

Freedom of Information Act 2000 (Section 50)

Decision Notice

Date: 18 May 2010

Public Authority: Department of Health

Address: Richmond House 79 Whitehall

London SW1A 2NS

Summary

The complainant requested details of the unit cost of the vaccine Cervarix, and the value of the contract with the vaccine manufacturer. The Department of Health (the "DoH") refused to provide this information, citing section 43(2). During the course of the investigation the DoH also stated that the information was exempt under sections 41 and 44. After investigating the case the Commissioner has decided that the information should be withheld under section 43(2). However, in applying late exemptions the DoH acted in breach of section 17(1)(b) and (c).

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 1 of the Freedom of Information Act 2000 (the "Act"). This Notice sets out his decision.

Background

2. Cervarix is a vaccine designed for cervical cancer prevention, and is manufactured by GlaxoSmithKline ("GSK"). In June 2008 the DoH



awarded a contract for its national human papillomavirus (HPV) immunisation programme to GSK for this vaccine.¹

The Request

3. The complainant contacted the DoH on 30 October 2008 and made the following request,

"I would like to request the unit cost of Cervarix; how many units [the DoH] is purchasing; and what the value of the contract is."

- 4. The DoH responded in an email dated 10 November 2010. It confirmed that it held information relevant to the request, but believed that this information was exempt from disclosure under section 43(2).
- 5. The complainant emailed the DoH on 16 December 2008 and requested an internal review.
- 6. The DoH acknowledged his request for an internal review in an email dated 22 January 2009. It informed him that it was currently seeking the views of third parties, and hoped to be in a position to respond by no later than 26 February 2009.
- 7. The DoH emailed the complainant again on 26 February 2009 and informed him that it was still unable to respond. It hoped to be able to respond by 6 March 2009.
- 8. The DoH carried out an internal review, and responded to the complainant in an email dated 16 March 2009. It informed him that after carrying out the review it was now prepared to disclose the number of units of Cervarix it was purchasing and this information was provided to him. However, it also stated that it still believed that the unit price and the overall value of the contract were exempt from disclosure under section 43(2). It informed the complainant of his right to complain to the Commissioner.

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The Investigation

Scope of the case

- 9. The complainant contacted the Commissioner on 18 March 2009 to complain about the way his request for information had been handled. The complainant specifically asked the Commissioner to consider whether the DoH was correct to withhold the outstanding information, i.e. the unit cost of Cervarix and the value of the contract.
- 10. Although not referred to by the complainant, the Commissioner has also considered whether the DoH met the requirements of section 17.

Chronology

- 11. The Commissioner wrote to the DoH on 11 January 2010 and asked it to provide him with a copy of the withheld information. He also asked it to provide further submissions regarding its use of section 43(2).
- 12. The DoH provided a full response in a letter dated 9 March 2010. It provided the Commissioner with a copy of the withheld information, and also detailed arguments to support its use of section 43(2). It also informed the Commissioner that it believed that the withheld information was also exempt under section 41 and section 44(1)(b).
- 13. The Commissioner emailed the DoH on 1 April 2010 and asked for some additional information in relation to its use of section 43(2). The DoH provided this information in an email dated 20 April 2010.

Analysis

Exemptions

Section 43

- 14. Section 43(2) states that information is exempt information if its disclosure under the Act would, or would be likely to, prejudice the commercial interests of any person (including the public authority holding it). This is a qualified exemption, and is therefore subject to the public interest test.
- 15. The full text of section 43 can be found in the Legal Annex at the end of this Notice.



- 16. In this case the DoH has argued that the disclosure of the withheld information would prejudice its own commercial interests, those of NHS bodies, and those of the vaccine manufacturer, GSK.
- 17. The Commissioner has first considered whether the withheld information, and the potential prejudicial effects described by the DoH, would relate to commercial interests.
- 18. The withheld information consists of information about the cost of units of the Cervarix vaccine, together with the overall value of the contract with GSK. As such, the Commissioner is satisfied that this information relates to commercial interests. Furthermore, after considering the DoH's arguments the Commissioner is satisfied that the potential prejudicial effects would relate to the commercial interests of the DoH, NHS bodies and GSK. Therefore he is satisfied that the withheld information falls within the scope of the exemption.
- 19. However, for this exemption to be engaged disclosure would have to prejudice, or be likely to prejudice, the commercial interests of the DoH, NHS bodies and GSK.
- 20. After considering the DoH's submissions to him the Commissioner notes that it has argued that disclosure of the withheld information:
 - would prejudice the commercial interests of the DoH,
 - would and would be likely to prejudice the commercial interests of NHS bodies, and
 - would prejudice the commercial interests of GSK.

The Commissioner has first considered whether the disclosure of the withheld information would prejudice the commercial interests of GSK.

21. The DoH has stated that it believes that the disclosure of the withheld information would prejudice the commercial interests of GSK. In reaching a decision on the question of prejudice the Commissioner has been mindful of the views of the Tribunal in *Hogan v ICO and Oxford City Council* [EA/2005/0026 & EA/20005/0030] which noted that ,

"The [...] prejudice test is not restricted to 'would be likely to prejudice'. It provides an alternative limb of 'would prejudice'. Clearly this second limb of the test places a much stronger evidential burden on the public authority to discharge." ²

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² EA/2005/0026 and EA/20005/0030, para 36.



22. The Commissioner has interpreted this to mean that in cases where a public authority has argued that disclosure would cause prejudice, whilst it would not be possible to prove that prejudice would occur beyond any doubt whatsoever, prejudice must be at least more probable than not.

Prejudice to the commercial interests of GSK

- 23. In cases where a public authority argues that disclosure of the requested information would or would be likely to prejudice a third party the Commissioner is guided by the views of the Tribunal in *Derry City Council v ICO* [EA/2006/0014]. In this case the Council argued that the commercial interests of a third party, Ryanair, would be likely to be prejudiced if the requested information were disclosed. The Council did not ask Ryanair for its views as to whether it believed its commercial interests would be likely to be prejudiced nor did Ryanair present any evidence to the Tribunal. The arguments put forward by the Council to the Commissioner as well as to the Tribunal were based upon the Council's thoughts on the point and not on representations made by Ryanair. In the absence of any evidence from Ryanair the Tribunal stated that it was unable to conclude that Ryanair's commercial interests would be likely to be prejudiced.³
- 24. The Commissioner acknowledges that the approach taken by the Tribunal may not be appropriate in every case and therefore public authorities may sometimes have to formulate their arguments based on their prior knowledge of a third party's concerns rather than directly contacting a third party. However the Commissioner still expects a public authority to provide evidence that these arguments genuinely reflect the concerns of the third party involved rather than merely speculate about the prejudice that may be caused to the third party.
- 25. After considering the information provided to him during the course of his investigation, the Commissioner is satisfied that the DoH has consulted with GSK, and that the arguments it has submitted in relation to the potential prejudice reflect the concerns of GSK.
- 26. The DoH has argued that the disclosure of the withheld information would prejudice GSK's position in other tenders for HPV vaccination programmes, and that disclosure would also prejudice GSK's position in other vaccine tenders. This is because disclosure would reveal information about GSK's pricing strategy.

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³ EA/2006/0014, para 24.



27. It has stated that GSK believes that the disclosure of any information that could lead to the calculation of the unit cost to the DoH of the HPV vaccine would provide valuable information to its competitors, "particularly in the HPV market where only two companies compete."

- 28. It has also said that the disclosure of the withheld information would give GSK's competitor a significant advantage in judging for example how high or low GSK would pitch its prices in future tenders. This would enable the competitor to adjust its prices accordingly.
- 29. Further to this, GSK has stated that,

"...releasing any of the requested information that either directly gives the purchase price or in combination enables the purchase price to be calculated, or enables the purchase price to be calculated when combined with information that is already in the public domain or can be easily estimated, is prejudicial to GSK's commercial interests. We consider that all the information that has been requested, either in totality or in part, could lead to the disclosure of the purchase price. The gross price per unit of Cervarix of £80.50 is already in the public domain. However if the net value of the contract became available, then this could be used to calculate the purchase price. Any price disclosure would inform our only HPV competitor of our pricing strategy and enable it to be more competitive in tenders in other countries in and outside Europe."

- 30. The Commissioner has gone on to consider these arguments in detail.
- 31. The Commissioner has noted that there are only two companies who produce an approved HPV vaccine GSK and Sanofi Pasteur.
- 32. The catalogue/list prices of the HPV vaccines are in the public domain. However, the DoH has explained that the prices are not the same across the global market. Vaccine manufacturers may offer lower prices in lower income countries, and higher prices in higher income countries. This 'tiered pricing' is seen as "a way to ensure equitable access to vaccines for the poor, and a profit incentive for vaccine producers through sales in higher income countries." The UK is one such higher income country.
- 33. In addition to this, the DoH has also explained that vaccine manufacturers do not always offer a single price in one country, and that prices may be lower than the catalogue/list price, e.g. a

http://www.who.int/immunization_financing/options/en/briefcase_vacproduction.pdf



discounted price may be offered for a country's national immunisation programme which is lower than the price being offered to private healthcare in that country.

34. Therefore, if information showing the discounted price that has been given to one country by one of the HPV vaccine manufacturers were to be disclosed, this information would be of significant use to that manufacturers' competitor, especially in a future tender in a country with a broadly similar income to the country in question. In this case the DoH has stated that,

"Disclosure of the information would confer an exclusive advantage on GSK's sole competitor, Sanofi, by giving it access to information about GSK's pricing strategy."

- 35. The Commissioner has noted that the withheld information in this case is both the unit cost of the HPV vaccine, Cervarix, and the value of the contract with GSK for the supply of that vaccine. Bearing in mind the fact that the catalogue/list price of Cervarix in this country is in the public domain, the withheld information does show the discounted price offered by GSK to the DoH. In addition to this, he is also satisfied that the unit cost, and the value of the contract, is inextricably linked, and that one could not be disclosed without disclosing the other.
- 36. The Commissioner has also considered the age of the information. The HPV vaccination contract was awarded to GSK in June 2008, and the information request was made in October 2008. Therefore the Commissioner is satisfied that the withheld information was relatively new at the time of the request.
- 37. The Commissioner has also noted the limited competition in this market. He believes that as there are only two manufacturers of an approved HPV vaccine, this means that it is highly likely that they will both be competing for future HPV vaccine contracts.
- 38. After considering these points, the Commissioner is persuaded that the withheld information would be very useful to GSK's competitor by giving valuable insight into GSK's pricing strategy that was current at the time of the request. Therefore the Commissioner is persuaded that the withheld information was commercially sensitive to GSK at the time of the request.
- 39. In considering the sensitivity of the withheld information the Commissioner has been particularly mindful of the timing of the

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⁵ http://www.gsk.co<u>m/media/pressreleases/2008/2008_pressrelease_10071.htm</u>



request. The DoH has confirmed that by the time of the internal review GSK was involved in an HPV vaccine tender for another European country. Furthermore, the Commissioner is also aware that GSK's competitor also took part in that tendering process.

- 40. As both vaccine manufacturers are highly likely to offer discounted prices for the HPV vaccine in national tenders, and that this discount varies depending on the income level of that country (see paragraphs 32 and 33 above), the Commissioner believes that given the timing of the request in relation to an upcoming HPV vaccine tender, the withheld information was of particular sensitivity to GSK. Were the withheld information to have been disclosed when the request was made, the Commissioner believes that GSK's competitors would have gained a valuable insight into its pricing strategy shortly before a tendering process for the same vaccine in a similar country to the United Kingdom.
- 41. Therefore, bearing in mind the test of prejudice as outlined at paragraphs 21 and 22 above, and taking into account the above factors, the Commissioner is persuaded that the disclosure of the withheld information at the time of the request would have prejudiced the commercial interests of GSK.
- 42. The Commissioner has gone on to consider whether the public interest in disclosing the withheld information is outweighed by the public interest in maintaining the exemption.

Public interest arguments in favour of disclosing the requested information

- 43. The complainant has argued that the other HPV vaccine brought "other benefits" to those offered by Cervarix. Therefore disclosure of the withheld information is necessary in order to allow the public to judge whether the DoH's decision to award the contract to GSK was made in the interests of the public, or for financial reasons. He has argued that the choice to award the contract to the vaccine produced by GSK was a controversial one, and there is a strong public interest in increasing public understanding of the decision making process.
- 44. The Commissioner believes that there is a strong public interest in increasing the transparency of the actions of public authorities. He also believes that there is a strong public interest in encouraging accountability in the spending of public money, especially when this spending comes from the budget of the DoH, and the potential knock on effect this will have in other areas of health spending.



45. In addition to this, and as referred to by the complainant, the Commissioner notes that there has been substantial public debate about the decision to award the HPV vaccine contract to GSK. He believes that the disclosure of this information would help inform that debate.

Public interest arguments in favour of maintaining the exemption

- 46. In considering the public interest arguments in favour of maintaining the exemption the Commissioner has been mindful of his conclusions that disclosure of the withheld information would have caused actual prejudice to the commercial interests of GSK. He believes that there is a strong public interest in avoiding unwarranted prejudice to the commercial interests of third parties, in this case GSK. As he has found that disclosure of the withheld information in this case would cause actual prejudice, he finds the public interest in avoiding this prejudice (by maintaining the exemption) particularly weighty.
- 47. In particular the Commissioner has again noted the limited nature of competition in the HPV vaccine market. He does not believe that it is in the public interest to give one of the competitors in that market an unfair advantage over the other.

Balance of the public interest arguments

- 48. In balancing the public interest arguments in this case the Commissioner has been particularly mindful that he has found that disclosure of the withheld information would cause actual prejudice to the commercial interests of a third party (GSK).
- 49. Whilst the Commissioner believes that the arguments in favour of accountability and transparency are particularly strong in situations involving the spending of large amounts of public money, this has to be weighed against the public interest in avoiding any unwarranted prejudice to the commercial interests of a private company. In this case the company was actively engaged in tendering for another HPV vaccine contract, and the Commissioner believes that the disclosure of the withheld information at the time of the request would have given a significant advantage to the third party's only competitor in that tender. He finds the argument that it is in the public interest to avoid such an unwarranted prejudice particularly weighty.
- 50. The DoH has argued that a lot of information has already been put into the public domain in order to inform public debate as to its choice of vaccine, and that this has promoted accountability. It has also argued



that it is itself accountable under the procurement process, as set out in the Public Contracts Regulations 2006. Furthermore, it has stated that,

"...taxpayers knew in July 2008 that the actual contract value was substantially lower than the maximum contract value at list price, as procurement savings were described as allowing the extension of the HPV vaccination programme to an additional 300,000 girls. Information in the public domain also included the award criteria and weighting system."

Therefore, the DoH has argued that the public interest in increasing the accountability in the spending of public money has already been somewhat satisfied.

- 51. The Commissioner recognises that there is already a lot of information in the public domain about the process during which the decision to award the contract to GSK was made. In addition to this, although he has acknowledged that there is a public interest in helping inform the debate about this decision, the Commissioner also believes that the effect that the disclosure of the withheld information would have on this public interest factor would be limited. The complainant has argued that it is in the public interest to establish whether the decision to award the contract to GSK was based on value for money, rather than the overall benefits of that company's vaccine over its competitors' vaccine. However, although the catalogue/list prices of these two vaccines are in the public domain, the discounted price offered by the other manufacturer to the DoH is not. Without this additional information the Commissioner believes that even if the withheld information were to be disclosed, it would be difficult to establish whether the decision to award the contract to GSK had been made primarily for financial reasons. Therefore, whilst the Commissioner believes that the disclosure of the withheld information would increase transparency and help inform public debate, that beneficial effect would be somewhat limited.
- 52. After considering these points the Commissioner has decided that the public interest in disclosure is outweighed by the public interest in maintaining the exemption. Therefore the withheld information should not be disclosed.
- 53. As the Commissioner has decided that the information should be withheld because of the prejudicial effect to the commercial interests of

⁶ For example, the award criteria for the HPV vaccine tendering process can be viewed at, http://www.immunisation.nhs.uk/files/HPV_tendering.pdf



GSK he has not gone on to consider the DoH's arguments in relation to its own commercial interests, or those of other NHS bodies.

Section 41

54. As the Commissioner has decided that the withheld information is exempt from disclosure under section 43(2) he has not gone on to consider the DoH's application of section 41.

Section 44

55. As the Commissioner has decided that the withheld information is exempt from disclosure under section 43(2) he has not gone on to consider the DoH's application of section 44.

Procedural Requirements

Section 17

- 56. The Commissioner has also considered whether the DoH met with the requirements of section 17. Section 17(1) requires a public authority, which is relying upon an exemption in order to withhold requested information, to issue a refusal notice within the time for complying with section 1(1) (e.g. within twenty working days of receipt of the request), which
 - (a) states that fact,
 - (b) specifies the exemption in question, and
 - (c) states (if that would not otherwise be apparent) why the exemption applies.
- 57. During the course of the investigation the DoH informed the Commissioner that it believed that the withheld information was also exempt from disclosure under sections 41 and 44. This had not been previously reported to the complainant by the DoH. In failing to do this the Commissioner believes that the DoH did not comply with section 17(1)(b) and (c).
- 58. The full text of section 17 can be found in the Legal Annex at the end of this Notice.



The Decision

59. The Commissioner's decision is that the DoH dealt with the request in accordance with the requirements of the Act in that it correctly withheld the requested information under section 43(2).

60. However, the Commissioner has decided that the DoH failed to meet the requirements of section 17(1)(b) and (c) in that it failed to notify the complainant that it was also seeking to rely upon sections 41 and 44.

Other matters

61. Although they do not form part of this Decision Notice the Commissioner wishes to highlight the following matters of concern:

<u>Late introduction of exemptions</u>

- 62. As detailed in the decision of the Tribunal in *Bowbrick v Information Commissioner & Nottingham City Council* [EA/2005/0006] the fact that an exemption is introduced after the initial refusal does not in itself disentitle an authority from relying upon it. ⁷ However, as detailed in 'The Decision' section of this Notice, the Commissioner would inevitably find that the authority had breached the requirements of section 17 by failing to inform the applicant of the exemption it sought to rely on within the appropriate timescale. In effect, the authority would be providing part of its refusal notice too late.
- 63. Furthermore, the application of an alternative or additional exemption at a late stage may suggest the initial refusal or internal review (or possibly both) was not afforded appropriate consideration.
- 64. In light of this the Commissioner expects the DoH to take steps to minimise the likelihood of additional exemptions being applied during the course of future investigations.

Time for internal review

65. Part VI of the section 45 Code of Practice makes it desirable practice that a public authority should have a procedure in place for dealing with complaints about its handling of requests for information, and that

⁷ Available at http://www.informationtribunal.gov.uk/DBFiles/Decision/i26/Bowbrick.pdf



the procedure should encourage a prompt determination of the complaint. As he has made clear in his 'Good Practice Guidance No 5', published in February 2007, the Commissioner considers that these internal reviews should be completed as promptly as possible.

66. While no explicit timescale is laid down by the Act, the Commissioner has decided that a reasonable time for completing an internal review is 20 working days from the date of the request for review. In exceptional circumstances it may be reasonable to take longer but in no case should the time taken exceed 40 working days. The Commissioner is concerned that in this case, it took over 60 working days for an internal review to be completed, despite the publication of his guidance on the matter.



Right of Appeal

67. Either party has the right to appeal against this Decision Notice to the First-tier Tribunal (Information Rights). Information about the appeals process may be obtained from:

First-tier Tribunal (Information Rights) GRC & GRP Tribunals, PO Box 9300, Arnhem House, 31, Waterloo Way, LEICESTER, LE1 8DJ

Tel: 0845 600 0877 Fax: 0116 249 4253

Email: <u>informationtribunal@tribunals.gsi.gov.uk</u>.

Website: www.informationtribunal.gov.uk

If you wish to appeal against a decision notice, you can obtain information on how to appeal along with the relevant forms from the Information Tribunal website.

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

Dated the 18th day of May 2010

Signed	•••••	• • • •	• • • •	• • • •	• • •	• • • •	• • •	• • •	• • •	• • •	• • •	• •	• • •	•••	•••	٠.	• •	٠.	•

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Legal Annex

Section 17

- (1) A public authority which, in relation to any request for information, is to any extent relying on a claim that any provision of Part II relating to the duty to confirm or deny is relevant to the request or on a claim that information is exempt information must, within the time for complying with section 1(1), give the applicant a notice which -
 - (a) states that fact,
 - (b) specifies the exemption in question, and
 - (c) states (if that would not otherwise be apparent) why the exemption applies.

(2) Where-

- (a) in relation to any request for information, a public authority is, as respects any information, relying on a claim-
 - (i) that any provision of part II which relates to the duty to confirm or deny and is not specified in section 2(3) is relevant to the request, or
 - (ii) that the information is exempt information only by virtue of a provision not specified in section 2(3), and
- (b) at the time when the notice under subsection (1) is given to the applicant, the public authority (or, in a case falling within section 66(3) or (4), the responsible authority) has not yet reached a decision as to the application of subsection (1)(b) or (2)(b) of section 2,

the notice under subsection (1) must indicate that no decision as to the application of that provision has yet been reached and must contain an estimate of the date by which the authority expects that such a decision will have been reached.

- (3) A public authority which, in relation to any request for information, is to any extent relying on a claim that subsection (1)(b) or (2)(b) of section 2 applies must, either in the notice under subsection (1) or in a separate notice given within such time as is reasonable in the circumstances, state the reasons for claiming -
 - (a) that, in all the circumstances of the case, the public interest in maintaining the exclusion of the duty to confirm or deny



- outweighs the public interest in disclosing whether the authority holds the information, or
- (b) that, in all the circumstances of the case, the public interest in maintaining the exemption outweighs the public interest in disclosing the information."
- (4) A public authority is not obliged to make a statement under subsection (1)(c) or (3) if, or to the extent that, the statement would involve the disclosure of information which would itself be exempt information.
- (5) A public authority which, in relation to any request for information, is relying on a claim that section 12 or 14 applies must, within the time for complying with section 1(1), give the applicant a notice stating that fact.
- (6) Subsection (5) does not apply where -
 - (a) the public authority is relying on a claim that section 14 applies,
 - (b) the authority has given the applicant a notice, in relation to a previous request for information, stating that it is relying on such a claim, and
 - (c) it would in all the circumstances be unreasonable to expect the authority to serve a further notice under subsection (5) in relation to the current request.
- (7) A notice under section (1), (3) or (5) must
 - (a) contain particulars of any procedure provided by the public authority for dealing with complaints about the handling of requests for information or state that the authority does not provide such a procedure, and
 - (b) contain particulars of the right conferred by section 50.

Section 43

- (1) Information is exempt information if it constitutes a trade secret.
- (2) Information is exempt information if its disclosure under this Act would, or would be likely to, prejudice the commercial interests of any person (including the public authority holding it).
- (3) The duty to confirm or deny does not arise if, or to the extent that, compliance with section 1(1)(a) would, or would be likely to, prejudice the interests mentioned in subsection (2).