Freedom of Information Act 2000 (Section 50)

Decision Notice

Date: 27 September 2007

Public Authority: National Institute for Health and Clinical Excellence ("NICE")
Address: MidCity Place
71 High Holborn
London
WC1V 6NA

Summary

The complainant requested an executable version of the economic model used by NICE in its assessment of Donepezil, Rivastigmine, Galantamine and Memantine, drugs that are used to treat Alzheimer's Disease. NICE refused to provide the information citing the exemptions in sections 36 and 41 of the Act. The Commissioner has decided that NICE appropriately relied upon section 41 when refusing to supply the information. He has also found that NICE breached section 10 of the Act in initially failing to respond to the request within twenty working days. The Commissioner has not ordered any remedial steps.

The Commissioner's Role

1. The Commissioner's duty is to decide whether a request for information made to a public authority has been dealt with in accordance with the requirements of Part I of the Freedom of Information Act 2000 ('the Act').This Notice sets out his decision.

Background

2. NICE is a Special Health Authority created under Section 11 of the National Health Services Act 1977 and a public authority listed in Part III of schedule 1 of the Act. One of NICE's functions is to carry out appraisals of the cost and clinical effectiveness of health technology. Health technology includes drugs, medical equipment and medical techniques. The appraisals ultimately result in guidance issued by NICE to the NHS recommending whether, or in what circumstances, particular technologies should be made available to patients on the NHS. The information requested by the complainant was used by one of NICE's Appraisal Committees ('ACs') when carrying out an assessment of Donepezil, Rivastigmine, Galantamine and Memantine, drugs that are used to treat Alzheimer's Disease.

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The Appraisal Process

3. Appraisals are carried out by NICE's Appraisal Committees which are made up of members appointed for a 3 year term and drawn from the NHS, patient/carer organisations, relevant academic disciplines and the pharmaceutical and medical devices industries.

4. Once a drug or other technology has been identified and formally referred to NICE for appraisal, an Assessment Group ('AG') is formally commissioned to prepare an Assessment Report ('AR'). The AG is an independent academic group that prepares an AR setting out its review of the clinical and cost effectiveness of the technology. In this case the AG is the Southampton Health Technology Assessment Centre ('SHTAC'). The review is based on a systematic review of the literature and manufacturer and sponsor submissions to NICE.

5. In some cases, including this one, the AG may produce an economic model in support of the AR. The economic model pertinent to this case is a series of Excel spreadsheets. A read-only version of the model ('RO model') is provided to consultees and commentators on request, subject to strict conditions limiting its use. Consultees are organisations that accept an invitation to participate in an appraisal. They include but are not limited to, the manufacturers or sponsors of the technology under review, national professional organisations and national patient organisations. Consultees are involved in the consultation on the draft scope of the appraisal, the AR and the development of the Appraisal Consultation Document ('ACD'). Commentators are organisations that engage in the appraisal process but are not asked to prepare a submission dossier. They have no right of appeal against the final determination that NICE makes at the end of an appraisal. Commentators include manufacturers of comparator technologies, related research groups such as the Medical Research Council and bodies such as the NHS Information Authority. In this case NICE also holds a working version of the economic model ('the executable model') but this is not disclosed to consultees, commentators or the public.

6. During the appraisal process the AC meets to develop the ACD which sets out its provisional views. To prepare for this, the AC is supplied with an Evaluation Report which comprises numerous pieces of information including, the full AR, comments made by consultees and commentators on the AR, an overview by NICE's Technical Lead for the appraisal and full submissions from professional, patient/carer and NHS organisation consultees amongst other material.

7. The ACD together with the Evaluation Report (with confidential material removed) is circulated to consultees and commentators and eventually to the public for comment. Once comments are received the AC meets again to reconsider the ACD in light of the feedback. It then completes its Final Appraisal Determination ('FAD'). This is circulated to the consultees so that they can determine whether or not to appeal. Subject to any appeal by the consultees, the FAD will form NICE guidance on the use of the appraised technology.

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8. Consultees are afforded a right of appeal which must be lodged within 15 working days from receipt of the FAD. It is not possible to appeal against a FAD merely because the appellant disagrees with it. The Appeal Panel will only consider appeals on one of the following grounds:

- NICE failed to act fairly and in accordance with its published procedures.
- The FAD is perverse in the light of the evidence submitted.
- NICE has exceeded its powers.

9. If there is no appeal, an appeal is dismissed or an appeal is upheld but the FAD does not need to be referred back to the AC, NICE makes arrangements for the guidance to be published. Further information about the appraisal process can be found in the "Guide to the Technology Appraisal Process" ('the Guide') which can be viewed on NICE's website at the following address, http://www.nice.org.uk/download.aspx?o=201971.

The Request

10. On the 28 February 2005, the complainant requested the following information under the Act:

" a copy of the NICE economic model that has been produced in support of the draft Appraisal Consultation Document (ACD). We would be grateful for a working version of the economic model rather than the read-only copy of the model".

11. NICE responded to the request by issuing a refusal notice dated 12 April 2005. In the refusal notice it explained that the executable model constituted the same recorded information as the RO model which was already in the complainant's possession in its capacity as a consultee to the appraisal process. NICE explained that it had considered its obligations under section 11 of the Act and had determined that it would not be reasonably practicable to provide the requested information in the format requested i.e. a working copy. In addition, it claimed that the executable model was exempt from disclosure by virtue of sections 41 and 36(2)(b) of the Act.

12. On 28 April 2005 the complainant provided submissions in response to NICE's refusal notice and sought an internal review of the original decision to refuse access.

13. On 13 May 2005, NICE advised the complainant that a response would be issued by 27 May 2005. It also informed the complainant of its 3 tier complaints procedure and explained that each tier would take up to 20 working days.

14. The complainant wrote to NICE on 18 May 2005 to express dissatisfaction at what it considered to be an unnecessarily bureaucratic complaints procedure. The complainant requested that the review be escalated to the 3rd tier so that a response could be provided within 20 working days.

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15. On 31 May 2005, NICE wrote to the complainant to confirm that it would expedite the complaint to the 3rd tier of the process. Accordingly it also confirmed that its 3rd tier complaints review panel was due to meet on 15 June 2005 to consider the matter and that the outcome would be communicated to the complainant by the end of June.

16. The outcome of the internal review was supplied to the complainant on 29 June 2005. The appeal panel upheld NICE's initial refusal on the basis that the requested information was exempt under section 41. Given that it concluded that the absolute exemption in section 41 was correctly applied it did not consider it necessary to go on to review the reliance upon section 36.

The Investigation

Scope of the case

17. On 6 July 2005 the complainant contacted the Commissioner to complain about the way the request for information had been handled. The complainant asked the Commissioner to consider whether NICE had appropriately refused to supply the requested information in accordance with the Act.

18. It is relevant at this stage to explain that NICE has asserted that the RO and executable models contain identical information. It has argued that both models show the formulae and data used in the analysis by the AG. The difference between the two models is that the RO model is locked and therefore the inputs and assumptions contained within it cannot be altered and the model re-run to produce new outputs. This is however possible if one has access to the executable model.

19. Section 1(1) of the Act provides a right of access to information held by a public authority. The term 'information' is defined in section 84 of the Act as, "information recorded in any form'. The Commissioner has had the opportunity to review both the RO and the executable models relevant to this case. He has concluded that NICE's assertion that, for the purposes of the Act, there is no additional 'recorded information' within the executable model is correct. He is satisfied that the difference between the two models is one of form and format rather than content.

20. However, taking this into account, the Commissioner is also mindful of section 11 of the Act. This states that,

> "(1) Where, on making his request for information, the applicant expresses a preference for communication by any one or more of the following means, namely –
>
> (a) the provision to the applicant of a copy of the information in permanent form or in another form acceptable to the applicant,
>
> (b) the provision to the applicant of a reasonable opportunity to inspect a record containing the information, and

(c) the provision to the applicant of a digest or summary of the information in permanent form or in another form acceptable to the applicant,

the public authority shall so far as reasonably practicable give effect to that preference".

21. NICE initially cited section 11 when refusing the complainant's request although it was not mentioned in the outcome of the internal review. NICE has also subsequently confirmed that it no longer seeks to rely upon section 11 in this case. However, it originally claimed that it would not be 'reasonably practicable' to supply the executable model to the complainant on the basis that (amongst other arguments) the intellectual property rights of the authors of the model would be infringed by releasing that version.

22. Although NICE no longer wishes to rely upon section 11 and therefore the Commissioner has not considered its application as part of the scope of his investigation, the Commissioner does wish to clarify that when considering whether or not it is 'reasonably practicable' to comply with an applicant's wishes, it is not appropriate for public authorities to take into account factors such as intellectual property rights of the authors. Any prejudice to such interests is more properly provided for within the exemptions in Part II of the Act. A non-exhaustive list of the factors which the Commissioner considers may be taken into account when considering section 11 is outlined in his Awareness Guidance 29. These include the following:

- the ease with which it is possible to meet the preference, for example how easily a copy could be made;
- whether or not the public authority has the means to comply with the request, i.e. if information is held in visual or audio format does it have the technical equipment to make copies;
- the cost of complying with the preference;
- the form that the original information is held in, for example is the information in an old or fragile document.
- where a request is made to inspect documents there may be security implications which mean that material can only be supplied in a different form.

23. In this case the Commissioner is aware that NICE holds both versions of the model in electronic form and that this can be communicated via email with ease. Therefore he considers that NICE could, in principal, have complied with the complainant's preference for a copy of the executable model. However, notwithstanding the Commissioner's view in this regard, he must go on to consider whether it is appropriate for the executable model to be released under the Act.

24. The Act is applicant and purpose blind, in other words, when public authorities receive requests for information under the Act they must consider whether it is appropriate to release the material sought to the general public. They are not

permitted to enquire why the information is required and can only consider the identity of the applicant in very limited circumstances, for example when determining if a request is vexatious (section 14), whether the material sought is in fact personal data of the applicant (section 40(1)) or when reaching a view about whether the information is reasonably accessible to the applicant via other means (section 21).

25. When communicating the outcome of its internal review to the complainant, NICE confirmed that the review panel had considered release to the general public when considering whether or not the exemptions had been appropriately cited. Therefore it disregarded the fact that the complainant was already in possession of the RO model in its capacity as a consultee when reaching its decision.

26. The Commissioner is required to undertake the same test when determining whether or not a public authority has appropriately refused a request for information. He has therefore considered whether NICE appropriately determined that the executable model requested by the complainant was exempt from disclosure to the general public by virtue of the exemptions cited.

27. The Commissioner is also aware that a limited amount of information within the executable model has been reproduced in the AR which is available on NICE's website. Specifically the economic model includes a number of graphs and a flowchart that have been reproduced in the AR. As this information is readily available the Commissioner has not given further consideration to this material. His investigation has focussed on the outstanding information within the scope of the request which has not been published in the AR.

Chronology

28. The Commissioner has set out the key correspondence between his office, the complainant and NICE below.

29. The complainant provided detailed submissions to the Commissioner in the initial letter of complaint dated 6 July 2005. The material provided included 3 independent 'expert opinions' obtained by the complainant which supported the assertion that in order to be able to fully understand the economic model and to provide informed feedback it was necessary to have access to the executable model.

30. Regrettably the complaint was not allocated to a case officer for investigation until 14 March 2006. Upon allocation the case officer wrote to the complainant and requested clarification on a number of points raised in the initial complaint. He also asked for copies of additional relevant correspondence to be provided.

31. The complainant replied on 17 March 2006 providing the clarification and additional documentation requested.

32. The case officer wrote an initial letter to NICE on 25 April 2006. This letter requested further information about the way in which the FOI request was handled. NICE was also asked to provide the case officer with a copy of the exempt information. The letter also provided some preliminary observations about the arguments cited by NICE to support its application of exemptions in response to the request.

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33. NICE reverted to the case officer with a comprehensive reply on 25 May 2006. In its response it provided further justification to support the application of the exemptions in both sections 41 and 36. It also provided various publications to assist the case officer in gaining a detailed understanding of its procedures and processes in relation to the appraisal of health technology.

34. On 7 November 2006 the case officer contacted NICE and requested some additional information about its reliance upon section 36 and in particular the qualified person statement.

35. NICE provided a response on 13 November 2006 which included further detail regarding section 36 and a copy of additional correspondence as requested.

36. On 12 January 2007 the complainant wrote to the case officer to make him aware of some additional evidence which was considered to be relevant to the case. The case officer replied to the complainant on the same day confirming that he would seek NICE's comments on the evidence.

37. On 16 January 2007 the case officer wrote to NICE asking it to comment on the additional evidence provided by the complainant.

38. On 17 January 2007 the case officer asked the complainant to clarify several points about the additional evidence recently submitted.

39. NICE provided a substantive response to the case officer on 30 January 2007. This included detailed comments about the additional evidence submitted by the complainant.

40. The case officer sought further information from NICE about the economic model in a letter dated 1 February 2007. On 2 February he also requested further information from the complainant about the public interest.

41. Responses were provided by NICE and the complainant on 27 February 2007 and 1 March 2007 respectively. Finally the case officer sought further clarification on a number of points from NICE on 15 June 2007 and a reply was provided on 13 July 2007.

Analysis

Exemptions

42. NICE has claimed that the requested information, the executable model, is exempt from the right of access provided by section 1(1)(b) of the Act by virtue of sections 41 and 36 of the Act.

Section 41 – information provided in confidence

43. This section of the Act states that,

"(1) Information is exempt information if –

(a) it was obtained by the public authority from any other person (including another public authority), and

(b) the disclosure of the information to the public (otherwise than under this Act) by the public authority holding it would constitute a breach of confidence actionable by that or any other person".

44. The Commissioner has been influenced by the approach of the Information Tribunal ('the IT') in the case of *Derry City Council v The Information Commissioner (EA/2006/0014)* in analysing the application of the section 41 exemption in this case. The IT explained the points to be determined in relation to section 41 in paragraph 30 of the Derry City Council decision. In summary, the relevant points to consider are as follows:

- was the information obtained by NICE from a third party?; and if so,
- would its disclosure constitute an actionable breach of confidence, that is:
    i. does the information have the necessary quality of confidence to justify the imposition of a contractual or equitable obligation of confidence?; if so
    ii. was the information communicated in circumstances that created such an obligation?; and, if so
    iii. would disclosure be a breach of that obligation?;
- and, if this part of the test is satisfied:
- would NICE nevertheless have a defence to a claim for breach of confidence based on the public interest in disclosure of information?

Did NICE obtain the information from a third party?

45. The Commissioner understands that both SHTAC and the National Coordinating Centre for Health Technology Assessment ('NCCHTA') are located within the Wessex Institute for Health Research and Development ('WIHRD'), which is part of the School of Medicine at the University of Southampton. The Commissioner has concluded that, for the purposes of the Act, all of these bodies are part of the University of Southampton which is itself a public authority subject to the Act. He has also determined that NICE obtained the executable model from SHTAC, a third party and that therefore point one above is satisfied.

Does the information have the necessary quality of confidence to justify the imposition of a contractual or equitable obligation of confidence?

46. In order for information to have the 'quality of confidence' it must have some value such that the person owed the duty of confidence would suffer detriment if it were disclosed. The information must not be publicly known and must not be trivial. The Commissioner is satisfied that neither the RO nor the executable version of the economic model in this case are publicly available. He has considered the content of the AR relevant to this case which can be downloaded from NICE's website at the following address, http://www.nice.org.uk/page.aspx?o=245910. As previously mentioned a limited

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amount of information from within the model is reproduced in the AR, such as graphs and a flowchart. However he is satisfied that the remainder of the information within the model has not been made public as a result of the publication of the AR.

47. The Commissioner is further satisfied that the information is not trivial in nature. NICE has explained that the information within the model is of considerable value to the AGs. The models are complex and represent significant innovation and academic achievement. The structure used to analyse the data, the way that it operates (the calculations) and the outputs are the elements of particular value and constitute intellectual property of the AG. The Commissioner recognises that it is possible to view the inputs, assumptions and calculations in both the RO model and the executable model. Therefore it would be possible, though not necessarily straightforward, to recreate the model with access only to the RO model. Clearly there is a risk therefore that the intellectual property rights of the AGs could be infringed as a result of disclosure of the RO model to the consultees. However, this risk is mitigated by the stringent confidentiality agreements that the consultees are required to sign prior to the RO model being made available to them. The Commissioner does not consider that this restricted disclosure, subject to confidentiality agreements, erodes the quality of confidence of the information.

48. Arguably, the executable model has an additional value because it can be used to produce further analyses using new inputs without expending the time and effort or obtaining the expertise necessary to recreate the model structure. Further, the Commissioner understands that the executable model includes an audit spreadsheet tool which allows the user to easily trace the links between the different cells of the spreadsheet. This function is prevented from running on the RO model, which means that it is more difficult, though not impossible, to trace the links between the spreadsheets. However, as mentioned in the "Scope of the Case" section of this notice, the Commissioner does not consider that there is any additional recorded information within the executable model for the purposes of the Act. Overall the model is of value because there is considerable potential for academic recognition and publication as well as commercial exploitation. In particular, some journals will only publish material if it is being published or made public for the first time. In this case the AR has been published as part of the Health Technology Assessment Programme monograph series and is available on the HTA website at http://www.ncchta.org/ProjectData/3_project_record_published.asp?PjtId=1398#outputs. This also shows that articles based on the research within the AR have been published in three different journals, further demonstrating the value of the information within the model.

Was the information communicated in circumstances that created such an obligation?

49. NCCHTA (on behalf of the Health Technology Assessment Programme) is responsible for commissioning AGs to create ARs for submission to NICE's appraisal committees. AGs are located within the Universities of Aberdeen, Birmingham, Exeter, Liverpool, Sheffield, Southampton and York. Contracts for

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the provision of ARs exist between the Department of Health ('DoH') and the Universities but are monitored by NCCHTA.

50. NICE has provided the Commissioner with a copy of the contract between the Secretary of State for Health and The University of Southampton. Clauses 7, 14 and 15 of the contract specifically address the issues of confidentiality and intellectual property rights. The Commissioner notes that NICE is not a party to the contract. However he considers that the contract together with other evidence supplied by NICE is sufficient to demonstrate that the executable model was communicated to NICE in circumstances that created an obligation of confidence.

51. NICE has explained that the basis upon which it is supplied with economic models and the commitments it has given in respect of confidentiality has developed during discussions with NCCHTA, individual Assessment Groups and the DoH over a period of time.

52. NICE has also acknowledged that the provision of the economic models to it is an agreed 'carve-out' to the confidentiality obligations in clause 7. Nevertheless, it maintains that clauses 7, 14 and 15 of the contract set out the starting point that material is confidential and of value to the parties to the contract and provides a basis for SHTAC to justify imposing restrictions on onward disclosures. Clause 7 states that,

> "During the Project Period, and prior to the publication of the full results, the Contractor [University of Southampton] shall not without the prior written consent of the Authority [DoH] release, or otherwise make available to third parties, information relating to the Agreement or the Project by means of any displays or oral presentations to meetings except that this obligation shall not restrict or prevent the Contractor or the Authority from submitting for publication or publishing any information in accordance with the Contract".

53. Clause 14.1 states that, "Intellectual Property Rights other than Background Intellectual Property Rights to all Results of the Project in which rights may arise as part of, incidental to or resulting from the Project shall vest in the Contractor".

54. NICE implemented a new appraisal process in 2003 which incorporated the provision of the RO model to consultees subject to a confidentiality agreement. Prior to 2003, models were referred to in some ARs but were not made available beyond the comment on them in the reports. Commenting on this approach a representative of the NHS Health Technology Assessment Programme indicated to NICE in an email of 4 April 2003 that the RO model would enable the reader to understand the structure and the assumptions without allowing someone to use the model for other purposes.

55. A meeting was held on 30 March 2004 to discuss the basis upon which the economic models would be provided to NICE. It was attended by representatives of NICE, the DoH and the AGs. The Commissioner was provided with an extract of the relevant minutes which confirms that both versions of the model are to be supplied to NICE and that the RO model is the version that can be provided to consultees.

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56. As already mentioned, NICE has asserted that the economic models are supplied to it by the AGs on the basis that only the RO model will be supplied to consultees and commentators and only if they agree to a confidentiality agreement. (The Commissioner understands that the reference to information within the model being confidential relates to data within the model, such as clinical trial material). Paragraph 4.4.1.9 of the Guide states that,

> "The Assessment Group may produce an economic model in support of the Assessment Report. If the model does not contain information that was designated as confidential in the submission, the Institute offers consultees and commentators the opportunity to receive by email a read-only version of the model, for information only. Requests for the model must be made in writing, and it is supplied on the basis that the consultee or commentator agrees, in writing, to the following conditions for its use.
>
> - The economic model and its contents are confidential and are protected by intellectual property rights, which are owned by the relevant Assessment Group. It cannot be used for any purpose other than to inform the recipient's understanding of the Assessment Report.
> - The model must not be re-run with alternative assumptions or inputs.
> - The consultees or commentators will not publish the model wholly or in part, or use it to inform the development of other economic models".

57. The Commissioner has also been supplied with copies of letters sent to NICE during 2005 by HTA Programme Director and the Director of Research and Development in the DoH. Both of these pieces of correspondence confirm that NICE may not transmit the executable model to anyone without the explicit consent of the holder of the IPR, the AGs. Further, the RO model may only be made available to consultees subject to the conditions listed above. In addition, the letter from the HTA Director indicates that consultees are not permitted to make copies of the model and that it must be deleted once the appraisal process and any subsequent appeal are complete.

58. In line with the section 45 code of practice, NICE consulted SHTAC about the request for the executable model in this case. SHTAC has clearly indicated that it considers that the economic model was imparted in circumstances that gave rise to an obligation of confidence and that any release of information would breach that obligation.

59. The Commissioner is satisfied that all of the evidence mentioned above demonstrates that NICE owes a duty of confidence to SHTAC in relation to the economic models. In particular it illustrates that the information was imparted to NICE on the basis that it would only be further disclosed subject to very specific conditions limiting its use and retention. He considers that SHTAC would therefore hold a reasonable expectation that neither the RO nor the executable version of the economic model would be disclosed to the public by NICE.

Would disclosure be a breach of the obligation?

60. The Commissioner is satisfied that if the requested information were released it would constitute a breach of the duty of confidence NICE owes to SHTAC.

If so, would NICE have a defence to a claim for breach of confidence based on the public interest in disclosure of the information?

61. In the Derry City Council case mentioned previously, the IT considered the appropriate balancing exercise to undertake when considering the section 41 exemption. It concluded that the appropriate starting point was, "the assumption that confidentiality should be preserved unless outweighed by countervailing factors". This is in contrast to the qualified exemptions in the Act which are subject to the public interest test set out in section 2(2). Under section 2(2)(b) there is an implied presumption in favour of disclosure which states that section 1(1)(b) does not apply if or to the extent that, "in all the circumstances of the case, the public interest in maintaining the exemption outweighs the public interest in disclosing the information". However, the IT also determined that it was required to, "move away from the concept of precisely defined categories of public interests that may be said to justify disclosure", such as wrongdoing or public harm. The Commissioner has also been influenced by this judgment when considering whether NICE would, in his view, have a public interest defence to a claim for breach of confidence.

62. It is also important to re-iterate at this point that the test that the Commissioner must consider is whether there is a public interest in the executable model being disclosed to the general public. However a number of the arguments used by the complainant to demonstrate that the section 41 exemption was incorrectly applied are, in the Commissioner's opinion, more relevant to an argument that the consultees require sight of the executable model in order for the appraisal process to be procedurally fair from a public law perspective. It is not within the Commissioner's remit to consider whether the appraisal process is appropriate or fair, neither is it his responsibility to determine what information should be made available to consultees as part of that process. He notes that the Appraisal Process used by NICE was at the time of his investigation the subject of a judicial review. One of the points considered as part of that review was whether the refusal of NICE to disclose the executable model to consultees breached the principles of procedural fairness.

63. Notwithstanding the comments above, the Commissioner has considered all of the evidence provided by both parties in this case when reaching a view about whether NICE would have a public interest defence were it to disclose the requested information. When reviewing the evidence he has been mindful of the need to restrict his consideration to the bearing that information has on the arguments surrounding the public interest in the general public having access to the executable model.

Arguments in favour of maintaining the duty of confidence

64. It is a well established principle that there is a public interest in one party maintaining a duty of confidence that it owes to another. In this case the Commissioner accepts that if the executable model were released it is likely to prejudice the ability of NICE to obtain such information from the AGs in the future. NICE has explained that the provision of the models by the AGs has been the subject of lengthy negotiations over a significant period of time. Whilst the AGs have been prepared to release executable versions of the model to NICE and RO

versions to consultees and commentators, they have been very specific that they are only prepared to do so if stringent confidentiality obligations are adhered to. Evidence to support the position that the AGs would refuse to supply the models to NICE in future if the requested information were released has already been mentioned above (e.g. specific confidentiality clauses).

65. The Commissioner notes that NICE is the primary purchaser of the economic models that the AGs produce. Therefore, he recognises that there is a question as to whether in fact the AGs would be in a position to refuse to supply the models to NICE in the future. However, he notes that, although NICE is the main consumer, other bodies do commission ARs. Further, the models are also used by the academics to produce other work for publication. In addition, the potential for exploiting the models arguably extends to the international academic sphere and the private sector including the pharmaceutical industry. Given the value of the model for the AGs the Commissioner accepts that if the information were disclosed under the Act the authors are likely to be reluctant to supply further similar information to NICE.

66. There is a strong public interest in ensuring that NICE is able to obtain the models from the AGs so that it has a full range of evidence and analysis upon which to base its recommendations about a particular health technology. The AGs are specifically appointed to feed into health technology appraisals because of their expertise in the particular area under review. The value that rigorous academic analysis can add is also well recognised. In order to make sound policy recommendations it is in the public interest to ensure that the most qualified academics are willing to supply NICE with their full workings and advice.

67. The Commissioner recognises that the AGs consider that both versions of the economic model constitute their intellectual property. They embody technical skill and academic endeavour and achievement of considerable value. He accepts that there is a public interest in allowing the AGs to benefit from their intellectual property. As mentioned above, the potential for commercial exploitation and academic recognition and publication would be significantly undermined if the material were disclosed to the general public. It is in the public interest to ensure that the academics that develop the models are able to compete and gain recognition within the global academic environment.

Public interest arguments in favour of disclosing the information

Accountability and transparency

68. The Commissioner accepts that there is a strong public interest in ensuring that NICE is fully accountable for its decisions and that it is as transparent as possible about the way in which it makes those decisions. NICE is charged with issuing guidance about the way that different health technologies are used within the NHS. The ability of patients to access health services is a contentious issue, particularly where resources are limited. Therefore it is important that, as far as is possible, the public has confidence in the way that resources are assessed and allocated. In particular, it is important that they are confident that NICE has made decisions in accordance with its published procedures. Where difficult recommendations have been made it is essential that the public is confident that

decisions have been made on the basis of the best evidence available. Arguably the more transparent NICE is about the evidence that has been used to inform its decisions the greater public confidence is likely to be.

69. In this case releasing the requested information would arguably increase public confidence in the decisions NICE has taken in relation to the Alzheimer's drugs under review. Enabling people to scrutinise the same evidence that was made available to the AC during the review process would demonstrate that NICE is willing to be fully transparent about the basis for its recommendations.

70. The Commissioner acknowledges that the arguments surrounding accountability and transparency have considerable weight in principle. However, in this case he considers there to be a number of relevant mitigating factors which limit the strength of this argument. He notes that NICE publishes a lot of information about the general appraisal process as outlined at the beginning of this decision notice. This includes publications such as the Guides to the Technology Appraisal Process and to the Methods of Technology Appraisal.

71. In addition, the appraisal process provides for stakeholders including drugs companies and patients to be represented within the designated consultee and commentator groups for individual projects. These groups are consulted about the evidence that is to be considered in a particular study and the factors that require testing. The Guide to the Methods of Technology Appraisal includes further information about the scoping exercise undertaken by NICE in paragraphs 2.1 and 2.2. As previously mentioned consultees are permitted access to the RO version of the model, subject to confidentiality agreements, to assist their understanding of the recommendations that NICE make in particular appraisals. At various stages of the appraisal consultees and commentators are provided with the optimum amount of information possible to inform their feedback.

72. Although consultees have access to a broader spectrum of information, the Commissioner notes that NICE also makes as much information as possible available to the general public in recognition of the need for transparency. Paragraph 4.2.3 of the Guide states that, "to ensure the appraisal process is as transparent as possible, the Institute considers it highly desirable that evidence pivotal to the Committee's decisions should be publicly available". It is also noted that the AR together with consultee and commentator comments are published on NICE's website during the appraisal period. Similarly the ACD is also made available on NICE's website whilst the appraisal process is still ongoing.

73. To support the contention that the requested information should be disclosed, the complainant referred to a House of Commons Select Committee report published on 3 July 2002. In the report the Committee commented on the desirability of NICE increasing the transparency of its procedures. The report recommended that, "all information which NICE uses in its decision making process is made available for public scrutiny". It also recommended that, "NICE should improve the transparency of its processes by striving to make information on how and why decisions are taken…as readily available to lay stakeholders as possible".

74. The Commissioner requested comments from NICE about the complainant's assertions outlined above. In its response NICE clarified that the Select

Committee's comment about making further information available had in fact related to industry material. It asserted that the Committee was making a comment about the lack of transparency by pharmaceutical companies, many of whom were apparently marking a considerable amount of their evidence submitted to NICE as commercial in confidence. NICE also referred to the second part of the recommendation made by the Committee which stated that, "if industry or others have previously unpublished data which they want to use to support their case then this should no longer be presented to NICE subject to confidentiality". The Commissioner understands that considerable progress has been made in reducing the volume of material deemed commercial in confidence since the Committee's report was published. This is reflected in paragraph 4.2.3 of the Guide.

75. NICE also clarified that the second comment about the need for greater transparency within the process, referred to declarations of interest, NICE committee minutes, membership and web links as opposed to evidence considered in a particular study. In support of its own position that it is as transparent as possible, NICE cited Lord Warner, the former Minister of State for Health. In October 2006 he said, "I do not accept that NICE has failed to communicate its ideas properly and appropriately. It has been extremely transparent at all stages of its process in putting information on its website and into the public arena".

76. The Commissioner also notes that the World Health Organisation ('WHO') conducted a review of NICE's Appraisal Process in 2003 and concluded that key principles of its approach represented, "the use of best available evidence in decision-making, transparency, consultation, inclusion of all key stakeholders, and responsiveness to change". It also stated that, "in all of these areas, it is clear that NICE is setting a new, international benchmark, for which it should be congratulated".

77. Bearing in mind all of the comments above, the Commissioner considers that the argument that there is a public interest in releasing the requested information on the grounds of transparency and accountability has limited weight given the amount of material that NICE already makes available to the public about its processes in general and its specific studies.

78. During the course of the Commissioner's investigation the complainant argued that it is the public interest to release the executable model so that its integrity can be tested by parties other than the AG and/or NICE. It has also pointed out that consultees who decide to submit an economic model as part of their evidence to the AC are required to provide an executable version so that it can be tested and re-run where it is considered necessary. In support of this argument the complainant referred to the fact that in August 2006 NICE cancelled an appeal hearing against its recommendations about a new glioma drug. A statement was published on its website which explained that this was due to an error that had been found in the AG economic model. In the circumstances NICE requested that the AC consider revised analysis. The complainant contended that the errors were not identified by the AC or the AG but by one of the consultees

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following the release of a version of the model which was not fully executable but did permit electronic audit.

79. The Commissioner sought a response from NICE about the complainant's comments. In its response, NICE confirmed that an error was detected in the glioma model. However it did not consider this directly relevant to this case. It explained that it is possible to 'audit' the model irrespective of which version is released and that for the purposes of the Act, the RO and executable models contain the same recorded information. Therefore it did not accept that it was necessary to release the executable version of the model to allow for errors to be detected. It also pointed out that this argument appeared to be more relevant to whether or not the consultees require access to a particular version of the model. As already explained earlier in this notice, this is not something that the Commissioner can consider. The Commissioner cannot consider whether or not the information should be made available to a limited and specific group of people. NICE also re-iterated that no economic models are released to the general public.

80. The Commissioner notes that concerns about the integrity of the economic model in this case have been raised by the complainant and others. This may be seen to add weight to the argument that there is a strong public interest in releasing either version to the public to enable people to scrutinise the data for themselves. However, he recognises that due to the complexity of the models, if errors were present it is probable that, other than the AG and the AC, consultees would be most likely to be in a position to identify them. He is also mindful that, according to NICE, it would be possible to do this using the RO version which the consultees are permitted to access. The consultees also have a right of appeal which can include challenging the evidence used by the AC. When considering this argument the Commissioner has also taken into account the fact that responsibility for quality assuring data used to inform recommendations lies with the AC and not with the consultees to an appraisal or the wider general public. Therefore the appraisal process provides for NICE's technical team to re-run the model to test different assumptions. Further, though it is not built into the formal process, the same team may carry out checks to ensure that the model works as described in the AR. This provides another check to ensure against errors. Therefore the Commissioner has not attributed particular weight to this argument in this case.

Challenging decisions

81. There is a public interest in people being able to challenge decisions made by public authorities which affect them from an informed standpoint. If the requested information were released it would assist members of the public to better understand the basis of NICE's decision and to challenge it.

82. When considering the weight attributable to this argument the Commissioner has been mindful of both the importance and impact of NICE's decisions on the public. Any decision which has the effect of limiting access to treatment on the NHS is likely to be contentious. However given that resources are finite it is necessary to have a process for determining how they will be distributed amongst all those in need. This is the task that NICE is charged with and it is perhaps

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inevitable that people who are unable to access treatment as a result of a NICE recommendation will be inclined to challenge it.

83. In addition, the Commissioner has considered the amount of information that is made available to the public during the course of the appraisal and the opportunities provided for the public to feed in to the final decision that NICE makes. Arguably in some cases the less information that is available to the public, the greater the public interest in releasing the requested information.

84. During the course of an appraisal the public is provided with a considerable amount of material, including the AR and the ACD. A summary of comments made by the public on the website about the ACD is fed back to the AC prior to it issuing the FAD. The Commissioner notes that in this particular case the Guidance Executive decided that additional data about the clinical and cost effectiveness of the drugs in question should be obtained for further consideration by the AC prior to publication of the final guidance. This data was obtained and considered and a second ACD was provided to consultees and the public for comment. The Commissioner also notes that subsequent to the request, the final FAD was revised from a recommendation that precluded any patient from receiving treatment to one that suggested that those with moderate to moderately severe disease could benefit from the treatment. The decision to obtain further data and to change the final decision demonstrates that the appraisal process does provide for and indeed has resulted in, amendments to the FAD. Although access to the requested information may assist the public in challenging NICE's decisions, the Commissioner has given this factor less weight given that a significant amount of information is already made available to the public, in particular the AR, which provides detailed information about the model and the assumptions. Indeed the AR is detailed enough that some members of the AC do not access the model and simply reach a view based on the detail within it.

85. In addition consultees who represent patients, carers and the pharmaceutical industry are provided with a full opportunity to comment on the ACD and the RO model. They are also provided with a right of appeal to challenge the FAD. Therefore the public is able to challenge decisions indirectly via the consultees. There is no mechanism beyond this for the public to provide detailed representations about the ACD or to appeal against the final recommendations. This is partly because NICE has established set parameters for each appraisal and to limit the amount of evidence that it must consider in order to assess drug technologies effectively and efficiently. The Commissioner acknowledges that the requested information would assist the public in challenging decisions outside of the appraisal process for example, by demonstrating against decisions that NICE has taken. A recent example of this was well documented in the national press when the Alzheimer's Society organised a protest march in November 2006 against the recommendations about Donepezil, Rivastigmine, Galanamine and Memantine. However, the Commissioner does not consider this argument sufficient to outweigh the duty of confidence owed to the AG, particularly given the information already made available to the public and the opportunities to feed into and challenge the decision within the appraisal process.

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86. When the complainant requested that the Commissioner make a decision in this matter a number of 'expert' opinions to support the disclosure of the requested information were submitted. The arguments and evidence put forward by the experts focus on the need for consultees to have access to the executable model so that they are able to re-run it using different assumptions and to feed this back to the AC. The Commissioner is not permitted to consider whether the consultees have a legitimate interest in access to the requested information distinct from other members of the public. He cannot order disclosure of the information to a restricted group and deny access to other members of the public.

87. However he has still considered the views put forward by the experts when weighing up the public interest in disclosure to the wider public. NICE has highlighted that the appraisal process does not require consultees to re-run the model or to submit feedback based on different assumptions. Notwithstanding this, the Commissioner considers that access to the model would in any event assist consultees and the wider public in challenging NICE's decisions. Whilst he acknowledges that the appraisal process may not provide for input derived from re-running the model, he considers that this information may nevertheless allow the public, including the consultees, to contest the decisions made by NICE. This may include challenging the overall appraisal process and the specific evidence that has been taken into account in a particular case. There is a public interest in being in a position to challenge decisions from an informed standpoint in order to improve the overall quality of those decisions. Although this argument is significant the Commissioner does not consider that it is sufficient to override the duty of confidence in this case.

88. Although not germane to the Commissioner's decision in this matter, he is aware that subsequent to the request the AC issued its final recommendations regarding the Alzheimer's drugs under review. These were appealed by some of the consultees and an Appeal Panel hearing was held on 13 and 14 July 2006. This appeal considered the issue of whether or not consultees should be given access to the executable model. The conclusions reached by the Appeal Panel are available on NICE's website at the following link, http://guidance.nice.org.uk/download.aspx?o=371762. As mentioned previously this point was also the subject of a judicial review.

Improving the quality of decisions

89. There is also an argument that disclosing the executable model would enable further academic scrutiny and debate. There is a public interest in enabling such debate to improve the quality of evidence that is available to bodies such as NICE when making the difficult decisions it is tasked with making. A number of experts in the field of economic modelling have made recommendations about best practice when using models. An article entitled, "Principles of Good Practice for Decision Analytic Modeling in Health-Care Evaluation: Report of the ISPOR Task Force on Good Research Practices-Modeling Studies" describes the importance of users of models in government and the private sector being able to evaluate

the quality of models according to scientific criteria of good practice. The article refers to the need for transparency and recognises the importance of modelers cooperating and comparing results in order to articulate the reasons for any discrepancies. This is arguably likely to lead to overall improvements in the quality of the models available and to general understanding of economic models. The article states that, "reasonable requests for copies of models with adequate user interface should be made available for peer review purposes". The Commissioner notes that the ability of consultees to access a restricted version of the model would appear to fit with this recommendation of best practice. In addition the article also recognises that, "the source code should generally remain the property of the modeller" and that any reasonable request for copies of the model can still be subject to, "conditions of strict security and protection of property rights". Therefore, although the Commissioner considers that disclosure may further academic debate and help to improve the quality of models available, he does not consider it sufficient, when balanced with the other public interest arguments, to outweigh the duty of confidence owed to SHTAC.

Informing public debate

90. NICE has been the focus of an ongoing public debate both in terms of how it operates and the specific contentious decisions that it makes. Arguably there is a public interest in disclosing the requested information to inform this ongoing debate. In particular there are groups that argue that NICE places too much store on the cost effectiveness of new drug technologies over other benefits. Most recently this has been considered by the Select Committee for Health. It has sought evidence from a number of sources including the pharmaceutical industry, patient groups, charities and medical practitioners about the work that NICE carries out.

91. In particular there has been a considerable amount of debate about the evidence and factors used by NICE when conducting its appraisal of the new Alzheimer's drugs. For example, questions have been raised about whether or not it is appropriate or fair to make a determination based of the use of Quality-Adjusted Life Years (QALY). However, given that the published AR and ACD explain all the evidence considered and specifically how the model operates and the assumptions made, the Commissioner considers the argument that the model itself should be released to further inform the debate to be of less weight.

92. In reaching a final conclusion, the Commissioner acknowledges in particular, the strength of the argument that disclosing the requested information is likely to increase academic debate regarding economic modelling and thereby improve the standard of models available to NICE and other bodies. However, the Commissioner is not persuaded that, overall in this instance, sufficient counter veiling arguments have been presented to offer a defence against breaching the duty of confidence owed. He is therefore satisfied that releasing the information would constitute a breach of confidence actionable by SHTAC.

Section 36 – Effective conduct of public affairs

93. In view of the fact that the Commissioner has concluded that section 41 has been appropriately cited in relation to all of the withheld information, he has not gone

on to consider whether section 36 was correctly applied by the public authority in this instance.

Procedural issue

94. The complainant requested information on 28 February 2005. NICE did not issue a Refusal Notice until 12 April 2005. In failing to respond to the request within twenty working days the public authority breached section 10 of the Act.

The Decision

95. The Commissioner's decision is that the public authority appropriately refused to provide the requested information citing section 41 of the Act. In doing so it complied with section 1(1) of the Act.

96. However, in failing to respond to the request within twenty working days the public authority breached section 10(1) of the Act.

Steps Required

97. The Commissioner requires no steps to be taken.

Other matters

98. In the initial letter to the Commissioner, the complainant expressed dissatisfaction with the internal review process provided by the public authority and described it as bureaucratic and prolonged. The complainant provided a copy of the internal review procedure to the Commissioner. It is a three stage procedure with the initial complaint being handled by the complaints manager. This can then be appealed to the Chief Executive. If the complainant remains dissatisfied with the Chief Executive's response then this can be appealed to two Non-Executive directors.

99. In this case the Commissioner notes that, following representations from the complainant, NICE agreed to expedite the internal review to the third stage. The outcome of the internal review was communicated to the complainant on 29 June 2005.

100. Section 45 of the Act states that the Secretary of State shall issue a code of practice providing guidance to public authorities as to the practice it would, in his opinion, be desirable for them to follow when discharging their obligations under

the Act. Subsection 2(e) requires that the code of practice must include provision of procedures for dealing with complaints about the way in which a request under the Act has been handled. Where it appears to the Commissioner that a public authority has failed to provide a complaints procedure which accords with the requirements of the Code of Practice he may issue a Practice Recommendation under section 48 of the Act. A Practice Recommendation must specify which provision of the Code of Practice the public authority has, in the Commissioner's opinion, failed to conform to. It should also specify the steps which ought to be taken to promote conformity with the Code of Practice.

101. The Commissioner has considered the 3 stage procedure adopted by NICE. He is concerned that the time required for completion of such a procedure may not satisfy the definition of "reasonable" in paragraph 42 of the Code of Practice and would draw NICE's attention to his Good Practice Guidance 5 available at:

http://www.ico.gov.uk/upload/documents/library/freedom_of_information/detailed_specialist_guides/foi_good_practice_guidance_5.pdf

102. In summary, this guidance states that the Commissioner considers that 20 working days is a reasonable time for completing an internal review and that in no case should the total time taken exceed 40 working days. It goes on to specify that the Commissioner does not expect an internal review process to have more than one stage.

103. In addition, both the Code and the Commissioner's guidance suggest that public authorities should publish their target times for dealing with complaints and information as to how successful they are in meeting those targets.

104. Although the Commissioner does not propose to take any further action in relation to the complaints process in this case he would expect NICE to amend its complaints procedure in relation to FOI requests in light of the aforementioned Code and guidance.

Right of Appeal

105. Either party has the right to appeal against this Decision Notice to the Information Tribunal. Information about the appeals process may be obtained from:

Information Tribunal
Arnhem House Support Centre
PO Box 6987
Leicester
LE1 6ZX

Tel: 0845 600 0877
Fax: 0116 249 4253
Email: informationtribunal@tribunals.gsi.gov.uk

Any Notice of Appeal should be served on the Tribunal within 28 calendar days of the date on which this Decision Notice is served.

Dated the 27th day of September 2007

Signed ……..

Graham Smith
Deputy Commissioner

Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF

LEGAL ANNEX

Section 1(1) provides that -

"Any person making a request for information to a public authority is entitled –

(a) to be informed in writing by the public authority whether it holds information of the description specified in the request, and

(b) if that is the case, to have that information communicated to him."

Section 10(1) provides that –

"Subject to subsections (2) and (3), a public authority must comply with section 1(1) promptly and in any event not later than the twentieth working day following the date of receipt."

Section 11(1) provides that –
"Where, on making his request for information, the applicant expresses a preference for communication by one or more of the following means, namely –

(a) the provision to the applicant of a copy of the information in permanent form or in another form acceptable to the applicant,
(b) the provision to the applicant of a reasonable opportunity to inspect a record containing the information, and
(c) the provision to the applicant of a digest or summary of the information in permanent form or in another form acceptable to the applicant.

The public shall so far as is reasonably practicable give effect to that preference."

Section 11(2) provides that –
"In determining for the purposes of this section whether it is reasonably practicable to communicate information by a particular means, the public authority may have regard to all the circumstances, including the cost of doing so"

Section 11(3) provides that –
"Where a public authority determines that it is not reasonably practicable to comply with any preference expressed by the applicant in making his request, the authority shall notify the applicant of the reasons for its determination

Section 36 provides that –

"(1) This section applies to –

(a) information which is held by a government department or by the National Assembly for Wales and is not exempt information by virtue of section 35, and

(b) information which is held by any other public authority.

(2) Information to which this section applies is exempt information if, in the reasonable opinion of a qualified person, disclosure of the information under this Act-

(a) would, or would be likely to, prejudice-
  (i) the maintenance of the convention of the collective responsibility of Ministers of the Crown, or
  (ii) the work of the Executive Committee of the Northern Ireland Assembly, or
  (iii) the work of the executive committee of the National Assembly for Wales,

(b) would, or would be likely to, inhibit-
  (i) the free and frank provision of advice, or
  (ii) the free and frank exchange of views for the purposes of deliberation, or

(c) would otherwise prejudice, or would be likely otherwise to prejudice, the effective conduct of public affairs.

Section 41 provides that –

"(1) Information is exempt information if-

(a) it was obtained by the public authority from any other person (including another public authority), and

(b) the disclosure of the information to the public (otherwise than under this Act) by the public authority holding it would constitute a breach of confidence actionable by that or any other person."