45 and 47G.

8. On 28 June 2011, the Department decided to release the three documents that the applicant had objected to being released. The Department decided that some of the information in these documents was exempt under ss 45 and 47F and should be edited before the documents were released. In addition, material not relevant to the request was to be edited before release.

9. By letter dated 4 August 2011, the applicant sought internal review of the Department's decision of 28 June 2011. The applicant accepted that one document had been sufficiently edited to remove exempt material, but objected to release of the other two documents.

10. On 2 September 2011, the Department varied its decision by exempting one of the two remaining documents in full.[1]

[1] The FOI applicant has not sought review of this decision.

11. By letter dated 6 October 2011, the applicant sought IC review of this decision under s 54M of the FOI Act.

Decision under review

12. The decision under review is the decision of the Department on 2 September 2011 to grant access to a document sought by the FOI applicant.

The scope of IC review of access grant decisions

13. Section 54M of the FOI Act permits applications to be made to the Information Commissioner for review of access grant decisions. The term 'access grant decision' is defined in s 53B of the FOI Act. A decision to give access to a document after consultation under s 27 is an access grant decision under s 53B. Section 27 provides for consultation in relation to business documents. The Department consulted the applicant under s 27 of the FOI Act before making a decision to grant access to the document subject to this IC review.

14. As was noted by the FOI Commissioner in the decision of *'E' and National Offshore Petroleum Safety and Environmental Management Authority* [2012] AICmr 3, the consultation provision in s 27 gives the applicant an opportunity to contend only that specified exemptions should apply and that access would be contrary to the public interest.

15. In this IC review, I must consider the applicant's submissions only in relation to the application of s 47G. Although the Department invited the applicant to make submissions in relation to s 45,[2] this is not one of the exemptions referred to in section 27 of the FOI Act and accordingly not an issue on which the applicant can validly make an 'exemption contention'.[3] I also cannot consider whether the Department correctly applied s 47F[4] or correctly edited irrelevant material under s 22 of the FOI Act from the document before release.

The business exemption (s 47G)

16. The document under review is a letter from the TGA to the applicant.

17. Section 47G(1) of the FOI Act provides:

> **Public interest conditional exemptions—business**
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> (1) A document is conditionally exempt if its disclosure under this Act would disclose information concerning a person in respect of his or her business or professional affairs or concerning the business, commercial or financial affairs of an organisation or undertaking, in a case in which the disclosure of the information:

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2 This exemption covers documents containing material obtained in confidence.

3 Section 27(1)(b) of the FOI Act.

4 This exemption covers personal privacy.

(a) would, or could reasonably be expected to, unreasonably affect that person adversely in respect of his or her lawful business or professional affairs or that organisation or undertaking in respect of its lawful business, commercial or financial affairs; or

(b) could reasonably be expected to prejudice the future supply of information to the Commonwealth, Norfolk Island or an agency for the purpose of the administration of a law of the Commonwealth or of a Territory or the administration of matters administered by an agency.

Would or could unreasonably adversely affect

18. The Australian Information Commissioner has issued Guidelines under s 93A of the FOI Act to which regard must be had for the purpose of performing a function, or exercising a power, under the FOI Act.[5] The Guidelines state:

> 6.164 The presence of 'unreasonably' in s 47G(1) implies a need to balance public and private interests, but this does not amount to the public interest test of s 11A(5) which follows later in the decision process …
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> 6.165 The test of reasonableness applies not the claim of harm but to the objective assessment of the expected adverse effect. For example, the disclosure of information that a business's activities pose a threat to public safety may have a substantial adverse effect on that business but it may be reasonably in the circumstances to disclose it. Similarly, it would not be unreasonable to disclose information about a business that revealed unlawful conduct.[6] These considerations necessitate a weighing of public interest (public safety) against a private interest (preserving the profitability of a business) but at this stage it bears only on the threshold question of whether the disclosure would be unreasonable.
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> …
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> 6.167 When disclosure would result in the release of facts already in the public domain, that disclosure would not amount to an unreasonable adverse effect on business affairs.[7]

19. The Department did not consider that disclosure of the document would have an unreasonable adverse effect on the applicant's business because the information in the document is already in the public domain. In particular, the Department states that the first five paragraphs of the letter summarise parts of the contents of a publically available report, as well as setting out the TGA's regulatory functions and powers.

20. The applicant submits that the letter itself is not in the public domain and while the information in it is similar to information in the public domain, it is not the same as the information publicly available.

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5 Office of the Australian Information Commissioner, *Guidelines issued by the Australian Information Commissioner under s 93A of the Freedom of Information Act 1982*.

6 *Searle Australia Pty Ltd v Public Interest Advocacy Centre and Department of Community Services and Health* (1992) 108 ALR 163.

7 *Re Daws and Department of Agriculture, Fisheries and Forestry* [2008] AATA 1075.

21. I have viewed both the document under review and the publically available material. Much of the information in the letter is in the public domain. The letter summarises information about the medical device from a publically available report, provides general information about adverse events, as well as information about the TGA and its processes.

22. To the extent that the information in the report is in the public domain, I do not consider disclosure would, or could reasonably be expected to, have an unreasonable adverse effect on the applicant's business affairs. As a result, I do not consider this information is conditionally exempt under s 47G(1)(a).

23. The only parts of the document not already in the public domain are six specific requests for information asked of the applicant by the TGA, the date of the letter, and the name of the addressee of the letter.[8]

24. The applicant submitted that the document was created during confidential consultation with the TGA and that it records that consultation process. The applicant says that details of the consultation, as well as the information imparted, has not entered the public domain. The applicant argues the nature of the information is shaped by the context in which it was imparted and recorded, and this context includes the time and date the information was sent and the people involved in sending and receiving the information.

25. The Department says it is well known that as part of the TGA's regulatory functions it makes enquiries of sponsors of medical devices. The TGA would have made the same inquiries of any sponsor whose medical device was adversely mentioned in a publically available report. Furthermore, because problems with the medical device have already been made public, the applicant cannot demonstrate any harm to its business if the TGA's requests for information about those problems are disclosed.

26. Section 55D(2) of the FOI Act provides that, in an application for IC review of an access grant decision, the applicant for IC review has the onus of establishing that I should make a decision adverse to the person who made the request.

27. To decide that the documents are exempt under s 47G(1)(a), I must be satisfied that disclosure would, or could reasonably be expected to, unreasonably affect the applicant in the conduct of its business affairs.

28. The applicant did not identify any specific adverse effect that would result from disclosure of these details and I have been unable to identify anything that could reasonably be said to flow from disclosure of the first five of the TGA's six requests for information put to the applicant.

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[8] The applicant argues that the person to whom the letter is addressed is not well known, however the TGA decided to edit the document to remove the addressee's name and position. This decision falls outside the scope of IC review.

29. The sixth request comprises a statement followed by a question. The statement is a factual one based on the information in the publicly available report. For the same reasons that I have given above in relation to the first five requests, this statement is not exempt.

30. The question that follows this statement does, in my view, reveal information that would only be known by the TGA and the applicant. The question arises because of the regulatory relationship between the TGA and the applicant. I consider that disclosure of this question could reasonably be expected to adversely affect the applicant with respect to its lawful business affairs.

31. However, I do not consider that release of the first five of the TGA's requests for information, or the date of the letter, would, or could reasonably be expected to, adversely affect the applicant in the conduct of its business. The TGA's requests for information follow naturally from the information about the medical device, which has already been detailed in a publically available report.

32. I consider that the question contained in the sixth of the TGA's requests for information is conditionally exempt under s 47G(1)(a) of the FOI Act.

33. I do not consider that the rest of this document is conditionally exempt under s 47G(1)(a) of the FOI Act.

Could prejudice the future supply of information

34. Section 47G(1)(b) will apply if disclosure of the information in the documents:

> could reasonably be expected to prejudice the future supply of information to … an agency for the purpose of the administration of a law of the Commonwealth … or the administration of matters administered by an agency.

35. The Guidelines state:

> 6.174 This limb of the conditional exemption comprises two parts:
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> - a reasonable expectation of a reduction in the quantity or quality of business affairs information to the government
> - the reduction will prejudice the operations of the agency.[9]
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> …
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> 6.176 Unlike the other limb of this conditional exemption, s 47G(1)(b) does not require that the prejudice to the future supply of business information be unreasonable. The unreasonableness of the prejudice may be considered in applying the public interest test under s 11B(5).

36. The applicant claims that disclosure of the document will prejudice the future supply of information to the TGA because it voluntarily provided information during the consultation process thinking it would be kept confidential. It says it expected the Department to also keep its correspondence with the applicant

[9] *Re Angel and the Department of the Arts, Heritage and the Environment* [1985] AATA 314.

confidential. If this information is released, the applicant says it will affect the future supply of voluntary information from organisations in a similar position.

37. Deputy President McMahon of the AAT said in *Telstra Australia Limited and Australian Competition and Consumer Commission*:

> Paragraph 43(1)(c)(ii)[10] looks directly to the future supply of information from any source and postulates an expectation of prejudice in the supply of that information if the release of information from source A may create a perception in the mind of source B that its information will also be released.[11]

38. While the applicant has said it will be less forthcoming in the future if the information in the documents is released, the test is whether release of the information would lead to a reduction in the quantity and quality of information given to the TGA by sponsors of medical devices on the Register and therefore prejudice the TGA's ability to perform its statutory or administrative functions.

39. I consider it is in the interests of organisations in the same position as the applicant to cooperate with the TGA: to minimise potential damage to their businesses by maintaining public confidence in their products. Sponsors can protect their commercial reputation by voluntarily providing information and working with the TGA when problems are identified.

40. Furthermore, ss 41MP(1) and 41MPA(1) of the *Therapeutic Goods Act 1989* impose an obligation on sponsors of products on the Register to report the occurrence of adverse events listed in ss 41MP(2) and 41MPA(2) to the TGA. The TGA also has formal powers under the Therapeutic Goods Act to require sponsors of medical devices on the Register to provide information in certain circumstances.

41. In such circumstances, I do not consider that release of the documents sought by the FOI applicant could reasonably be expected to prejudice the future supply of information to the TGA in relation to medical devices on the Register.

42. The document is not conditionally exempt under s 47G(1)(b) of the FOI Act.

The public interest test (s 11A(5))

43. I have found that the question in the sixth of the TGA's requests for information from the applicant in the document subject to this IC review is conditionally exempt under s 47G(1)(a) of the FOI Act. Section 11A(5) provides that, if a document is conditionally exempt, it must be disclosed 'unless (in the circumstances) access to the document at that time would, on balance, be contrary to the public interest'.

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10 Section 43(1)(c)(ii) of the FOI Act was repealed and substituted by the *Freedom of Information Amendment (Reform) Act 2010*, with effect from 1 November 2010. Section 43(1)(c)(ii) was in substantially the same terms as s 47G(1)(b).

11 [2000] AATA 71 (7 February 2000), [24].

44. As the Guidelines explain,

> [t]he pro-disclosure principle declared in the objects of the FOI Act is given specific effect in the public interest test, as the test is weighted towards disclosure.[12]

45. Of the factors favouring disclosure set out in s 11B(3), two are relevant to this IC review: promoting the objects of the Act and informing debate on a matter of public importance.

46. Against these factors must be balanced the factors against disclosure. The FOI Act does not specify any factors against disclosure, but the Guidelines include a non-exhaustive list of such factors.[13] The applicant made no submissions as to why release of the document would be contrary to the public interest. Of those factors listed in the Guidelines, the ones with potential relevance to this IC review are:

- could reasonably be expected to prejudice an agency's ability to obtain confidential information
- could reasonably be expected to prejudice an agency's ability to obtain similar information in the future
- could reasonably be expected to prejudice the competitive commercial activities of an agency.

47. As discussed above, I do not agree with the applicant's submissions that disclosure of the information sought would prejudice the future supply of similar information to the TGA.

48. Release of the conditionally exempt material in the TGA's letter to the applicant could reasonably be expected to prejudice its competitive commercial activities. As mentioned above, the material reveals information that would only be known by TGA and the applicant and arises because of the regulatory relationship between the TGA and the applicant.

49. In deciding whether disclosure of the document would be contrary to the public interest I am required to balance the public interest in making information available to the public about a matter of public importance, that is, public health as well as how the TGA deals with the sponsors of medical devices when problems are reported with the medical device, with the private interests of the applicant in preserving its competitive commercial activities, professional reputation and profitability.

50. On balance, I consider the factors favouring access outweigh those that do not. The applicant has not discharged the onus on it to establish that access to the document should be refused.

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12 *Guidelines* [6.12].

13 *Guidelines* [6.29].

51. Giving the applicant access to the document would not, on balance, be contrary to the public interest.

Findings

52. The document subject to this IC review is not conditionally exempt under s 47G of the FOI Act.

Decision

53. Under s 55K of the FOI Act, I affirm the Department's decision of 2 September 2011.

Toni Pirani
Acting Freedom of Information Commissioner

22 March 2013

Review rights

If a party to an IC review is unsatisfied with an IC review decision, they may apply under s 57A of the FOI Act to have the decision reviewed by the Administrative Appeals Tribunal. The AAT provides independent merits review of administrative decisions and has power to set aside, vary, or affirm an IC review decision.

An application to the AAT must be made within 28 days of the day on which the applicant is given the IC review decision (s 29(2) of the *Administrative Appeals Tribunal Act 1975*). An application fee may be payable when lodging an application for review to the AAT. The current application fee is $816, which may be reduced or may not apply in certain circumstances. Further information is available on the AAT's website (www.aat.gov.au) or by telephoning 1300 366 700.