Tribunals Service
Information Tribunal

Information Tribunal Appeal Number: EA/2007/0004
Information Commissioner's Ref: FS50088131

Heard in chambers
On 9 October 2007

Decision Promulgated
30 October 2007

BEFORE

Deputy CHAIRMAN

Mr H Forrest

and

LAY MEMBERS

MR H FITZHUGH
MR D WILKINSON

Between

Mrs A Randall

Appellant

and

INFORMATION COMMISSIONER

Respondent

and

Medicines and Healthcare Products Regulatory Agency

Additional Party

Decision

The Tribunal upholds the decision notice dated 28 November 2006 and dismisses the appeal.

Reasons for Decision

Introduction

1. Mrs Randall is in very poor health. She has been obliged to give up her job in the health service, where she had worked for over 30 years, as a result. She believes that her condition is caused by having taken the Hepatitis B vaccine. She is determined that the ill effects of the vaccine should be properly established, not just for her benefit, but so that others may not be similarly afflicted. To this end, she has been seeking information about the vaccine.

The request for information

2. In two letters, on 19 October and 15 November 2005, she asked the Medicines and Healthcare Regulatory Agency (MHRA), an executive agency of the Department of Health for information about the Hepatitis B vaccine, or Engerix B, its trade name. Her requests were for:

    i. Information that SmithKline submitted for licensing the product Engerix B; details of the research SmithKline carried out to declare their product safe; details of any problems found and at what doses;

    ii. Information regarding any recalled batches and batch numbers for the 1980s, 1990s and 2000s.

    iii. Information on the filtration process in the late 1980s and 1990s at the manufacturing plants, and when this was introduced. Information on what particles were known to be filtering through at the time that the vaccine was in use.

    iv. Information relating to a leaflet about the safety of the Hepatitis B vaccine.

    v. Details of the SmithKline public liability insurance.

3. On 5 December 2005, the MHRA wrote to Mrs Randall, in response to requests (i) and (ii), enclosing some information for (i), but stating the MHRA has no record of any recalls, for (ii). The information provided for (i) consisted of three technical Appendices, numbered 4, 5 and 6: 4 contained an independent assessment of the safety data on Engerix B; 5 contained an assessment of the efficacy of the drug in clinical trials; 6 contained a study of the side effects and safety of the drug.

4. Not surprisingly, Mrs Randall asked for more information: where was the main report, to which these were the appendices? Where were the other appendices, 1, 2 and 3? What had happened to her other requests?

The complaint to the Information Commissioner

5. Mrs Randall was dissatisfied with the MHRA's replies. She had first complained to the Information Commissioner (IC) on 6 September 2005. She complained again, and, prompted by the IC, the MRHA conducted an internal review of her requests. Eventually, on 13 June 2006, the MRHA provided Mrs Randall with the information it held in answer to question (iii), on the filtration process, and (iv), about a leaflet that had been issued about the safety of the Hepatitis B vaccine. Mrs Randall was told that the MRHA did not hold any information in answer to (v), details of SmithKline's public liability insurance.

6. In response to request (ii), the MHRA stated that it had no records of any recalls for the years 1988 to 1999, or, having checked the records again, for 2000. In response to the outstanding items in request (i), the MHRA said that it would not disclose further information, relying on section 12 of the Freedom of Information Act (FOIA). In a letter to the IC, of 20 June 2006, it clarified its position in relation to section 12:

> "The information Mrs Randall is now seeking may we believe be contained in the MHRA's archived records. Our records show that the archive contains 25 boxes of documentation that may be relevant to Mrs Randall's request. An average archive box contains 6 or more volumes of papers depending on size, and each volume will typically contain 250 pages. The indexing of the boxes is incomplete, so it would be necessary to go through them all, and the documents contained in them, in order to locate the requested information. To determine whether we hold the information requested by Mrs Randall and to locate and retrieve it would therefore require examining up to 37500 pages of documents. Any redactions necessary to protect exempted material would then have to be made, and copies taken. Although the MHRA has made no precise estimate of the amount of time that this process would take, as it is difficult to arrive at a reasonably exact figure, it is clear to us that it would take considerably in excess of 24 hours, and thus be in breach of the appropriate limit under section 12 of the FOIA.
>
> Due to the incompleteness of the indexing, neither would it be helpful to ask Mrs Randall to refine her request. However Mrs Randall refines her request, the totality of the relevant archive holdings would still need to be searched, and thus the section 12 limit breached."

The Legal Framework

7. Mrs Randall's right to receive the information comes from section 1(1) of FOIA:

(1) Any person making a request for information to a public authority is entitled –

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

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

Section 12 removes these rights if the cost of obtaining and providing the information is too great:

12: 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.

The appropriate limit is defined in the Freedom of Information and Data Protection (Appropriate Limit and Fees) Regulations 2005. Regulation 3 provides:

The appropriate limit

3(1) This regulation has effect to prescribe the appropriate limit referred to in … section 12(1) and (2) of [FOIA].

(2) In the case of a public authority which is listed in Part I of Schedule 1 to [FOIA], the appropriate limit is £600.

Estimating the cost of complying with a request – general

4 (1) This regulation has effect in any case in which a public authority proposes to estimate whether the cost of complying with a relevant request would exceed the appropriate limit.

(3) In a case to in which this regulation has effect, a public authority may, for the purposes of its estimate, take account only of the costs it reasonably expects to incur in relation to the request in –

(a) Determining whether it holds the information,

(b) locating the information, or a document which may contain the information,

(c) retrieving the information, or a document which may contain the information, and

(d) extracting the information from a document containing it.

(4) To the extent to which any of the costs which a public authority takes in to account are attributable to the time which persons undertaking any of the activities mentioned in paragraph (3) on behalf of the authority are expected to spend on those activities, those costs are to be estimated at a rate of £25 per hour.

The Department of Health, as a central government department, is listed in Part I of Schedule 1; the £600 limit therefore applies to the MHRA, as an executive agency of the Department. £600 pays for 24 hours work at a rate of £25 per hour. The effect of section 12 therefore is that the MHRA is not obliged to comply with Mrs Randall's request if it estimates that the cost of compliance would exceed 24 hours work.

The Decision Notice

8. The IC considered this response, clarified a number of other matters with the MHRA, and issued a decision notice on 28 November 2006, concluding that the MHRA had dealt with Mrs Randall's requests in accordance with the requirements of FOIA. The costs of locating and retrieving the information would exceed the cost limit provided in section 12; such information as they held, which they could access, had been provided, and the other items were not held.

The Issues in the Appeal

9. Mrs Randall appealed that decision notice to the Tribunal. At a Directions Hearing on 25 May 2007, the Tribunal gave a direction identifying the issues to be determined in the appeal:

    1) Whether the Information Commissioner was correct in deciding that the MHRA were entitled to rely on the exemption in section 12 of the Freedom of Information Act, that the MHRA had properly estimated that the cost of complying with the request for information would exceed the appropriate limit; which in this case is £600, 24 hours work at £25 an hour.

    2) How far, in assessing whether the limit imposed by section 12 is exceeded, account should be taken of any offer to pay towards the cost of accessing the information.

    3) The relevance of any duty on public authorities to keep information in an accessible format, and to index it, so that it is in practice accessible; and in particular the relevance of the obligations in the Code of Practice.

    4) How far the general public interest in making information relating to the health and safety of medicines available for research and debate should be taken into account.

    5) How far Mrs Randall's personal interest in accessing the information [should be taken into account], given that she is potentially prevented from accessing information that might assist her in receiving treatment, compensation and in pursuing benefit claims.

Evidence

10. Ms Jones, the head of the Corporate Policy Unit at the MHRA, gave evidence describing the archives maintained by the MHRA. They hold over 40,000 boxes containing the technical data relating to applications for licences for medicines for the UK from late 1960s/1970 to 2005. Very little of this material is indexed in such a way that its contents are accessible: "The data archive has been managed by a range of people and organisations, in a range of different ways, since the late 1960s". From the records, Ms Jones was able to identify 25 potentially relevant boxes of material, 3 of which had been withdrawn from the archive on August 2004, and for one of which, there was no trace in the archive. It was not possible to tell what was in the remaining 21 boxes without opening and examining them. There

was no catalogue or index of the contents. The remaining information requested by Mrs Randall could be in any of the boxes. On occasion, up to 140 volumes (each of up to 1000 pages or more, depending on the type of file used) could be submitted to support an application for a new drug, covering all the required evidence including trial data, scientific data, pharmaceutical data, toxicological data and so on.

Consideration and analysis

11. Mrs Randall's first request was general and extensive in scope: information supplied by SmithKline in support of their application for a license; details of the research SmithKline carried out to declare their product safe; details of any problems found and at what doses. That information might be found in any or all of the 21 boxes remaining in the archive. It is clear to us that to attempt the task of sorting through the information contained in the boxes, identifying it and copying the information to Mrs Randall would take very considerably longer than the 24 hours, 3 working days, set as the cost/time limit by the Fees Regulations and section 12.

12. Section 12 removes the obligation to comply with the duty to disclose information in section 1 if the authority estimates that the cost of complying with the request would exceed the appropriate limit. The authority's estimate that the time required would exceed 24 hours work is sensible, realistic and supported by cogent evidence. Mrs Randall is not therefore entitled to have the information disclosed to her under the Freedom of Information Act.

13. The effect of section 12 is not to impose a limit, leaving the authority obliged to carry out work up to that limit; it is to remove the information from the scope of the section 1 duty to disclose altogether.

The effect of an offer to pay

14. Is the authority's estimate of the cost affected by Mrs Randall's offer to pay the costs of searching and retrieving the information? On the face of it, if a request for information is accompanied by an offer to pay, then the Authority should take that into account in estimating the cost of locating and retrieving the information, and the cost to the authority could then be estimated at nothing: section 12 would not apply.

15. There are objections in principle to such an argument: is the cost referred to in section 12, the cost to the authority, or is it simply the cost, whoever pays? Was Parliament's intention in enacting section 12 to limit the cost to the public purse, or to limit the amount of information that had to be disclosed? If people can effectively purchase any amount of information, by paying the costs, does that introduce an imbalance into the flow of information: people, or organisations, with means can obtain unlimited information; people without are subject to the section 12 limit?

16. However, on the facts of this case, it is not necessary for us to decide such interesting questions. Firstly, although Mrs Randall several times refers to an offer to pay the costs, it is not clear that she has ever made such an offer. What she has done is to enquire what she might get if she were to offer. It is clear that any offer to pay is hedged with qualifications: "What would I receive for my £600 and the £25 per hour after – I could end up with parting with all my money and to receive rubbish that is of no use that is not scientific and not acceptable for benefit and current use

of the information or useful information on the product for the condition"; (submission to tribunal, 9.6.07); or "I need to see what I will be receiving for my information requested as with such an hourly [rate] and cost one does not want to end up with rubbish served as information… " (letter to MHRA, 25.7.06).

17. Understandably Mrs Randall asks "Please could you break down all the entire cost of the information of each area of information and unit of information that I have requested" (letter, 25.7.06). Unfortunately, it is precisely that breakdown that cannot be provided, given the lack of an index or catalogue of the information in the boxes. Any offer that Mrs Randall has made to pay for the costs of retrieving the information is conditional, and the condition cannot be met.

18. For the same reason, it would not help if Mrs Randall were more specific in her requests. If, for example, instead of asking for all the information SmithKline had submitted, she asked only for information relating to clinical trials, or only for the results of those clinical trials, rather than the raw data of the trials themselves, the result would be the same. Such a request would reduce the amount of information requested, and while that would reduce copying costs, it would not reduce location or retrieval costs: the entire 21 boxes would still have to be searched to locate the results of any clinical trails.

19. Section 16 of FOIA imposes a duty on public authorities to provide advice and assistance, so far as it would be reasonable to expect the authority to do so, to people who request information. The MHRA say there is nothing practical they can do to assist Mrs Randall to refine her request to manageable proportions within the section 12 limit, given the lack of an index. The Information Commissioner agreed with this in his decision notice, and so do we.

The Code of Practice on Managing Records

20. The lack of an effective index means that the information is in practice inaccessible, not just to requesters under FOIA, but to anyone else, including MHRA staff. Ms Jones is aware of the problem: "Whilst we now keep more detailed records of the material in each box, the inherited archive remains difficult to search"; "we are currently exploring the cost of a major exercise to review and formally index the older boxes. But, given the volume of boxes, it is likely that the exercise will be expensive and time consuming and we would have to make a robust business case for funding an exercise of this scale".

21. Mrs Randall argues that the MHRA are in breach of the requirements of the Code of Practice issued under section 46 of FOIA on the keeping, management and destruction of records. We have no jurisdiction in this appeal to consider such questions: our jurisdiction on appeal is given by sections 57 and 58 of FOIA; essentially, in appeals of this sort, it is to see whether the decision notice is in accordance with the law, when it dealt with the complaint (under section 50 of the Act) that the request for information had not been dealt with by the public authority in accordance with the Act. The Code does not itself impose legally binding obligations, but sets out guidance to public authorities. However, we note and endorse the Commissioner's view in the Decision Notice: "While recognising these as legacy issues, and acknowledging that not all the Authority's historic records are poorly indexed, the Commissioner believes that the public authority should consider

re-indexing the relevant records in order to both conform to the section 46 Records Management Code of Practice and improve its ability to respond to requests under the Act". We see from Mrs Jones' evidence that that consideration is in progress.

Public and private interests in disclosure

22. Lastly, we considered the two remaining issues identified at the directions hearing for consideration: how far should we take into account the public interest in making information relating to the safety and health of medicines available for research and debate; and how far can we take into account Mrs Randall's personal interest in accessing the information, given in particular, her state of health and the possibility of accessing information that might assist her in receiving treatment or compensation? We accept that there is a significant public interest in making the information available. So far as Mrs Randall's personal interest is concerned, it is often said that FOIA is "purpose blind"; it does not matter who is requesting the information or why they are requesting it. Nevertheless, no one who has read the papers could fail to have sympathy and concern for her predicament.

23. However, neither issue has any bearing on the application of section 12. It follows from our analysis of section 12 above, in paragraphs 12 and 13, that the effect of section 12 is absolute, regardless of the significance of the information involved; if the limit is exceeded, the effect is that that the obligation to disclose information in section 1 does not apply. Questions of public or private interest have no bearing, with regard to section 12. The effect of section 12 is in marked contrast to several of the exemptions in the Act which are subject to a public interest test, set out in section 2. This requires a balance to be struck between the public interest in disclosure and any particular exemption claimed. Section 2 does not apply to section 12.

Conclusion

24. Our conclusion therefore is that the decision notice should be upheld. The public authority correctly estimated that the cost of complying with Mrs Randall's request would exceed the appropriate limit, of 24 hours work, to locate, retrieve and extract the information; and therefore the authority are not obliged to release the information requested, beyond what has already been released.

25. Our decision is unanimous.

Humphrey Forrest

Deputy Chairman Date: 30 October 2007