

Freedom of Information Act 2000 (FOIA)

Decision notice

Date: 27 January 2020

Public Authority: Department of Health and Social Care
Address: 39 Victoria Street
London
SW1H 0EU

Decision (including any steps ordered)

1. The complainant has requested information from the Department of Health and Social Care ("DHSC") about the reimbursement prices of bicalutamide 50mg tablets in the April 2018 drug tariff and details about the manufacturers and wholesalers that provided information. The DHSC originally refused to provide the information by citing section 12 but, after a previous decision of the Commissioner's ordered a fresh response, the DHSC withheld the information under section 41(1) (information provided in confidence) and section 43(2)(commercial interests).
 2. The Commissioner's decision is that the DHSC has correctly withheld the information under section 41(1) and section 43(2) of the FOIA.
 3. The Commissioner does not require the DHSC to take any steps.
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Request and response

4. On 3 May 2018 the complainant made the following request for information under the FOIA:

"Under the Freedom of Information Act 2000, please provide me with the following information:

 1. *What information and data has been used to calculate the current reimbursement price for bicalutamide 50mg tablets, which is in the April 2018 Drug Tariff as Category M at a value of £2.20.*

Please provide:

 - 1(a). *Details of manufacturers that supplied information, including the information they provided and the dates upon and for which this information was provided*
 - 1(b). *Details of wholesalers that supplied information, including the information they provided and the dates upon and for which this information was provided*
 - 1(c). *The data and calculation upon which the reimbursement price was determined'*
 2. *Please provide details of the manufacturers who provide data for the quarterly revision of Category M prices under the voluntary Scheme M which is backed by section 261 of the National Health Service Act 2006*
 3. *Please provide details of the wholesalers who provide data for the quarterly revision of Category M prices under the voluntary Scheme W which is backed by section 261 of the National Health Service Act 2006"*
5. The DHSC responded on 1 June 2018 and refused to provide the requested information citing the following FOIA exemption – section 43(2)(commercial interests).
6. The complainant asked for an internal review on 6 June 2018. Despite several reminders, the DHSC did not provide an internal review to the complainant until 21 March 2019 when it stated that it was amending its position from section 43(2) to section 12(1).
7. The Commissioner did not accept the application of section 12 and in the decision notice that followed, FS50787920¹, the DHSC was ordered to issue a fresh response that did not rely on section 12.
8. The DHSC responded in the alternative on 21 May 2019 citing section 41(1) (information provided in confidence) and section 43(2)

¹ <https://ico.org.uk/media/action-weve-taken/decision-notices/2019/2614828/fs50787920.pdf>

(commercial interests) to all the information, except that highlighted in the next paragraph.

9. The information requested at point 1(c) was refused solely under section 43(2).

Scope of the case

10. The Commissioner considers that the scope of this complaint is the DHSC's application of section 41(1) and section 43(2) to the requested information.

Background

11. The majority of the following background information is from the DHSC's internal review. The reimbursement price is what pharmacy contractors are reimbursed for the medicines they dispense against NHS prescriptions and these prices are set out in the Drug Tariff and published monthly. The price is set by the Secretary of State for Health using the information provided, in confidence, by the manufacturers and the wholesalers. Pharmacies are required to dispense even if they make a loss on the transaction.
12. The Drug Tariff is produced by the National Health Service Business Services Authority (NHSBSA) on behalf of the DHSC. The Drug Tariff² outlines what will be paid to pharmacy contractors and this includes the reimbursement paid to them for generic medicines. Reimbursement falls under three categories - A, C and M.
13. Scheme M was a voluntary agreement negotiated between the DHSC and the British Generics Manufacturers Association which is the representative body of generic manufacturers. At the time of the request, bicalutamide 50mg tablets were in Category M and readily available as a generic. The reimbursement price was calculated based on pricing information submitted by manufacturers under a voluntary agreement that set out the role and responsibilities of the DHSC and the

² <https://www.nhsbsa.nhs.uk/pharmacies-gp-practices-and-appliance-contractors/drug-tariff/back-copies-drug-tariff>

generics industry in collecting data to inform Category M pricing reimbursement. Category M reimbursement prices usually change on a quarterly basis.

14. Scheme W was a parallel voluntary agreement between the DHSC and the representative bodies of pharmaceutical wholesalers.
15. Category M reimbursement prices are set using volume and sales data (net of discounts and rebates) provided by Scheme M members. Scheme W data is used to verify Scheme M data. Where data is not received from manufacturers it can be determined by information from wholesalers. Scheme W expired on 31 December 2018 and Scheme M on 30 June 2019.
16. The Health Service Products (Provision and Disclosure of Information) Regulations 2018 have made it a mandatory requirement (from 1 July 2018, subject to transitional arrangements) for this data to be provided to the DHSC by the manufacturers and wholesalers. Members of Scheme M now supply information under the regulations because the scheme has expired.
17. The data used to set reimbursement prices and concessionary prices is provided by manufacturers and wholesalers under voluntary arrangements that state that the information will remain confidential to the DHSC and the company providing the information. Documentation on these schemes is publicly available on The National Archives website and the NHSBSA website.
18. The type of information collected under both schemes is income generated for each generic medicine by strength, pack size, volume, and trade price lists. However, the DHSC states that there is no publicly available information released by the DHSC on the sale price charged by the wholesalers or manufacturers, the reimbursement prices or how concessionary prices are arrived at. Manufacturers and wholesalers may, however, publish their own price lists.
19. Under point 1(a) the DHSC stated to the complainant that it was withholding the information under sections 41 and 43. It explained that the DHSC held information about the dates upon which the information was provided. Data submitted under Scheme W is used in verifying Scheme M data. The reimbursement price set for the bicalutamide in the April 2018 Drug Tariff was based on information provided by 26 January 2018 by participating manufacturers. The companies that participated in Scheme M provided information based on October to December 2017 sales data.

20. Under point 1(b) of the request the DHSC stated that it was withholding the information under sections 41 and 43. Companies participating in Scheme W provided information in January 2018 from their sales data between October and December 2017 and that the information regarding bicalutamide 50mg was provided by 1 February 2018.
21. Under points 1(c), 2 and 3 the DHSC stated that it was withholding the information under section 43. The information regarding points 2 and 3 was also withheld under section 41. The DHSC now accepted that the complainant would have been content with a general list of manufacturers and wholesalers participating in Schemes M and W at the time of the request but was withholding it nonetheless.

Reasons for decision

Section 41 – information provided in confidence

22. The Commissioner has gone on to consider whether the DHSC correctly withheld the requested information under section 41(1).
23. Section 41(1) of FOIA provides that –
 - "(a) Information is exempt information if 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."*
24. The Commissioner's advice on section 41 states that
 - "information will be covered by section 41 if –*
it was obtained by the authority from any other person,
its disclosure would constitute a breach of confidence.
*a legal person could bring a court action for that breach of confidence, and that court action would be likely to succeed."*³
25. Section 41 is designed to give those who provide confidential information to public authorities, a degree of assurance that their

³ <https://ico.org.uk/media/for-organisations/documents/1432163/information-provided-in-confidence-section-41.pdf>

confidences will continue to be respected, should the information fall within the scope of an FOIA request.

Was the information obtained from any other person?

26. Section 41(1)(a) states that the information must have been obtained from "*any other person*". The term means a 'legal person'. The Commissioner's guidance explains that this could be an individual, a company, another public authority or any other type of legal entity.
27. The requested information is information provided by third party suppliers (manufacturers and wholesalers) in order that the DHSC could calculate reimbursement prices. The Commissioner accepts that the organisations providing this information are for the purposes of this exemption another person in line with section 41(1)(a).
28. Having established that the withheld information was obtained from another person, the Commissioner must next consider whether or not its disclosure to the public (otherwise than under FOIA), would constitute a breach of confidence 'actionable' by that or any other person.

Would disclosure constitute an actionable claim for breach of confidence?

29. The usual test for section 41 cases is set out in the case of *Coco v Clark* [1969] RPC 41 which sets out three elements that must be present in order that a claim can be made. According to the decision in this case a breach of confidence will be actionable if:
 - the information has the necessary quality of confidence;
 - the information was imparted in circumstances importing an obligation of confidence; and
 - there was an unauthorised use of the information to the detriment of the confider.
30. However, for that claim to be 'actionable' within the meaning of section 41(1)(b) of FOIA, a public authority must establish that an action for breach of confidence would, on the balance of probabilities, succeed.

Does the information have the necessary quality of confidence?

31. In order for information to have the necessary quality of confidence, it must be more than trivial and not otherwise accessible.
32. Bicalutamide is a generic drug which is primarily used in the treatment of prostate cancer. Dispensing contractors are paid for dispensing and providing certain drugs against NHS prescriptions. The Drug Tariff is produced monthly by the NHSBSA for the DHSC though category M

prices generally change quarterly. The Commissioner views the information outlined in the 'background' to this decision notice to be important information as it involves a drug used for a serious condition and is clearly more than trivial.

33. The Commissioner then considered whether the information is otherwise accessible. The reimbursement price is calculated from the information provided by the suppliers. Although the suppliers may well publish their own price lists, the Commissioner accepts that there is no information in the public domain regarding exactly what suppliers and what figures have been provided to the DHSC from which the reimbursement price is arrived at, as it is confidential to the DHSC.
34. The Commissioner therefore accepts that the withheld information has the necessary quality of confidence.

Was the information imparted in circumstances importing an obligation of confidence?

35. To underpin its argument that the requested information is confidential, the DHSC quotes paragraph 25 of Scheme M from March 2010:

"The information submitted to the Department shall remain confidential to the Department and the Scheme member and shall be used for no purpose other than that envisaged in this agreement save with the consent of the Scheme member's specific information or the British Generics Manufacturers Association in respect of aggregated information".

36. The DHSC also quotes paragraph 21 of Scheme W from June 2005:

"The information submitted to the Department will remain confidential to the Department and the Scheme member".

37. The DHSC explains that the arrangements as set out in paragraphs 19-24 of Scheme M and paragraphs 17-20 of Scheme W make it clear that the manufacturers and wholesalers have not agreed that the commercially sensitive information shared with the DHSC can be released outside its policy officials. The exception to this is that paragraph 26 of Scheme M permits disclosure of aggregated information to the British Generics Manufacturers Association.
38. Although the Commissioner is not able to specify, the DHSC has recently explained that some of the information within the scope of the request was not provided under the terms of Scheme M or W but it considers that information to be confidential nonetheless.

39. Files used for the calculation of the Category M tariff are stored in a restricted area of the DHSC shared drive which indicates the high level of security attached to this information. Only a limited number of named analysts (DHSC states six staff at the time of the internal review) in the Medicine and Pharmacy Directorate have access to this drive. Back-up copies are stored outside the DHSC IT system on an encrypted hard drive kept in a secure locked location.
40. The complainant argues that it is irrelevant what commitments the DHSC has given to the providers of the information that it will remain confidential. If the information is disclosable under the FOIA, then these promises have been improperly given by the DHSC.
41. The Commissioner accepts that the information was given with an expectation that confidentiality would be maintained and that the information be stored accordingly.

Would disclosure be detrimental to the confider?

42. The nature of the information is professional rather than personal. Any disclosure has to be assessed against the detriment to the confider's interests which, in this case, are commercial.
43. Firstly, the DHSC addressed point one of the request with regard to its application of section 41:

"What information and data has been used to calculate the current reimbursement price for bicalutamide 50mg tablets, which is in the April 2018 Drug Tariff as Category M at a value of £2.20."

44. The public authority explained to the Commissioner that the data used to set reimbursement prices is provided by manufacturers and wholesalers under voluntary but explicitly confidential arrangements between the DHSC and the companies concerned which had been negotiated with the industry representative bodies. It explains that the information within the scope of the request was shared under "*revised long-term arrangements for reimbursement of generic medicines (Scheme M)*" and "*new long-term arrangements for reimbursement of generic medicines (Scheme W)*"⁴.

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https://webarchive.nationalarchives.gov.uk/20130123204650/http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4114370

45. The DHSC explains that since July 2018, subject to transitional provisions, information to set reimbursement prices has been provided to the DHSC under *The Health Service Products (Provision and Disclosure of Information) Regulations 2018*. All the information within the scope of the request, however, was prior to this and was provided under schemes M and W. The DHSC lists examples of the information collected under these schemes – income generated for each generic medicine by strength, pack size, volume and trade price lists. The full extent of information that the DHSC can obtain from the manufacturers and wholesalers is contained in the relevant provisions of schemes M and W.
46. The DHSC acknowledges that manufacturers and wholesalers may choose to publish their own price lists and other information but that the DHSC does not release information on the sale price charged as a result of the information it is supplied with under schemes M and W. The DHSC provided links as to how this information is used as part of determining reimbursement prices⁵. Paragraph six of the side letter states that the British Generics Manufacturers Association will treat any information received under the scheme as commercially confidential. The DHSC considers that disclosing the requested information would constitute a breach of confidence. It argues that the information has the necessary quality of confidence and that disclosing it would be an unauthorised use and that any such disclosure would be a disclosure to the public.
47. The DHSC further contends that any such disclosure would be, or is likely to be detrimental to the manufacturers and wholesalers that submitted information to it. Releasing the information would alert their competitors and customers to their position in the market. The DHSC maintains that, although the information was a year old at the point the review was provided, the release of the information could still damage the commercial and reputational interests of suppliers for the following reasons:

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https://webarchive.nationalarchives.gov.uk/20130123201658/http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_115260

and

<https://www.nhsbsa.nhs.uk/pharmacies-gp-practices-and-appliance-contractors/drug-tariff>

- competitors may gain valuable information about the marketing strategies and prices of other participants in the market;
 - the information could be valuable to potential new entrants to the market who will be able to set their prices with more certainty; and
 - the information could be valuable to existing suppliers to the market, who can use the information to undercut the prices of competitors and attract customers away from competitors.
48. The DHSC went on to argue that commercial detriment could also follow if the information was released, as customers could gain valuable information about the marketing strategies and prices of the suppliers to the market which could enable them to negotiate lower prices with existing suppliers or new suppliers.
49. The DHSC categorises the risks to wholesalers and suppliers as both commercial and reputational and state that reputational risks could potentially become commercial risks.
50. The complainant points out that the Association of the British Pharmaceutical Industry listed manufacturers who were voluntary Pharmaceutical Pricing Regulation Scheme members. This request asks for details of the manufacturers and wholesalers who are providing pricing information to the DHSC and the complainant can see no issue in the public authority responding to that element.
51. The complainant also queries the detriment to the suppliers in releasing pricing information as the major wholesalers who may provide information to the DHSC are owned by the same company as a major pharmacy chain. Alliance Healthcare is owned by the same company as Boots; AAH is owned by the same company as Lloyds pharmacy; Phoenix is owned by the same company as Rowlands pharmacy. The complainant states that these three companies together supply 79% of medicines to the NHS. Each of these companies could easily find out the price that the other wholesalers are charging, because each of the pharmacies will have an account with each of the wholesalers and access to the price list, unlike the public.
52. The complainant challenges the DHSC's argument that manufacturers and wholesalers might not disclose the information it requires to set reimbursement prices. Providing this information is now mandatory and suppliers would know that the DHSC could set lower reimbursement prices to control the costs to the public which would not be in their interests.

53. The Commissioner accepts that this information is now mandatory and that for that reason it may well be easier to compare prices by obtaining published lists, however, the Commissioner is only considering the situation at the time of the request where the information was voluntary and it was unknown exactly who provided this information. She accepts therefore that the release of this information could be detrimental to the confider.

Is there a public interest defence for disclosure?

54. As section 41 is an absolute exemption there is no requirement for an application of the conventional public interest test. However, disclosure of confidential information where there is an overriding public interest is a defence to an action for breach of confidentiality.

55. The Commissioner's guidance on section 41 states that case law on the common law duty of confidence won't succeed and consequently won't be actionable in circumstances where the public authority (in this instance, the DHSC) can rely on a public interest defence.

56. Recent case law (albeit concerning the Human Rights Act) means that it no longer has to be an exceptional case to override the duty of confidence and developments around the law of confidence have meant that the public interest test has been modified into a test of proportionality.

57. Generally when the Commissioner assesses the public interest test for qualified exemptions, the public interest in favour of disclosure has to be outweighed by the public interest in maintaining whatever exemption is in question. In other words, the default position is to disclose unless the public interest in non-disclosure outweighs it. The test in the case of section 41 though is the reverse and the public interest in disclosure has to outweigh the public interest in maintaining the duty of confidence.

58. As explained earlier, when she is considering section 41 the Commissioner is not setting out the public interest test in the normal way she would when the exemption is qualified. However, the Commissioner does need to consider if there is a public interest defence that would outweigh the need to maintain the confidentiality of this information.

59. The complainant has provided lengthy and detailed public interest arguments which cannot all be reproduced here. The main arguments are as follows:

- The information requested is about how the government sets the prices of medicines paid for by the public from the drugs budget

(£18.2 billion annually) and disclosure would enable better scrutiny, involvement and influence over the DHSC's decision-making process.

- The complainant states that one of the aims of the information request is to establish as fact which wholesalers are providing information to the DHSC. This information is unknown despite three companies supplying 79% of the public's medicines in the UK.
 - It would ensure the process for reimbursing medicines purchases was open and transparent which may result in cost decreases.
 - It would help to ensure clarity around fairness, equity, value for money and quality of care in the process of setting medicine prices which are paid for by the public and are the subject of significant public concern.
 - Disclosure could lead to better value for money through better price control. The annual hospital drug spend has increased by £2.47 billion in the three years to 2017/18. The complainant argues that, although the reasons are unknown, this figure arguably demonstrates inadequate control by the DHSC on escalating drug prices. The requested information would show whether or not the price paid by the NHS for a specific drug during a specific timeframe was appropriate.
60. The Commissioner considers that the complainant's main public interest arguments for disclosing this information is greater transparency with the potential that this may lead to better value for money. However, the complainant also suggests that disclosure would not set a precedent as it relates only to one medicine at a specified period which it is in the public interest to disclose because of the circumstances and what the complainant characterises as unusual pricing activity.
61. The complainant underlines the fact that manufacturers and wholesalers have been required by legislation to provide information about drugs pricing to the DHSC since July 2018. The Secretary of State is entitled to that information by law. Therefore, the provision of the information in response to this FOI request, which predates the introduction of that legal requirement, would have no effect on the Secretary of State's ability to acquire the information he or she now receives. It would have no effect on the Secretary of State's ability to set reimbursement or concessionary prices reflecting market prices.
62. The DHSC accepts that there are factors that could provide a public interest in favour of disclosing the requested information such as

transparency in how much the DHSC reimburses pharmacy contractors compared to the medicine prices charged by suppliers. Any negative impact on suppliers could benefit the public in the form of increased competition by new suppliers entering the market which could lower the cost reimbursed by the DHSC to pharmacy contractors.

63. However, the DHSC's view is that these factors that might form a public interest defence for disclosure do not outweigh those in maintaining confidentiality. The DHSC's opinion is that the data used to determine reimbursement prices within the Drug Tariff is commercially sensitive and subject to an obligation of confidence to the manufacturers and wholesalers. It believes that release of the information is likely to be met with significant claims against the DHSC and the consequent diversion of public funds.
64. Disclosure could lead to prices being undercut, the loss of customers, the need to negotiate lower prices, or even the withdrawal of products from the market to the potential detriment of patients.
65. Since 1 July 2018 (subject to transitional arrangements) the provision of this type of information is now statutory and protected by a duty of confidentiality. The DHSC suggests that it would be surprising if information under an older voluntary scheme could be disclosed on public interest grounds.
66. The DHSC suggests that disclosure could impact on the Secretary of State's ability to properly perform his functions by setting reimbursement prices that truly reflect market prices in accordance with section 164 and the 2013 regulations. The DHSC goes on to say that if it disclosed information it would be detrimental to its reputation and raise questions about whether it understands the commercially sensitive nature of the data shared. Distrust could lead to the supply chain resisting and not sharing this information, despite the fact that it is now a statutory requirement to do so. A breach of the regulations might lead to formal action which would delay setting reimbursement prices and cost time and resources. Potentially, companies may also withdraw products from the market.
67. The public authority then speculates on the possible wider effects. Suppliers share supply chain information which supports the DHSC's management and mitigation of the impact of medicines supply problems. Patients could then be affected by lack of access to medicines and/or increased costs in finding alternative treatments.
68. The DHSC concludes by stating that it considers that it would not have a public interest defence for disclosure and, as such, a court action brought by suppliers would be likely to succeed.

69. Many of the arguments the DHSC has put forward have been questioned by the complainant, such as the withdrawal of products from the market. The complainant states that this is more likely to lead to another manufacturer supplying it at a lower price which is in the public interest. The Commissioner is also not persuaded by the more tenuous examples set out in paragraphs 66 and 67 where potential scenarios of suppliers not complying with the law are outlined.
70. However, the DHSC provided various pieces of supporting evidence for its views to the Commissioner, one being a report⁶ which had been commissioned by the BGMA "on the supply of generic medicines in the UK to inform whether the existing market and regulatory mechanisms are appropriate in the current context". The Commissioner notes that the Oxera Report concluded that the reimbursement framework incentivises strong competition among different manufacturers of a specific product. The report explains that *"the same level of reimbursement price applies irrespective of the cost of procurement of the specific medicines for the pharmacy at a specific point of time"*. It further explains that *"given a Drug Tariff price at any point of time, the lower the Price to Pharmacy offered on a specific product, the higher the revenues of the pharmacy and the higher the incentive to dispense that specific product"*. The implication is that *"when faced with an open prescription for a particular molecule, the pharmacy has the incentive to dispense the product with the lowest Price to Pharmacy"*. The report states that this drives competition between the various suppliers of branded and generic versions of that product. It acknowledges that the extent of competition varies according to the type of pharmacy and other factors however *"the reimbursement mechanisms set up by the DHSC provide an ongoing incentive for price competition"* (paragraphs 2.32 to 2.35).
71. The Commissioner does not accept some of the DHSC's speculations about what could result from the release of this information. The complainant emphasises that the information is for one drug within a specific timeframe and does not set a precedent but that there is a significant public interest in establishing whether the reimbursement price was appropriate. However, the Commissioner has concluded that the limited nature of the request and whether its release would establish anything beyond the reimbursement price being appropriate regarding one drug for a particular period of time is insufficient to warrant ordering

⁶ <https://www.oxera.com/wp-content/uploads/2019/06/Oxera-study-on-the-supply-of-generic-medicines-in-the-UK-26-June-2019.pdf>

disclosure. At the time of the request the information was provided voluntarily and all the suppliers were promised confidentiality. Having carefully taken into account the many arguments put forward by the complainant for the release of this information, the Commissioner has concluded that the public interest defence is not strong enough to warrant disclosure.

72. As the Commissioner has decided that the requested information that has been withheld under section 41 should not be disclosed, she has not gone on to consider section 43(2) except regarding point 1(c).

Section 43 – commercial interests

73. As stated earlier in this decision notice, the DHSC cited sections 43(2) and 41(1) regarding all the requested information with the exception of point 1(c) of the request where it solely applied section 43(2) to the calculation upon which the reimbursement price was determined. It explained that additional data that is also used as part of calculating the reimbursement price involves the use of Prescription Costs Analysis data⁷ which is incorporated into a calculation.
74. The calculation depends on the insertion of figures representing key components of the calculation. In the review the DHSC referred to these as “alpha” and “gamma”. The average manufacturer selling price is also used in the calculation and this is provided by the manufacturers. The DHSC contends that if it disclosed what “alpha” and “gamma” were it would allow any company to calculate the average manufacturer selling price for any Category M product in the Tariff, not just bicalutamide. The public authority was, however, content to disclose the calculation formula “Gamma x Average Price + Alpha”.
75. Section 43(2) of the FOIA states that information is exempt if its disclosure would, or would be likely to, prejudice the commercial interests of any person, including the public authority holding it.
76. The Commissioner has defined the meaning of the term “commercial interests” in her guidance on the application of section 43 as follows:

“...a commercial interest relates to a person’s ability to participate competitively in a commercial activity”⁸

⁷ <https://www.nhsbsa.nhs.uk/prescription-data/dispensing-data/prescription-cost-analysis-pca-data>

⁸ <https://ico.org.uk/media/for-organisations/documents/1178/commercial-interests-section-43-foia-guidance.pdf>

Most commercial activity relates to the purchase and sale of goods but it also extends to other fields such as services. The prejudice can be to the commercial interests of any person (an individual, a company, the public authority itself or any other legal entity).

77. The exemption is subject to the public interest test which means that, even if it is engaged, the Commissioner needs to assess whether it is in the public interest to release the information.
78. In order for section 43(2) to be engaged the Commissioner considers that three criteria must be met:
- Firstly, the actual harm that the public authority alleges would or would be likely to occur if the withheld information was disclosed has to relate to commercial interests.
 - Secondly, the public authority must be able to demonstrate that some causal relationship exists between the potential disclosure of the information being withheld and the prejudice which the exemption is designed to protect. Any prejudice that results must also be real, actual or of substance.
 - Thirdly, there is a need to establish whether the level of likelihood of prejudice being relied upon by the public authority is met, whether disclosure would or would be likely to result in prejudice or there is a real and significant risk of the prejudice occurring.⁹
79. The DHSC argues that the release of the key components of the calculation would, or would be likely to, prejudice its own commercial interests. The DHSC sets the Drug Tariff in accordance with the provisions of section 164 of the National Health Service Act 2006 and the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013. The regulations set out what the DHSC may refer to in determining the price but they do not set out the calculation.

⁹ <https://ico.org.uk/media/for-organisations/documents/1178/commercial-interests-section-43-foia-guidance.pdf>

80. The public authority explains that it keeps the meaning of alpha and gamma protected by the same internal security restrictions and ¹⁰safeguards as set out in paragraph 39.
81. The DHSC has an interest in the smooth running of all elements of the scheme for determining reimbursement prices within the Drug Tariff. It contends that this underpins the smooth operation of the NHS to the benefit of the public. It lists the objectives of the scheme as follows:
- Maintain/improve the quality of service to patients in the community;
 - Transparent operation of the generic medicines market;
 - Promote a competitive pharmaceutical market;
 - Secure value for money for the NHS;
 - Ensure the arrangements work well in light of the characteristics of the supply chain;
 - Ensuring that the cost and complexity of arrangements for the supply of generic medicines to the NHS is not disproportionate to public finances or a disproportionate burden on companies; and
 - Contribute to the efficient and sustainable working of the generic medicines market.
82. The DHSC argues that its interests are in securing value for money for the NHS. This relies on the smooth operation of all aspects of the system for the setting of reimbursement prices, which it considers to be commercial interests.
83. The DHSC's view is that the disclosure of the calculation including what "alpha" and "gamma" are, risks giving any company a commercial advantage. It claims that the information could be used to calculate the average manufacturer selling price for any medicine in the Drug Tariff, not just bicalutamide. The DHSC presents a scenario where a company is aware that there is one main competitor for their product and knowing the average manufacturer selling price would give them information about their competitor's selling price. Companies would also have a clearer idea of the exact link between their selling price and how this translates into a reimbursement price when the calculation is applied. They could change their pricing strategy based on this information, attaining a higher reimbursement price leading to increased costs to the taxpayer and the NHS.
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84. The wider implications from the release of information that could allow any company to calculate any manufacturer average selling price could have an adverse impact on the DHSC's commercial interests. Companies could withdraw from the market in a protest at the negative impact upon their commercial interests which would be likely to prejudice the DHSC's ability to set reimbursement prices that truly reflect market prices. Disclosing information about this calculation potentially discloses information about how all Category M reimbursement prices are calculated in the Tariff. The DHSC acknowledges that the data from companies is now mandatory and action can be taken, if that data is not provided, disclosure would still negatively impact on its functions. There would be likely to be costs and time spent in dealing with delays or failures in sending data when promptness is required to fairly set reimbursement prices that reflect market prices.
85. The DHSC again argues as it did with section 41 that manufacturers and wholesalers could withdraw from the market to the detriment of patients as it could lead to reduced competition and higher prices for taxpayers.
86. The Commissioner also accepts that there is a causal relationship between the potential disclosure of the requested information and the prejudice that this exemption is designed to protect, therefore the second criterion is met.
87. Finally, the Commissioner needs to establish whether the level of likelihood of prejudice that is being relied upon by the DHSC is met. To meet the lower threshold of "would be likely to" result in prejudice, the Commissioner considers that the chance of prejudice occurring must be more than a hypothetical possibility; there must be a real and significant risk.¹¹ Regarding the higher threshold, there must be a stronger evidential burden on the public authority and prejudice must be more likely than not.
88. The public authority has not explicitly claimed the higher threshold or the lower threshold but it is clear from its submission that its arguments are set at the lower bar. The Commissioner considers that the disclosure of this information "would be likely to prejudice" the DHSC's commercial interests because the release of the requested information is likely to be used by its commercial competitors to its detriment and consequently affect its future commercial prospects when setting reimbursement

¹¹ The Information Tribunal in *John Connor Press Associates Limited v The Information Commissioner* (EA/2005/0005, paragraph 15)

prices. The third criterion has therefore been met and the exemption is engaged.

89. Although the Commissioner accepts that the exemption is engaged, it is necessary for her to go on to consider whether the public interest favours maintaining the exemption or disclosing the requested information.

Public interest arguments in favour of disclosure

90. The complainant points out that the DHSC's arguments are very similar to those it presented for section 41 and consequently the complainant's views on disclosure are the same as for section 41. However, on the specific point of the calculation, the complainant suggests that it is a simple matter of multiplication which, if disclosed, would be likely to lead to lower reimbursement prices rather than higher.
91. More generally, if the objectives of the DHSC for Scheme M and Scheme W are as set out in paragraph 81, there is a public interest in knowing how these schemes are working. The complainant suggests that the increase in expenditure, as previously outlined, may mean that objectives are not being met. The complainant argues that some of the DHSC's arguments are far-fetched and that the public authority seems to be simultaneously arguing that it is protecting prices to preserve market competition whilst arguing that market competition would increase NHS costs.
92. The complainant asserts that the lack of transparency over the pricing mechanism is not in the public interest because it effectively means that the DHSC could be "held to ransom" by suppliers able to charge any price they wished.
93. The DHSC acknowledges that there is a public interest in transparency and openness in the way the reimbursement price is calculated and the way it reimburses pharmacy contractors. Releasing the calculation may benefit the public in the form of increased competition as there would be the potential for new entrants to gain entry to the market with more certainty and cheaper prices. New suppliers would potentially lower the cost reimbursed by the DHSC to pharmacy contractors.

Public interest arguments in favour of maintaining the exemption

94. However, the DHSC maintains that losing the commercial confidentiality of the calculation for setting reimbursement prices is likely to have an adverse impact on the smooth running of the scheme which it has responsibility for, as explained earlier in this decision notice.

95. The DHSC highlights the potential impact on the Secretary of State to properly perform their function in setting reimbursement prices that reflect market prices. If these prices are set too high it goes against the public interest to secure value for money, if too low pharmacies will make a loss on individual transactions which they cannot recover. The ability to set reimbursement prices is intended to mitigate this and ensure a smooth running system.
96. The complainant disputes this point stating that the Category M retained margin system allows community pharmacies to retain an agreed £800 million each year from the purchase of these medicines. Pharmacies might have to be reimbursed more or less than previously but the adjustment is designed to hold the reimbursement profit at £800 million.
97. The DHSC suggests that there are wider implications in that the supply chain information is voluntary. If the manufacturers did not provide this information due to distrust from the release of commercially prejudicial information such as that requested, this could affect patients if it impacted on the DHSC's ability to manage and mitigate medicine supply problems.

Balance of the public interest arguments

98. The Commissioner agrees with the complainant that there is some inconsistency in the DHSC's position. Nevertheless in the matter of the detailed components of the calculation, the potential consequences that might ensue to the DHSC and its commercial interests are difficult to calibrate. Any possibility of manipulation resulting from disclosure has the potential to lead to unknown financial consequences, positive or negative. To the extent that there could be increased costs to the DHSC and, ultimately, the NHS then release is clearly not in the public interest. The Commissioner therefore accepts that disclosing the key components of the calculation is not in the public interest and that the DHSC correctly cited section 43(2) to withhold the information at point 1(c).

Right of appeal

99. 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,
LEICESTER,
LE1 8DJ

Tel: 0300 1234504
Fax: 0870 739 5836
Email: grc@justice.gov.uk
Website: www.justice.gov.uk/tribunals/general-regulatory-chamber

100. 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.

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

Signed

Pamela Clements
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