

Freedom of Information Act 2000 (FOIA)

Decision notice

Date: 16 April 2019

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 and the manufacturers and wholesalers providing data for Category M drugs. The information was initially withheld by the DHSC under section 43(2) commercial interests. At a much later date the internal review cited section 12(1) of the FOIA – the cost of compliance and withdrew its reliance on section 43(2).
2. The Commissioner's decision is that the DHSC has not demonstrated that compliance with the request would exceed the appropriate limit and is therefore not entitled to rely on section 12(1). The DHSC breached section 16 of the FOIA, as it failed to provide the complainant with advice and assistance in order to understand what information the complainant was seeking. The DHSC also failed to comply with section 17(5) in that it did not provide a refusal notice citing its reliance on section 12 within 20 working days of receiving the request.
3. The Commissioner requires the public authority to take the following steps to ensure compliance with the legislation:
 - Issue a fresh response to the request which does not rely on section 12(1) of the Act.

4. The public authority must take these steps within 35 calendar days of the date of this decision notice. Failure to comply may result in the Commissioner making written certification of this fact to the High Court pursuant to section 54 of the Act and may be dealt with as a contempt of court.

Request and response

5. On 3 May 2018, the complainant wrote to the DHSC and requested information in the following terms:

"I am writing to request information under the Freedom of Information Act.

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:

- *Details of manufacturers that supplied information, including the information they provided and the dates upon and for which this information was provided*
- *Details of wholesalers that supplied information, including the information they provided and the dates upon and for which this information was provided*
- *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."

6. The DHSC responded on 1 June 2018 and refused to provide the requested information citing the following FOIA exemption – section 43(2) commercial interests.
7. The complainant asked for an internal review on 6 June 2018.
8. Despite several reminders, the DHSC did not provide an internal review to the complainant until 21 March 2019. It stated that it was amending its position from section 43(2) to section 12(1).
9. The DHSC's response to the Commissioner's investigation is the internal review that was finally provided after her investigation had started. The Commissioner has not been provided with the withheld information

because the DHSC altered its position from section 43(2) to section 12(1) indicating that the information could not be provided within the fees limit.

Background

10. The Commissioner has been provided with most of the following background information by the DHSC. The Drug Tariff is produced by the National Health Service Business Services Authority (NHSBSA) on behalf of the DHSC. The Drug Tariff¹ 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.
11. The term Category M is applied to drugs which are readily available as a generic. The request concerns bicalutamide 50mg tablets which is Category M because it was readily available as a generic and the reimbursement price was calculated based on information provided by manufacturers under a voluntary agreement that set out the role and responsibilities of the DHSC and the generics industry in collecting data to inform Category M pricing reimbursement. Category M reimbursement prices usually change on a quarterly basis.
12. Scheme W was a parallel voluntary agreement between the DHSC and the representative bodies of pharmaceutical wholesalers.
13. 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 will supply information under the regulations after the scheme expires.
14. 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. The reimbursement price is what pharmacy contractors are reimbursed for the medicines they dispense against NHS prescriptions and these prices are published monthly. The price is set by the Secretary of State

¹ www.nhsbsa.nhs.uk/sites/default/files/2019-02/Drug%20Tariff%20March%202019.pdf

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.

15. 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.²
16. 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 or the reimbursement prices or how concessionary prices are arrived at. Manufacturers and wholesalers may, however, publish their own price lists.

Scope of the case

17. The complainant contacted the Commissioner on 20 September 2018 to complain about the way her request for information had been handled. She explained that bicalutamide is a medicine supplied to patients on the NHS and that the prices are determined by the DHSC. The complainant argued that sufficient weight had not been given to the public interest which favours disclosure.
18. The complainant has provided many reasons for disclosure both here and in a related request **FS50790878** but the Commissioner is only able to consider the matter of the fees limit as this is what the DHSC has ultimately applied to the request.
19. The Commissioner considers that the scope of this case is whether the public authority has correctly applied section 12 of the FOIA to this request. She will also consider whether the DHSC complied with its obligations under section 16 to provide advice and assistance to the complainant.

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

Reasons for decision

Section 12

20. Section 12(1) of the FOIA states that:

'(1) Section 1(1) does not oblige a public authority to comply with a request for information if the authority estimates that the cost of complying with the request would exceed the appropriate limit.'

21. The appropriate limit is set in the Freedom of Information and

Data Protection (Appropriate Limit and Fees) Regulations 2004 ('the Fees Regulations'). The appropriate limit is currently £600 for central government departments and £450 for all other public authorities. The Fees Regulations also specify that the cost of complying with a request must be calculated at the rate of £25 per hour. This means that in practical terms there is a time limit of 24 hours or £600 in respect of the DHSC. In estimating whether complying with a request would exceed the appropriate limit, Regulation 4(3) of the Fees Regulations states that an authority can only take into account the costs it reasonably expects to incur during the following processes:

- determining whether it holds the information;
- locating the information, or a document containing it;
- retrieving the information, or a document containing it; and
- extracting the information from a document containing it.

22. A public authority does not have to make a precise calculation of the costs of complying with a request; instead only an estimate is required. However, it must be a reasonable estimate. In accordance with the First-Tier Tribunal in the case of *Randall v IC & Medicines and Healthcare Products Regulatory Agency EA/2007/0004*, the Commissioner considers that any estimate must be '*sensible, realistic and supported by cogent evidence*'³.

³ <http://informationrights.decisions.tribunals.gov.uk/DBFiles/Decision/i136/Randall.pdf> (paragraph 12)

The DHSC's view

Part one of the request

23. The DHSC explained that a search of the Strategic Data Collection Service NHS Digital Collection Portal had been carried out which identified 250 items. It gave what it describes as a reasonable estimate of 10 minutes per item to identify whether each item is within the scope of the request. On this basis it would take a minimum of 41.67 hours to extract the information at a cost of £1041.67, well in excess of the fees limit.

Part two of the request

24. The DHSC stated that exhaustive searches had been carried out of all the areas where information within the scope of the request could be found. These areas were:
- folders on the Department's shared drive;
 - archived folders on an external hard drive not kept on site; and
 - the mailboxes of the relevant policy official, their line manager and the shared generic medicine mailbox.
25. These searches returned 1800 items. Taking a reasonable estimate of 5 minutes per item to identify whether each item is within the scope of the request, would take a minimum of 150 hours at a cost of £3750 to extract the requested information, well in excess of the fees limit.

Part three of the request

26. Again the DHSC stated that exhaustive searches had been carried out of all the areas where information within the scope of the request could be found. These areas were:
- folders on the Department's shared drive;
 - archived folders on an external hard drive not kept on site; and
 - the mailboxes of the relevant policy official, their line manager and the shared generic medicine mailbox.
27. The searches returned 1800 items. Taking a reasonable estimate of 5 minutes per item to identify whether each item is within the scope of the request, would take a minimum of 150 hours at a cost of £3750 to extract the requested information, well in excess of the fees limit.

The complainant's view

28. Firstly, the complainant questions why the DHSC has applied the fees limit so late in the day and suggests that it is surprising that this has not been claimed previously, given the extent by which the cost of meeting the request exceeds the appropriate limit, according to the DHSC's calculations. The complainant argues that the DHSC has changed its reasoning and is seeking to avoid disclosing the information.
29. The view of the complainant is that the DHSC's figures are not an accurate reflection of the costs of meeting the request and that they have been inflated in order to defeat the request rather than to serve public access to information.
30. The complainant argues that the costs are absurd as the requested information is specific and relates only to bicalutamide 50mg tablets and to certain dates. The DHSC calculates reimbursement prices for Category M medicines each quarter. If the DHSC was to spend the figure it has calculated each quarter merely to identify the information it needs to determine the price to charge for each of the relevant medicines in Category M (currently 621) it would be spending what the complainant calculates as £5.4 million each quarter on that task alone.
31. The complainant goes on to say that the figure above has been calculated by the DHSC as the time taken just to locate the information. Given the amount of tasks that would subsequently have to be performed to calculate the reimbursement prices, the complainant questions its efficiency.
32. The complainant's specific argument regarding part one of the request is that the DHSC could have used narrower search terms based on bicalutamide 50mg tablets and the dates requested. Rather than the 10 minutes the DHSC estimated to check each of the 250 items, one minute per record would be appropriate and that software could have been employed to reduce the time to search inside the contents of the files more quickly.
33. Regarding parts two and three of the request, the complainant explained that a general list of manufacturers and wholesalers was sufficient which it was suggested is likely to be held by the DHSC on a spreadsheet or in a database that could be interrogated by its IT team.
34. In summary, the complainant calculated that the entire request could be provided for around £102, as opposed to the £8541.67 the DHSC calculated.
35. The complainant underpins the argument by stating that the request was for prices already used to calculate bicalutamide 50mg tablets which it must already hold in a readily accessible form. In reality, the

complainant believes that the provision of the requested information would be a much simpler task than the DHSC has suggested.

The Commissioner's view

36. Firstly, it would appear that the DHSC hadn't identified the requested information in order to withhold it previously under section 43(2).
37. The disparity between the complainant's calculations and the DHSC's calculations are so marked that there would seem to be a problem either in the interpretation of the scope of the request or the method of calculation or both.
38. The first part of the request asks for the information and data used to calculate the reimbursement price of a specific Category M drug in the April 2018 Drug Tariff. It also asks for "details" of the manufacturers and wholesalers that provided it, the information they provided, the dates and the data and calculation upon which it was determined. Most of this information must be held on a spreadsheet/s and the data and calculation are clearly known by the DHSC, even if they are subject to an exemption. It may be that the word "details" has been interpreted at its broadest involving a trawl of the relevant mail boxes for non-specific information about manufacturers and wholesalers that does not appear to be within the scope of the request. Had the DHSC asked the complainant, this matter could have been clarified. The second and third part of the request seems to have been similarly widened in interpretation, though the most obvious interpretation would seem to be that a list of manufacturers and wholesalers is required which the complainant has confirmed. Any doubt could have been eradicated by communication with the complainant.
39. The speculative calculations provided by the complainant are understandable because they are clearly not in possession of all the facts and the methodology which is why the request was made. However they are based on sound reasoning. The calculations provided by the DHSC seem to the Commissioner to be based either on a misapprehension concerning the request that resulted in it broadening to the extent where it exceeded the fees limit.
40. The Commissioner considers the calculations to be based on far too wide an interpretation of the request. She is not convinced that the majority of this information could not be obtained from existing spreadsheets and therefore the DHSC has not proved that complying with the request would exceed the appropriate limit and cannot rely on section 12(1) of the FOIA.

Section 16 – duty to provide advice and assistance

41. Section 16 of the FOIA states:

"(1) It shall be the duty of a public authority to provide advice and assistance, so far as it would be reasonable to expect the authority to do so, to persons who propose to make, or have made, requests for information to it.

(2) Any public authority which, in relation to the provision of advice or assistance in any case, conforms with the code of practice under section 45 is to be taken to comply with the duty imposed by subsection (1) in relation to that case."

42. The complainant does not accept that the DHSC complied with its duty to provide advice and assistance. The original request invited the DHSC to contact the complainant for clarification at the time, rather than 11 months later.
43. The Commissioner agrees with the complainant. The problem with providing advice and assistance in this instance stems from the commercial prejudice exemption being applied originally and subsequently not relied on at review. It should also be noted that, although the DHSC was not relying on section 43(2), the public authority implied that commercial prejudice might well apply should a refined request be made. As the review was so delayed, any attempt to provide advice and assistance was by then rendered futile.

Section 17(5)

44. Section 17(5) of the Act states:

"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."

45. The DHSC originally withheld the requested information under section 43(2). It did not provide the complainant with a refusal notice stating its reliance solely on section 12 within the statutory timeframe for compliance, consequently it breached section 17(5) of the Act.

Other matters

46. In order to conform with the section 45 Code of Practice, an internal review should take no more than twenty working days to complete and up to a maximum of 40 working days only in exceptional circumstances. The Commissioner considers that it is completely unacceptable that the

DHSC provided its review nine months after it was requested. The Commissioner has previously commented on the DHSC's inability to complete reviews in a timely fashion and the situation has not improved.

Right of appeal

47. 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@hmcts.gsi.gov.uk
Website: www.justice.gov.uk/tribunals/general-regulatory-chamber

48. 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.

49. 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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