Freedom of Information Act 2000 (Section 50)

Decision Notice

Date: 16 November 2009

Public Authority: North West London Hospitals NHS Trust
Address: Northwick Park Hospital
Watford Road
Harrow
HA1 3UJ

Summary

The complainant requested information in relation to the treatment costs incurred by the public authority as a result of a failed human clinical trial conducted on its premises for an anti-inflammatory drug widely referred to as TGN1412. The public authority refused to comply with the requests made in 2006 by virtue of the provisions of section 12 (appropriate cost limit) of the Act by aggregating these requests and treating them as a single request. It nonetheless went on to withhold part of the requested information by virtue of the exemptions at sections 41 and 43(2) (confidential information and commercial interests) of the Act. In terms of the request made in 2007, the public authority relied on section 12 in relation to part of the requests and withheld the information held in relation to the remainder of the requests by virtue of the exemptions at sections 41 and 43(2). The Commissioner finds that section 12(2) applied to a limited part of the requests made in 2006. He however went on to consider the exemptions applied in relation to the remainder of the requests and finds that the public authority wrongly applied the exemption at section 41. The Commissioner accepts that section 43(2) is engaged for some of the information, but he has decided that the public interest in maintaining the exemption does not outweigh the public interest in disclosure. He has therefore ordered the public authority to disclose the withheld information and additionally finds the public authority in breach of sections 17(1) (late refusal notice), 17(5) (late reliance on section 12), and sections 1(1)(b) and 10(1) (failure to disclose requested information within 20 working days).

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.

The Request

2. In 2006, Parexel, an independent drug trial company conducted a human clinical trial on the premises of the public authority for a drug widely referred to as TGN1412. The adverse effect of the drug however resulted in the hospitalization of the trial participants. Following the incident, the complainant made a number of requests for information relating to the cost incurred by the public authority in treating the trial participants. The requests are outlined below in the order in which they were made.

04 November 2006

i. '*Who paid the cost of the treatment of each of the patients from the Parexel Unit following the incident? Was it paid out of hospital general funds or wholly or partly funded by Parexel? Unless, fully funded by Parexel, please supply full details of the cost and level of contribution by Parexel*'

ii. '*Who paid the costs of having to supply the additional intensive care services as a result of the young men who suffered from the experiments having to "take over" the intensive care unit at Northwick Park Hospital?*'

iii. '*Have there been any previous incidents of persons under experimentation in the Parexel Unit having to be treated in the hospital?*'

iv. '*If so please answer the questions under 1 above as applied to those costs in the last three financial years in particular as to whether Parexel or the hospital funds had to meet the costs of these?*'

22 February 2007

i. '*Whether confidentiality applies to the PCT's who contributed to the £338,000? Were these PCT's parties to the confidential agreement to which you refer?*'

ii. '*How much of the £338,000 was paid by those PCTS and which PCTS these were?*'

iii. '*What the reason was for a public body to enter into a binding confidentiality agreement and what the cost versus the benefit to the taxpayers of such an arrangement were, from a common sense point of view the causation of these particular costs to the NHS was entirely the commercial arrangements between PAREXEL and TeGenero to carry out these experiments with no benefit to the Trust save for, presumably, a commercial lease arrangement of premises within the hospital?*'

3. In a letter simply dated '*15 February* ' the public authority addressed the requests of November 2006.

4. The public authority referred to section 12 of the Act but it is not clear which aspects of the requests it could not comply with within the appropriate cost limit. According to the public authority,

'*The Trust estimates that the time which would be taken in determining whether the information which you requested is held, locating the documents containing the information, retrieving those documents and extracting the information from them would exceed 18 hours……..Accordingly, relying on section 12 of the Act, your request for access under FOIA is refused by the Trust.*'

5. It went on to add;

'*However, the Trust is keen to act in the spirit of the legislation and, despite the fact that the application of the appropriate limit means that the Trust does not have to supply the information which you have requested, I have provided a response to your questions in so far as I am able to do so.*'

6. In terms of request (i) as to who paid for the cost of treating the trial volunteers, the public authority stated;

'*The Trust has resolved the issue of payment of its expenses associated with the care provided to individuals participating in the trial. Any additional costs fall to be paid by the Primary Care Trusts.*

'*A legal agreement has been reached between the parties involved that imposes confidentiality obligations on the Trust. The information relating to the agreement is therefore exempt from disclosure under the following provisions of the Act…*'

7. It accordingly relied on sections 41 and 43(2) to withhold the information contained in the legal agreement referred to above.

8. It similarly relied on the above argument (i.e. for sections 41 and 43(2)) in relation to whether or not the treatment was paid out of general hospital funds or wholly or partly funded by Parexel.

9. In terms of the full details of the cost and level of contribution by Parexel, the public authority explained that the total cost of care provided was £338,000 but relied on the above argument (i.e. for sections 41 and 43(2)) to withhold information regarding the '*level of contribution and its source..*'

10. In terms of request (ii), the public authority explained that no additional costs were incurred as a result of the admission of the trial volunteers, and that it did not commission any outside agency to provide care to other patients on a private basis as a result of the trial.

11. In terms of requests (iii) and (iv), the public authority explained;

'*The Trust has provided some very limited support to patients in the Parexel units in the past. Details are not held separately by the Trust however.*'

12. On 22 February 2007, the complainant requested an internal review of the public authority's decision in relation to the requests of 04 November and also made the additional requests which have been outlined above.

13. The public authority responded in a letter dated 30 April 2007. Specifically in relation to the application of the exemption at section 12 to the 04 November request, the public authority explained;

'*….the reliance on the 18 hour limit is as a reflection of the time which would be taken in dealing with your request as a whole. The most time consuming part of your request is likely to have been the question about previous incidents which the Trust did not hold separately.*'

14. It went on to explain that it had considered the remainder of the requests of 04 November as it would have done had the provisions of section 12 not applied, and the information subsequently withheld was by virtue of the application of sections 41 and 43(2). The public authority did not add anything further to its previous decision.

15. In terms of request (i) of the request of 22 February, the public authority simply stated;

'*The confidentiality agreement is confidential to the parties.*'

16. In terms of request (ii), the public authority explained that disclosing the information requested would breach of the confidential stipulations imposed on it under the Agreement. The information requested was therefore exempt from disclosure by virtue of sections 41 and 43(2) for the same reasons set out in its letter of 15 February. It also concluded that the public interest favoured maintaining the exemption at section 43(2).

17. In terms of request (iii), the public authority explained it would be unable to disclose the reasoning for its decision to enter into a confidentiality agreement with Parexel without confirming details of the agreement and therefore considered the information requested exempt from disclosure by virtue of sections 41 and 43 (2) of the Act.

The Investigation

Scope of the case

18. On 02 July 2007 the complainant contacted the Commissioner to complain about the way her request for information had been handled. The complainant specifically asked the Commissioner to review the public authority's reasons for withholding all the information requested in the letters dated 04 November 2006 and 22 February 2007 namely its application of sections 12,41 and 43 of the Act.

Chronology

19. The Commissioner wrote to the complainant on 23 July 2008. He outlined the information she had requested on 04 November 2006 and 22 February 2007 as well as the scope of his investigation and invited her to comment if need be.

20. The complainant did not question the scope of the investigation.

21. On 04 August 2008, the Commissioner wrote to the public authority inviting its comments on the application of sections 12, 41, and 43(2).

22. The public authority did not respond until 17 September 2008. It explained that all of information requested is contained in an agreement (Agreement) between the public authority and Parexel. It provided the Commissioner with a redacted copy of the Agreement stating that it would be liable for a breach of confidence if an unredacted copy was disclosed to the Commissioner

23. In relation to the application of section 12, the public authority initially explained that it was applied to all of the information requested in November 2006. The public authority however pointed out the fact that it had subsequently provided a response in relation to requests (i) and (ii) by applying the exemptions at sections 41 and 43(2) to the Agreement containing the withheld information.

24. However, in a subsequent letter dated 19 May 2009, the public authority informed the Commissioner that it was maintaining its reliance on section 12 in relation to requests i and ii of November 2006 without excluding the application of the exemptions at sections 41 and 43(2).

25. The public authority had also previously explained that contrary to its response to the complainant in relation to request ii of November 2006, it had indeed incurred additional costs following the clinical trials but declined to go into further details due to the confidentiality stipulations in the Agreement. The public authority's explanation on this point is however reproduced in the Confidential Annex to this Notice.

26. The public authority also confirmed that it was relying on sections 41 and 43(2) in relation to the requests i and iii of February 2007. However, in relation to request ii (February 2007), the public authority agreed to disclose the names of the relevant PCTs but withheld their contribution because to determine the amount paid '*at the time*' by the PCTs towards the treatment costs would exceed the appropriate cost limit and it was therefore exempt from complying with this request by virtue of section 12 of the Act.

27. On 23 September 2008, the Commissioner wrote to the public authority requesting a number of clarifications. The Commissioner also explained that he may resort to an Information Notice in accordance with his powers under section 51 of the Act if the public authority did not voluntarily provide him with an unredacted copy of the Agreement.

28. The public authority responded to the Commissioner's queries on 07 October 2008 but declined to voluntarily provide an unredacted copy of the Agreement. It further clarified that contrary to its explanation to the complainant in relation to request ii of November 2006, extra costs were incurred as a result of the Parexel incident but the information requested as to who had borne the cost of treatment was exempt by virtue of sections 41 and 43(2) of the Act as this was part of the Agreement.

29. On 03 November 2008, the Commissioner wrote to the public authority and requested copies of the lease agreement between the public authority and Parexel at the time of the TGN1412 trial, the public authority's incident reporting policy and procedures at the time of the trial, and, if held, the contract between Parexel and TeGenero (manufacturer of TGN1412) in relation to general clinical trials and/or the human trial conducted for TGN1412.

30. The public authority responded on 20 November 2008. It provided the Commissioner with copies of the lease agreement, and incident reporting policy and procedures as requested. The public authority however explained that it did not hold a copy of the contract between Parexel and TeGenero.

31. On 10 December 2008 the Commissioner issued an Information Notice requesting an unredacted copy of the Agreement between the public authority and Parexel.

32. On 13 January 2009 the Commissioner was provided with an unredacted copy of the Agreement.

33. There was further correspondence between the Commissioner and the public authority between January 2009 and April 2009.

Findings of fact

34. Parexel International is a contract research organisation which provides services (including clinical studies) for companies in pharmaceutical, biotechnology and medical device industries.

35. In March 2006, it conducted a human clinical trial for a drug referred to as TGN1412 on behalf of TeGenero, a pharmaceutical company. The trial resulted in the hospitalization of the trial participants due to an adverse reaction to the drug.

36. On 25 May 2006, the Medicines and Healthcare Products Regulatory Agency (MHRA) published a final report on the events following an investigation. The report concluded that the adverse incidents resulting from the trials did not involve errors in the manufacture of TGN1412 or in the manner it was administered to the participants during the trial.

37. In July 2006, TeGenero, the sponsor of the trial filed for insolvency before compensation settlements were agreed with the trial participants.

Analysis

38. A full text of all the statutory provisions referred to in this section can be found in the Legal Annex.

Procedural matters

39. By virtue of the provisions of section 17(5), a public authority relying on the provisions of section 12 in refusing to comply with a request is required to do so within 20 working days following the request.

40. The Commissioner therefore finds the public authority in breach of section 17(5) for the late application of section 12.

41. By virtue of the provisions of section 17(1), a public authority relying on an exemption to deny a request for information is required to do so within 20 working days following the request.

42. The Commissioner therefore also finds the public authority in breach of section 17(1) for the late reliance on sections 41 and 43(2).

Exemption

Section 12 – (November 2006 and request (ii) of February 2007)

43. By virtue of the provisions of section 12(1), a public authority is not obliged to comply with a request for information if it estimates that the cost of complying with the request would exceed the appropriate cost limit prescribed by the Secretary of State in the relevant regulation.

44. The appropriate limit is prescribed in the Freedom of Information and Data Protection (Appropriate Limit and Fees) Regulations 2004 as £600 for public authorities listed in Part 1 of Schedule 1 to the Act, and £450 for any other public authority. This is estimated at £25 an hour.

45. The appropriate cost limit for the public authority is £450 as it is not a public authority listed in Part 1 of Schedule 1 to the Act.

46. Section 12(2) further provides that a public authority is not obliged to comply with the duty to confirm or deny it holds requested information (in accordance with section (1)(1)(a)) if to do so would exceed the appropriate cost limit.

47. The Commissioner notes that the complainant made multiple requests in the letter of November 2006. Section 12(4) of the Act provides that, in certain circumstances set out in the Fees Regulations[1] requests can be aggregated so that the estimated total cost of complying with any of the requests is to be taken

[1] The Freedom of Information and Data Protection (Appropriate Limit and Fees) Regulations 2004 – Statutory Instrument 2004 No. 3244

to be the estimated total cost of complying with all of them. Regulation 5 of the Fees Regulations sets out the relevant condition in this case and provides that multiple requests can be aggregated in circumstances where the two or more requests relate to any extent, to the same or similar information. Although this test is very broad, it is possible that one or more requests may not meet this test and the Commissioner has therefore considered whether he is satisfied that the requests relate to the same or similar information.

48. The Commissioner is satisfied that the requests of November 2006 could have been aggregated and considered under section 12 of the Act as they all relate to the costs incurred for the treatment administered to individuals taking part in clinical trials at the Parexel Unit.

49. The Commissioner therefore finds that the public authority took the correct approach in applying section 12 to the requests of November 2006. Nevertheless, section 16 imposes a duty on public authorities to provide advice and assistance so far as it would be reasonable to persons who propose to, make, or have made, requests for information to it. Although, the public authority did not explicitly state to the complainant that she could restrict her requests to (i) and (ii), it is implicit in the public authority's refusal notice (dated 15 February) that it would not have exceeded the appropriate limit to disclose the information relating to these specific requests hence the application of the exemptions at sections 41 and 43(2) to the requested information as contained in the Agreement.

50. In light of the above, the Commissioner went on to specifically consider the application of section 12 to requests (iii) and (iv) of November 2006. Before that however, he considered the application of section 12 to request (ii) of February 2007.

Request ii of February 2007

51. According to the public authority, the trial participants were '*patients whose NHS care was, at the time, funded by …*' Redbridge, Surrey, Newham, Kensington & Chelsea, and Islington PCTs.

52. However, in terms of the amount contributed by the PCTs, the public authority explained that the cost to the PCTs was determined in accordance with the service level agreement (SLA) in place at the time. It explained that the figures relating to the cost of treating the trial participants were not separately recorded as part of its expenditure, and would have been paid for in accordance with the SLA.

53. According to the public authority, under the SLA, an anticipated level of patient care activity is agreed with each individual PCT for a financial year, and the costs associated with each type of activity are based on national or local tariffs.

54. The amount required to finance the service level agreement is therefore determined by multiplying the anticipated activity by the relevant tariff costs. One twelfth of the total annual value of the SLA is then paid in equal instalments each month, and adjusted accordingly in line with the actual patient care activity

undertaken. Invoices are produced as well as contract monitoring reports but none of these documents contain any references to patients either by name or any other identifier. It also explained that the PCTs could end up renegotiating the amount billed when levels of activity rise above what was initially anticipated.

55. To further illustrate the position, the public authority provided the Commissioner with randomly selected copies of a typical invoice and contract monitoring report. Having examined both documents, the Commissioner is satisfied that the figures recorded were not attributed to treatment administered to specific patients, and were instead recorded in line with the SLA (i.e. based on the agreed cost for a type of treatment activity).

56. The public authority therefore argued that to provide the cost incurred in relation to the Parexel patients would entail making a number of assumptions and calculations from the invoices issued at the relevant period. It however went on to describe the process involved and the estimated time it would take to retrieve this information if this was '*indeed possible*'.

57. The public authority explained that it would have to go through each of the six trial participants' medical notes to establish exactly when they were each admitted and the number of days spent on a relevant ward (i.e. the intensive care unit (ITU) or private patient's wing). It estimated it would take approximately an hour to look up the patient numbers on the Patient Administration System (PAS).

58. It would then need to obtain the six records in question from the medical records library and review each one to confirm the number of bed days each patient spent in ITU or in private patients' wing. The public authority estimated this would take approximately six hours.

59. The cost incurred from their treatment on the ITU would then be calculated by multiplying the number of bed days per PCT with the agreed tariffs. It explained that costs incurred whilst the patients were on the private patients' unit is available and would not need to be calculated. On the face of it, the combined figures would be the cost of treatment but this would not have been the amount paid to the PCTs.

60. The figure obtained from the above process does not factor in the possibility that the quarterly payments for the relevant period under the SLAs could have been re -negotiated and would therefore no longer reflect calculations which were made strictly in line with agreed tariffs and anticipated or actual levels of activity. Once the quarterly or annual sum is agreed, it is not broken down by patient or a group of patients.

61. The public authority added that it would not be possible to accurately extract the total number of bed days each patient spent in the ITU from the PAS as '*at the time in question, the data for ITU on PAS was unreliable and certainly not reliable enough to use for billing as reconciliations at the time showed significant discrepancies. The SLA team therefore used manual records for calculations.*'

62. Therefore, to extract the amount paid by the PCTs, the public authority would need to review the relevant SLA files, possibly make assumptions, and undertake calculations rather than simply extract a set figure either recorded or accurately extracted from the available base data.

63. The process involved as described by the public authority is reproduced below.

64. The ITU would then need to '*analyse their manual records to obtain the information provided for invoicing the PCTs*'. It estimated that this would take 3 hours.

65. It would take the SLA team 10 hours '*to review their ITU data files and the PCT paper files for the five PCTs*.'

66. The finance department would then need to '*review sales ledger for the five PCTs*.' It estimated that this would take 5 hours.

Commissioner's Assessment

67. Needless to say, for a public authority to rely on the provisions of section 12(1), it must be satisfied that it actually holds the information requested. This is as opposed to relying on section 12(2) which only applies where a public authority is unsure as to whether the information requested is held and only a search, (the cost of which would exceed the appropriate cost limit), could conclusively clarify the position.

68. From the above facts, the Commissioner is not persuaded that the position regarding the amount paid by the PCTs in relation to the cost incurred for the treatment administered to the trial participants falls under either sections 12(1) or 12(2) of the Act.

69. From the public authority's explanation, the amount paid by the PCTs '*at the time*' was not separately recorded. Notwithstanding the fact that their condition was precipitated by the Parexel trials, the costs incurred for their treatment was included in the SLA agreements between the public authority and the relevant PCTs, and whilst the Commissioner is not entirely persuaded by some aspects of the retrieval process described by the public authority, from the public authority's explanation, he understands there is no specific figure recorded as the amount paid by the PCTs.

70. Based on the public authority's explanation on this point (which is clarified in more detail in the Confidential Annex), it would appear a specific amount was earmarked but because this was included in the SLAs, it is unclear whether this amount was ever actually paid by the PCTs. It is however clear from the explanation provided that a figure was not specifically recorded as the amount paid.

71. Notwithstanding, the available base data cannot be relied on with any degree of accuracy as they cannot be used to determine the actual quarterly amounts let alone broken down to reflect the specific amount the relevant PCTs were actually

billed for the treatment administered. According to the public authority, the figures derived from the ITU and private patients' wing do not also accurately reflect the cost of treatment.

72. The Commissioner therefore finds that the specific amount paid by the PCTs for the treatment administered to the trial participants is not held as a record for the purposes of the Act and should have been so confirmed by the public authority in accordance with the duty imposed by section (1)(1)(a).

Requests iii and iv of November 2006

73. The public authority initially explained that it would cost more than £450 to comply with the above requests. According to the public authority, '*if* (it had) *treated patients from the Parexel Unit in the past, this would probably have been noted in their medical records.*' However, to access that information, it would have to go through the medical records of presumably every patient since Parexel began conducting clinical trials on its premises.

74. The public authority explained that the public authority did not routinely record incidents resulting from Parexel clinical trials or any other trials on its premises. It explained that the relationship between the public authority and Parexel was one of landlord/ tenant, and it was not responsible for regulating Parexel's conduct or for monitoring the trials it carried out on site.

75. The public authority however informed the Commissioner that it had checked its Incident Reporting system and that the only incident recorded in relation to the Parexel trials is the one of 2006. According to the public authority, incidents involving either Parexel staff or Parexel trial participants would not be logged by the public authority unless the individuals involved required treatment from the public authority and the circumstances leading to the treatment were of a nature that would be considered an 'incident'.

76. Paragraph 3 of the public authority's Incident Reporting Policy in place at the time of the request contains the scope of the policy. It states that the policy is concerned with the reporting of all incidents including patient safety incidents, health safety and non-clinical incidents as well as near misses which occur during the course of the public authority's business. It also states that the policy applies to all incidents including amongst others; incidents involving volunteers, visitors, contractors (if it is not covered by their own incident reporting policy/procedure), and all incidents occurring on the public authority's property or involving its equipment.

77. The Commissioner therefore asked the public authority to further clarify why it would need to review all the medical records created in the period of the request in order to comply with the request in light of the requirements of the Incident Reporting Policy.

78. The public authority explained that general occurrences of treatment for Parexel trial participants would not in all cases be classed as incidents within the scope of the Incident Reporting Policy. It reiterated that it had in the past provided a small

level of support to Parexel trial participants that '*were not reported as Incidents within the scope of the policy and were therefore presumably perceived as general occurrences of treatment.*'

79. In reaching his decision, the Commissioner considered two possible interpretations of the requests.

80. The Commissioner considers request iii could be interpreted as a request for the number of times the public authority administered treatment to Parexel trial participants pursuant to previous '*incidents* ' within the period specified and very likely to constitute recorded incidents or at least within the scope of the Incident Reporting Policy (i.e. similar to the 2006 incident).

81. If the request was interpreted in that way, then from the public authority's explanation, apart from the 2006 incident, no other incidents occurred since Parexel began to lease the public authority's premises because no other incident was recorded on the Incident Reporting System as is mandatory.

82. Nevertheless, the Commissioner accepts that the requests could also be interpreted as the number of times Parexel trial participants were treated by the public authority in the last three financial years prior to the request. The public authority has already confirmed that it had previously treated Parexel trial participants. However, to comply with the request, it would need to review the medical records of all adult patients for the period in question.

83. The public authority explained that the relevant period covers all adult outpatient appointments and all adult patients who attended A&E from 2002/03 to 2005/2006 based on the assumption that Parexel only conduct human trials on adult patients.

84. It explained that in terms of A&E attendance, an electronic CAS card is generated for each visit but it was not routinely recorded on these cards whether the attendance was a result of a clinical trial or indeed one conducted by Parexel. It added that if a patient was subsequently admitted then their medical records may also need to be checked. It confirmed that a total of 412,352 adult patients attended A&E during the period in question. It went on to explain that it would take 3 to 4 minutes to search and review each CAS card to determine if a Parexel drug trial was noted.

85. In terms of outpatient attendances, the public authority confirmed there are approximately 750,000 paper records held for the relevant period including archived records held offsite and in microfiche. It explained that it would need information from the Patient Administration System to retrieve a relevant medical record before reviewing the case notes for the information requested. According to the public authority, it would take approximately 20 minutes to retrieve and manually review the records not held in its archives.

86. The archived records held offsite would need to be ordered at a cost of 80 pence per record, and reviewed for approximately 20 minutes. It added that it would take up to 60 minutes for an averaged microfiche record to be either reprinted or

viewed in order to determine if it contains the information requested. The public authority also confirmed that at any point in time, approximately 15-20% of if its medical records are out on loan to clinical departments. It explained that because records move between clinical departments on a regular basis, their location would need to be constantly checked on the PAS but it could not estimate how long it would take to locate any of the relevant records on loan.

87. The public authority also argued that even if it had spent 18 hours looking through the relevant records, it would have been possible to only consider a very small number of records, and any information found (if any at all) would not be a realistic indication of the number of previous Parexel trial participants who had been treated by the public authority.

88. The Commissioner notes that some aspects of the retrieval process have not been adequately explained by the public authority. Nevertheless, in light of the fact that approximately 750,000 manual records and 412, 352 electronic CAS cards would need to be reviewed in order to comply with request iii, the Commissioner is satisfied that even if the estimated retrieval time was discounted, it would still exceed the appropriate cost limit to comply with this request. Furthermore, in light of the funding arrangements for patients' treatment, it is also highly unlikely in any event that the public authority would have been able to comply with request iv if indeed treatment had been administered to Parexel trial participants within the period requested..

89. The Commissioner therefore finds that the public authority correctly refused to comply with request iii and by extension request (iv) by virtue of section 12(2) as he is persuaded that it would have exceeded the appropriate limit for it to confirm or deny whether it had treated Parexel trial participants within the period specified by the request.

90. However, as already noted above, a public authority has a duty to provide advice and assistance. In the Commissioner's view, the public authority should have considered whether it could comply with the request within a narrower timescale and advised the complainant as such. In addition, it may have been worthwhile to clarify whether the complainant was after information in relation to 'incidents' similar to that of March 2006 involving volunteers at the Parexel unit as opposed to general occurrences of treatment administered to those at the unit.

91. The Commissioner therefore finds the public authority in breach of section 16 of the Act.

Section 41 - Requests i & ii of 04 November, and Requests i & iii of 22 February

92. As noted above, the public authority explained that information relating to the above requests is contained in the Agreement between the public authority and Parexel.

93. The Commissioner is satisfied that the Agreement contains information in relation to requests i and ii of 04 November.

94. In terms of request i of 22 February, the Commissioner notes that this was a request for the applicability or otherwise of the confidentiality stipulations to the PCTs (and by implication whether they were parties to the Agreement), rather than for substantive terms of the Agreement. To that extent therefore, the Commissioner is prepared to accept that the requested information is contained in the Agreement.

95. In terms of request iii of 22 February, the Commissioner is satisfied that responding to these requests would have necessitated the disclosure of information contained in the Agreement in relation to the rationale behind it. To that extent therefore, he is again prepared to accept the requested information is contained in the Agreement.

96. Information may be exempt from disclosure by virtue of the exemption at section 41 if it was provided to a public authority by another person and disclosure of the information to the public otherwise than under the Act by the public authority holding it would constitute an actionable breach of confidence.

97. There are two components to this exemption; the information must have been obtained by the public authority from another person, and its disclosure would give rise to an actionable breach of confidence. A person may be an individual, a company, a local authority, or any other legal entity.

98. In the Commissioner's view, a written agreement between two parties is not caught by the exemption at section 41 because it does not constitute information provided by one party to the other. This view was supported by the Tribunal in Derry City Council v Information Commissioner (EA/2006/0014) at paragraphs 32 (a) & (c).

99. The Agreement between Parexel and the public authority is outlined in a letter written by Parexel to the public authority. It is clear from the contents of the Agreement that the terms agreed were the subject of prior discussions between Parexel and the public authority. The Agreement therefore does not contain any information that could reasonably be described as information which would not have been the subject of prior discussions between Parexel and the public authority, and which the latter would therefore not have been aware of prior to signing the Agreement.

100. According to the public authority however, although there were prior discussions between the public authority and Parexel, the Agreement was drawn up by Parexel and provided in confidence to the public authority. It was therefore under an equitable obligation not to disclose the information contained in the Agreement as to do otherwise could lead to a legitimate action by Parexel for breach of confidence.

101. The public authority further argued that this case could be distinguished from the Derry case referred to above on the basis that the information withheld in this case was part of an agreement and not a contract between parties for a service.

102. The Commissioner is however not persuaded by the public authority's arguments on this point. It is clear from the wording of section 41(1)(a) that for information to be withheld from disclosure by virtue of the above exemption, it must have been provided to a public authority in confidence. However, it is not the physical passing of documents from one party to the other that is the key requirement. Instead, it is the fact that any specific information contained therein could reasonably be described as having originated from only one of the parties. It is therefore irrelevant in the Commissioner's view whether or not the Agreement constitutes a contract for service.

103. The document in question in this case is an agreement between Parexel and the public authority. This fact alone makes it highly unlikely to constitute information generated by Parexel without the public authority's knowledge. Also, it would be unreasonable to suggest that all the terms of the Agreement were not known to the public authority prior to it being signed in October 2006.

104. The Commissioner therefore finds that the information held in relation to the above requests was incorrectly withheld by virtue of the exemption at section 41(1)(a) of the Act.

Section 43 (2) - Requests i & ii of 04 November, and requests i & iii of 22 February

105. Additional details can be found in the Confidential Annex.

106. In light of the above finding, the Commissioner has gone on to consider whether or not the exemption at section 43(2) of the Act was correctly engaged in relation to the same requests noted above.

107. Information is exempt by virtue of section 43(2) 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.

108. The test therefore is whether or not disclosing the requested information *would* or *would be likely to prejudice* the *commercial interests* of the parties to the Agreement.

Commercial interests of the public authority

109. The public authority explained that it considered its ability to enter into confidential agreements with third parties to the benefit of the public as important to its ability to maintain its commercial efficacy.

110. The public authority further argued that its financial interests were indistinguishable from its commercial interests and vice versa, and disagreed that a distinction needed to be drawn between commercial and financial interests.

111. In the Commissioner's view, a commercial interest relates to a person's ability to participate competitively in a commercial activity i.e. the purchase and sale of goods or services. Therefore, the Commissioner has to determine whether the

public authority had a commercial interest in relation to the TGN1412 trial conducted on its premises.

112. The Commissioner notes that the relationship between Parexel and the public authority is one of Landlord and Tenant rather than a contractual relationship for the provision of services. In other words, there is no commercial relationship between both parties which is tied to its ability to provide healthcare.

113. The primary role of the public authority is to provide medical services at a cost to the taxpayer. The National Health Service's underlying objective is not the provision of medical services as a profitable venture. Rather, it is to make healthcare accessible to all UK citizens and residents, hence the reason it is funded from the public purse. However, the relationship between TeGenero and the public authority is important here. If the public authority was funding the TGN1412 trial or indeed any other clinical trials conducted by Parexel on its premises, an argument could perhaps be made that the public authority had a commercial interest in relation to the success of the trial. For instance, the funds provided could have entitled the public authority to products or services provided by TeGenero at a subsidised rate.

114. The public authority would therefore need to ensure that it puts itself in an advantageous position by offering the most competitive funding option in order to receive any subsequent benefits. However, as noted above, that is not the case here. According to the public authority, its involvement in the TGN1412 trial was strictly to lease out part of its premises for that purpose to Parexel, the company which conducted the trial on behalf of TeGenero. There is little doubt that there is a financial incentive in being able to enter into such lease arrangements but that is not the same as ensuring it is in a competitive position when spending public money.

115. In light of the above findings, the Commissioner is not persuaded that on the basis of the nature of its relationship with Parexel, the public authority had a commercial interest to protect within the contemplation of section 43(2) of the Act. He has therefore not gone on to consider the public interest test.

Commercial Interests of Parexel

116. Parexel, as noted above is an independent medical research company. It generally operates as a contract research organisation and provides services for companies in the pharmaceutical, biotechnology, and medical device industries. As opposed to the public authority, Parexel is a privately funded company engaged at the time in a competitive activity on which it has partly built its reputation. The Commissioner is therefore satisfied that in the circumstances of this case, the public authority does have a commercial interest to protect within the contemplation of section 43(2).

Test of Prejudice

117. As the Commissioner has found that the public authority did not have a commercial interest to protect within the contemplation of section 43(2), he

proceeded to consider whether disclosure of the withheld information at the time of the request, would or would have been likely to prejudice Parexel's commercial interests.

118. According to the public authority disclosing information relating to the above requests *would* have prejudiced Parexel's commercial interest.

119. Full details of the public authority's submissions regarding the anticipated prejudice to Parexel's commercial interests can be found in the Confidential Annex.

120. The Commissioner however considers it sufficient to note that the public authority explained Parexel was of the view (a view shared by the public authority) that disclosing the information contained in the legal agreement would prejudice its negotiations with TeGenero in relation to the compensation claims by the trial participants.

121. According to the public authority, it had publicly explained that the issue of treatment costs was resolved to its satisfaction, and referred the Commissioner to the Secretary of State for Health's response to a Parliamentary question on this point. The question and response are reproduced below;

(Redacted name): To ask the Secretary of State for Health whether the North West London Hospitals NHS Trust has recovered the costs from the relevant parties for treating the patients who suffered an adverse drug reaction to the treatment TGN1412.

(Redacted name): I am informed that the payment position has been resolved. A legal agreement has been reached between the parties and that agreement contains confidentiality stipulations.

122. The public authority therefore argued that the implications of disclosing the requested information in the context of the ongoing negotiations and threat of litigation were sufficient to demonstrate the existence of prejudice to Parexel's commercial interest.

Commissioner's Assessment

Requests i and ii (November 2006)

123. In the Commissioner's view, arguing that disclosure '*would* ' be prejudicial to a person's commercial interest places a stronger evidential burden on a public authority, and the possibility of prejudice must therefore be more probable than not.

124. In Hogan v Oxford city council & The Information Commissioner (EA/2005/0026 & EA/2005/0030), the Information Tribunal also stated that;

'*The application of the 'prejudice' test should be considered as involving a number of steps. First, there is a need to identify the applicable interest(s) within the relevant exemption…….Second, the nature of 'prejudice' being claimed must be considered….A*

third step for the decision-maker concerns the likelihood of occurrence of prejudice ' (paragraphs 28 – 34).

125. The Commissioner has already accepted that Parexel has a commercial interest to protect within the contemplation of section 43(2) which in this case is primarily related to the potential damage to its reputation generally as a medical research organisation and specifically in relation to conducting clinical trials.

126. He is also satisfied that the public authority has been able to demonstrate a causal relationship between the prejudice anticipated and the contents of the Agreement. The Commissioner is therefore persuaded that disclosing the information held in relation to requests i and ii of November 2006 could have been prejudicial to the ongoing negotiations between Parexel and TeGenero in relation to the compensation claims made by the trial participants.

127. However, in terms of the likelihood that disclosure would have consequently had a prejudicial effect on the commercial interests of Parexel, the Commissioner took into account the events which occurred after the TGN1412 trial, and prior to the complainant's requests.

128. The Commissioner notes that the clinical trials in question generated a lot of media publicity which would have been unlikely to strengthen neither Parexel's nor TeGenero's commercial reputation. It is therefore reasonable to suggest that the damage to Parexel's commercial interests had already been done and disclosing the requested information would not have exacerbated the harm already caused by the adverse publicity.

129. It is also plausible to argue that the damage to Parexel's commercial interests would have been mitigated by virtue of the fact that although Parexel did not escape criticism entirely, the MHRA concluded the adverse effects of TGN1412 on the trial participants were not as a result of any serious failings in the conduct of the trial.

130. Therefore, the Commissioner does not consider the disclosure of the information requested would have caused any more damage to the commercial interests of Parexel than that already caused by the publicity generated as a result of the adverse reaction by the participants to TGN1412.

131. As noted above, *would prejudice* places a much stronger evidential burden on a public authority. In the Commissioner's view, whilst there is no indication that there would have been no prejudice whatsoever to the commercial interests of Parexel had information relating to the above request been disclosed, there is no evidence to suggest that the disclosure of the details of the Agreement in question would be any more prejudicial to Parexel's commercial interests than the harm done (if any) as a result of publicly available information regarding the clinical trials conducted on the public authority's premises in 2006.

132. For the above reasons as well as additional reasons in the Confidential Annex, the Commissioner is not persuaded that the possibility of prejudice would have

been more probable than not if the information requested had been disclosed at the time of the request.

133. However, in the circumstances of this case, the Commissioner has decided to exercise his discretion to consider whether disclosure would meet the lower threshold of *'would be likely to*' in section 43(2).

Would be likely to Prejudice

134. In the Commissioner's opinion, the lower threshold means that the possibility of prejudice should be real and significant, and although not as likely to occur as would be expected under the higher threshold, the possibility of prejudice should not be too remote and certainly more than hypothetical.

135. The Commissioner has already noted above that the adverse publicity generated by the failed clinical trial would not have particularly enhanced Parexel's reputation. However, he is willing to accept that the disclosure of the requested information could have had an impact on the ongoing negotiations between Parexel and TeGenero and consequently would have been likely to prejudice Parexel's commercial interests.

136. He therefore finds that the disclosure of the requested information would have been likely to prejudice Parexel's commercial interests and consequently the exemption is engaged for requests i and ii of Nov 2006. .

Request i (22 February)

137. In terms of request i of February 2007, the Commissioner is not persuaded that disclosing the requested information would or would have been likely to prejudice Parexel's commercial interests. As noted above, the request is essentially for information as to whether the PCTs were party to the Agreement and/or whether the confidentiality stipulations were also extended to the PCTs.

138. Revealing whether or not the PCTs were party to the agreement and/or bound by the confidentiality stipulations does not, in the Commissioner's view amount to information which would have been prejudicial to Parexel's commercial interests. Whether considered in isolation or in the context of the other withheld information, it is not of a nature which could be regarded as prejudicial to Parexel's commercial interests. Consequently the Commissioner does not consider that the exemption is engaged for this request.

Request iii (22 February)

139. As noted above, the public authority explained that it had interpreted the above request as information relating to the reasoning for its decision to enter into a confidentiality agreement with Parexel.

140. Strictly speaking, most of the information regarding the above request is on the first page of the Agreement, however, in a broad sense, the whole of the agreement would need to be considered to adequately explain the position.

Therefore, as already noted, the public authority was correct to conclude that disclosing requested information would inevitably reveal details of the Agreement.

141. For the same reasons as above, the Commissioner finds that the disclosure of the requested information would have been likely to prejudice Parexel's commercial interests.

Public Interest Test – requests i and ii (November 2006) & request iii (22 February)

142. In light of the above findings, the Commissioner has gone on to consider in all the circumstances of this case, the public interest in disclosing the information withheld in relation to the above requests.

Public interest arguments in favour of disclosing the requested information

143. In Guardian Newspapers Ltd and Heather Brooke v The Information Commissioner and BBC (EA/2006/0011 and EA/2006/0013), the Tribunal commented that;

'*While the public interest considerations in the exemption from disclosure are narrowly conceived, the public interest considerations in favour of disclosure are broad-ranging and operate at different levels of abstraction from the subject matter of the exemption. Disclosure of information serves the general public interest in the promotion of better government through transparency, accountability, public debate, better public understanding of decisions, and the informed and meaningful participation by the public in the democratic process.*' (Paragraph 87).

144. Although the above case was in relation to the exemption at section 35 of the Act, similar principles inform the general public interest in the disclosure of information.

145. Specifically however in relation to this case, the Commissioner considers that disclosing the information requested would shed more light on the financial burden or otherwise imposed on the public authority as a result of the clinical trials conducted by Parexel on its premises. Disclosure would also inform any public scrutiny of the expenditure incurred by the public authority during the period in question.

146. It would better inform the public as to whether adequate measures, financial or otherwise were in place to ensure that clinical trials conducted on the public authority's premises did not have an adverse effect on its ability to provide adequate healthcare facilities to the general public.

147. Disclosure could also promote a debate about whether the potential advantages of conducting clinical trials on the public authority's premises outweigh any potential disadvantages. For instance, disclosure could inform the debate over where the responsibility for treatment costs resulting from clinical trials should lie; the trial sponsors, or the NHS.

Public interest arguments in favour of withholding the requested information

148. The public authority argued that the then Secretary of State for health had addressed the issue in Parliament without undermining the confidentiality of the Agreement between the public authority and Parexel. In other words, a measure of accountability had been achieved without disclosing details of the Agreement. It reiterated that it was in the public interest for it to be able to conduct negotiations in confidence and disclosure would undermine its ability to do so in future.

149. The public authority also explained that it could be liable for breach of confidence if the information was disclosed.

Balance of the public interest arguments

150. The Commissioner considers there is a significant public interest in informing the debate about the cost of clinical trials to the NHS especially where those trials are funded by external private bodies. It is important for the public to be allowed to reach an informed view as to whether any cost implications do not outweigh the advantages those clinical trials bring to the NHS. Furthermore, in view of the broader context of the outcome of the trial and the impact on the participants, it is important that both the public authority and Parexel are fully accountable, and in the Commissioner's view, the disclosure of the contents of the Agreement would have enhanced the transparency of the process in relation to provision of remedies to the participants as a result of the detriment that they suffered.

151. The Commissioner accepts however that this needs to be weighed against the commercial implications for the NHS as well as the pharmaceutical companies which fund the clinical trials and the medical research companies which conduct the trials on their behalf.

152. However, as the Commissioner has previously pointed out, in the circumstances of this case, he is not persuaded that disclosure would have any negative commercial implications on the public authority as its role was primarily to provide a suitable location and possibly some equipment the needed to conduct the trial. In addition, the Commissioner does not accept that complying with a decision to disclose information under the Act would make the public authority liable for breach of confidence.

153. Furthermore, in light of the information already in the public domain regarding the failed TGN1412 clinical trial, the Commissioner is not persuaded that disclosure of the information in the Agreement would have had a significant adverse impact on the commercial interests of Parexel. He however notes, as he has already decided, that the ongoing compensation negotiations could have been affected by disclosure. Nevertheless, the Commissioner considers that in light of the information already publicly available, the need to protect the negotiations did not outweigh the public interest in the full accountability of the public authority in relation to its role in the trial.

154. The Commissioner would also like to point out that privately run companies or organisations entering into contractual relationships with public authorities would be aware of the implications of the provisions of the Act. He would also reiterate that, in his view, notwithstanding the advent of the Act, the financial benefit of public sector contracts means that private companies are highly unlikely to be deterred from bidding for them.

155. The Commissioner therefore finds that, in all the circumstances of this case, the public interest in maintaining the exemption at section 43(2) of the Act does not outweigh the public interest in disclosing the requested information in relation to requests i and ii (Nov 06) and request iii (Feb 07).

Procedural Requirements

156. By virtue of the provisions of sections 1(1)(b) and 10(1), a public authority is required to disclose information to an applicant under the Act within 20 working days.

157. In light of the Commissioner's findings in relation to requests i and ii (November 2006) and i and iii (February 2007), he finds the public authority in breach of sections 1(1)(b) and 10(1) of the Act for not disclosing the information held in relation to these requests.

The Decision

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158. The Commissioner's decision is that the public authority dealt with the following elements of the request in accordance with the requirements of the Act:

- It correctly refused to comply with requests iii and iv of November 2006 by virtue of the provisions of section 12(2) of the Act.

159. However, the Commissioner has also decided that the following elements of the request were not dealt with in accordance with the Act:

- The public authority incorrectly refused to comply with request ii of February 2007 by virtue of section 12 of the Act. Instead the Commissioner finds that the information was not held by the public authority.

- The public authority breached section 16(1) of the Act for failing to advise the complainant that she could refine her request in relation to the previous incidents.

- The public authority breached section 17(1) of the Act for the late reliance on the exemptions at sections 41 and 43(2).

- The public authority breached section 17(5) of the Act for the late reliance on the provisions of section 12.

- The public authority additionally breached sections 1(1)(b) and 10(1) of the Act for failing, at the time of the request, to disclose the information held in relation to requests i and ii of November 2006 and requests i and iii of February 2007.

Steps Required

160. The Commissioner requires the public authority to take the following steps to ensure compliance with the Act:

    - Disclose the Agreement (redacting the signature of the signatory on behalf of Parexel) between the public authority and Parexel as contained in the letter dated 19 October 2006.

161. The public authority must take the steps required by this notice within 35 calendar days of the date of this notice.

Other matters

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

163. The Commissioner would like to record his concerns regarding the length of time it took the public to complete its internal review in relation. The public authority completed its review on 30 April 2007 more than 40 working days after the review was requested on 22 February 2007.

164. The Commissioner's position as explained in the 'Freedom of Information Good Practice Guidance No. 5' published in February 2007 is that internal reviews should take no longer than 20 working days, and in exceptional circumstances which have been clearly explained to the complainant, the total time taken should not exceed 40 working days. Although the delay does not constitute a breach of the Act, the Commissioner would like to make it clear that this does not accord with good practice. He therefore expects the public authority to be aware of his position as provided in the published guidance as his office will monitor the public authority's compliance or otherwise via future complaints made against it.

165. Although the public authority did not conduct an internal review in relation to the requests of February 2007, the Commissioner accepts that because they are closely linked to the requests of November 2006, an additional internal review was not strictly necessary.

Failure to comply

166. Failure to comply with the steps described above may result in the Commissioner making written certification of this fact to the High Court (or the Court of Session in Scotland) pursuant to section 54 of the Act and may be dealt with as a contempt of court.

Right of Appeal

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

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

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

Dated the 16th day of November 2009

Signed ……

Anne Jones
Assistant Commissioner

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

LEGAL ANNEX

General Right of Access

Section 1(1) provides that -
"Any person making a request for information to a public authority is entitled –

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

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

Section 1(2) provides that -
"Subsection (1) has the effect subject to the following provisions of this section and to the provisions of sections 2, 9, 12 and 14."

Section 1(3) provides that –
"Where a public authority –

(a) reasonably requires further information in order to identify and locate the information requested, and

(b) has informed the applicant of that requirement,

the authority is not obliged to comply with subsection (1) unless it is supplied with that further information."

Section 1(4) provides that –
"The information –

(a) in respect of which the applicant is to be informed under subsection (1)(a), or

(b) which is to be communicated under subsection (1)(b),

is the information in question held at the time when the request is received, except that account may be taken of any amendment or deletion made between that time and the time when the information is to be communicated under subsection (1)(b), being an amendment or deletion that would have been made regardless of the receipt of the request."

Section 1(5) provides that –
"A public authority is to be taken to have complied with subsection (1)(a) in relation to any information if it has communicated the information to the applicant in accordance with subsection (1)(b)."

Section 1(6) provides that –
"In this Act, the duty of a public authority to comply with subsection (1)(a) is referred to as "the duty to confirm or deny"."

Time for Compliance

Section 10(1) provides that –
"Subject to subsections (2) and (3), a public authority must comply with section 1(1) promptly and in any event not later than the twentieth working day following the date of receipt."

Section 10(2) provides that –
"Where the authority has given a fees notice to the applicant and the fee paid is in accordance with section 9(2), the working days in the period beginning with the day on which the fees notice is given to the applicant and ending with the day on which the fee is received by the authority are to be disregarded in calculating for the purposes of subsection (1) the twentieth working day following the date of receipt."

Section 10(3) provides that –
"If, and to the extent that –

(a) section 1(1)(a) would not apply if the condition in section 2(1)(b) were satisfied, or
(b) section 1(1)(b) would not apply if the condition in section 2(2)(b) were satisfied,

the public authority need not comply with section 1(1)(a) or (b) until such time as is reasonable in the circumstances; but this subsection does not affect the time by which any notice under section 17(1) must be given."

Section 10(4) provides that –
"The Secretary of State may by regulations provide that subsections (1) and (2) are to have effect as if any reference to the twentieth working day following the date of receipt were a reference to such other day, not later than the sixtieth working day following the date of receipt, as may be specified in, or determined in accordance with the regulations."

Section 10(5) provides that –
"Regulations under subsection (4) may –

(a) prescribe different days in relation to different cases, and
(b) confer a discretion on the Commissioner."

Section 10(6) provides that –
"In this section –
"the date of receipt" means –

(a) the day on which the public authority receives the request for information, or
(b) if later, the day on which it receives the information referred to in section 1(3);

"working day" means any day other than a Saturday, a Sunday, Christmas Day, Good Friday or a day which is a bank holiday under the Banking and Financial Dealings Act 1971 in any part of the United Kingdom."

Exemption where cost of compliance exceeds appropriate limit

Section 12(1) provides that –
"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."

Section 12(2) provides that –
"Subsection (1) does not exempt the public authority from its obligation to comply with paragraph (a) of section 1(1) unless the estimated cost of complying with that paragraph alone would exceed the appropriate limit."

Section 12(3) provides that –
"In subsections (1) and (2) "the appropriate limit" means such amount as may be prescribed, and different amounts may be prescribed in relation to different cases."

Section 12(4) provides that –
"The secretary of State may by regulations provide that, in such circumstances as may be prescribed, where two or more requests for information are made to a public authority –

(a) by one person, or
(b) by different persons who appear to the public authority to be acting in concert or in pursuance of a campaign,

the estimated cost of complying with any of the requests is to be taken to be the estimated total cost of complying with all of them."

Section 12(5) – provides that
"The Secretary of State may by regulations make provision for the purposes of this section as to the costs to be estimated and as to the manner in which they are estimated.

Duty to Provide Advice and Assistance

Section 16(1) provides that –
"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.

Section 16(2) states-
"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 subsection (1) in relation to that case.

Refusal of Request

Section 17(1) provides that -
"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."

Section 17(2) states –

"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 t 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."

Section 17(3) provides that -

"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."

Section 17(4) provides that -

"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.

Section 17(5) provides that –

"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."

Section 17(6) provides that –

"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."

Section 17(7) provides that –

"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."

Information provided in confidence.

Section 41(1) provides that –
"Information is exempt information if-

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

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

Section 41(2) provides that –
"The duty to confirm or deny does not arise if, or to the extent that, the confirmation or denial that would have to be given to comply with section 1(1)(a) would (apart from this Act) constitute an actionable breach of confidence."

Commercial interests.

Section 43(1) provides that –
"Information is exempt information if it constitutes a trade secret."

Section 43(2) provides that –
"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)."

Section 43(3) provides that –
"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)."