

## Freedom of Information Act 2000 (Section 50)

### Decision Notice

Date 29 November 2006

**Public Authority:** Medicines & Healthcare Regulatory Agency (an executive agency of the Department of Health)

**Address:** Market Towers  
1 Nine Elms Lane  
London  
SW8 5NQ

### Summary

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The complainant submitted a request to the MHRA for information relating to the safety of Engerix B (the Hepatitis B Vaccination). The public authority advised that it would be unable to supply all the information requested as to do so would exceed the 'appropriate limit' under section 12(1) of the Act. Having investigated this case the Commissioner is satisfied that the application of section 12(1) by the public authority was correct.

### The Commissioner's Role

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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

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2. The complainant submitted two requests for information. These were received by the public authority on 19 October 2005 and 15 November 2005. The public authority identified from these requests that the complainant was seeking the following information relating to the safety of the Hepatitis B Vaccine (Engerix B):
  - 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 were 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 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 your vaccination 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 15 November 2005 the public authority wrote to the complainant to explain that a search for information relevant to her requests had been completed. However, the public authority required more time to consider whether the information was exempt from disclosure under the Act.
  4. The public authority responded to the requests on 5 December 2005. The complainant was supplied with copies of documents relating to the licensing of Energix B and advised that no information was held relating to recalled batches.
  5. The complainant was not satisfied that she had received all the information requested and wrote to the public authority on 26 January 2006 to express her dissatisfaction.
  6. In response to the complainant's concerns the public authority conducted a review of its response to her request. This internal review recommended that further action was required in respect of the requests.
  7. Having considered the recommendations of the internal review the public authority's licensing department advised the complainant in a letter dated 28 April 2006 that it would be unable to supply all the information requested by the complainant as to do so would exceed the 'appropriate limit' under section 12(1) of the Act.

## **The Investigation**

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### **Scope of the case**

8. On 6 September 2005 the complainant contacted the Commissioner to complain that the public authority had failed to provide her with the information she had requested under the Act.
9. The public authority has confirmed that the information referred to in requests (iii)-(iv) was sent to the complainant on 13 June 2006.
10. The Commissioner's investigation has therefore concentrated on establishing whether the decision to apply section 12(1) of the Act to the information referred to in requests (i) and (ii) is correct.
11. The Commissioner has also considered whether the public authority fulfilled its duty to provide advice and assistance to the complainant, in accordance with section 16 of the Act.

## Chronology

12. On 3 March 2006 the Commissioner wrote to the public authority to request details of the steps that had been taken to respond to the complainant's requests and an update as to the current status of the requests.
13. The public authority responded on 10 March 2006 by explaining that an internal review had been undertaken and recommendations of the action required in order to respond to the requests had been made to its licensing department.
14. The Commissioner advised the complainant in a letter dated 14 March 2006 that in view of the action being taken by the public authority his office did not intend to investigate the matter any further at that stage.
15. On 12 May 2006 the complainant wrote to the Commissioner to explain that she was not happy with the response she had received to the internal review, dated 28 April 2006. In this letter the public authority had advised that it would be unable to comply with the request as to do so would exceed the 'appropriate limit' under section 12(1) of the Act.
16. The Commissioner wrote to the public authority on 26 May 2006 to ask how it had calculated that the cost of supplying the information would exceed the appropriate limit prescribed in the Freedom of Information and Data Protection (Appropriate Limit and Fees) Regulations 2004 ('the Regulations'). The Commissioner also asked whether steps had been taken to provide the complainant with advice and assistance in accordance with section 16 of the Act, with a view to assisting the complainant in narrowing the scope of the request to bring the cost of compliance below the appropriate limit.
17. The public authority provided the Commissioner with its response on 20 June 2006.
18. On 6 July 2006 the Commissioner wrote to the complainant outlining his initial findings in the case and seeking informal resolution of the complaint. As the complainant did not respond to the Commissioner within the stipulated timeframe the complaint was closed. Having subsequently received further correspondence from the complainant on 19 August 2006, the decision was made to reopen the case and issue a Decision Notice outlining the Commissioner's conclusions.
19. Before drafting the Decision Notice the Commissioner wrote to the public authority on 28 September 2006 seeking confirmation that the complainant had been provided with the outstanding information referred to in requests (iii)-(v). On 5 October 2006 the public authority confirmed that the outstanding information had been sent to the complainant on 13 June 2006.
20. The Commissioner wrote to the public authority again on 10 October 2006 seeking confirmation that section 12(1) of the Act was only being applied to the information outlined in requests (i) and (ii). The Commissioner also asked for details of how records are usually archived and indexed by the public authority. The public authority provided the information required on 12 October 2006.

## Analysis

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### Procedural matters

#### Section 12 – exemption where cost of compliance exceeds appropriate limit

21. The Commissioner has considered whether the decision to refuse requests (i) and (ii) under section 12(1) of the Act was correct. 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.”*

22. The Regulations prescribe the ‘appropriate limit’ as being £600 for Central Government and £450 for other public authorities, with staff costs calculated at a rate of £25 per hour. As an executive agency of the Department of Health the ‘appropriate limit’ for this public authority is £600.
23. The public authority explained that although the complainant was provided with some of the information relevant to requests (i) and (ii) the remainder may be contained in its archives. The public authority established that the archive contains 25 boxes of documents that may be relevant to this request. On average each box contains 6 or more volumes of papers and each volume contains approximately 250 pages. Due to incomplete indexing of the boxes it would be necessary for the public authority to go through all 25 of the boxes in order to determine whether the relevant information is held. The public authority explained that this would require the examination of over 37,500 pages of documents. The public authority concluded that to comply with requests (i) and (ii) would take longer than 24 hours and would therefore exceed the appropriate limit under section 12(1) of the Act.
24. The Commissioner wrote to the public authority on 10 October 2006 to seek clarification on how its records are usually archived and indexed.
25. The public authority explained that, prior to the introduction of an electronic system, information was indexed manually according to its product licence number and a record was kept of which product licence number was in which numbered box. The level of detail in the indexes varied from detailed, where the category of information that was going into the box for a given product licence was recorded (for example PL00001/0001: Experts Reports in box 100), to a listing which would only give the overall product licence number against the box number (for example PL00001/0001 in boxes 100-134). In this case the public authority had been able to determine that there were 25 boxes relating to the relevant product licence number. However, the indexes did not contain sufficient detail to determine whether the requested information was held. Consequently, a full review of the boxes would be required.
26. Having considered the explanation provided by the public authority the Commissioner is satisfied that to determine whether the information in question is held would exceed the appropriate limit provided in section 12(1) of the Act.

## Section 16 – Duty to provide advice and assistance

27. The Commissioner has considered whether the public authority fulfilled in its duty to provide advice and assistance to the complainant, in accordance with section 16 of the Act. 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”*

28. On 26 May 2006 the Commissioner wrote to the public authority to ask whether steps had been taken to provide the complainant with advice and assistance in accordance with section 16 of the Act, with a view to assisting the complainant in narrowing the scope of the request to bring the cost of compliance below the appropriate limit.
29. In its letter dated 20 June 2006 the public authority advised that due to the incompleteness of the indexing it did not consider that it would be helpful to ask the complainant to reframe her request as *“the totality of the relevant archive holdings would still need to be searched”*.
30. The Commissioner concludes that as a result of the incomplete indexing the provision of advice and assistance would not have been beneficial in this instance as the public authority would still have needed to carry out a search of all the relevant boxes in order to establish if the information was held.

## The Decision

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31. The Commissioner’s decision is that the public authority dealt with the request for information in accordance with requirements of the Act.

## Steps Required

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32. The Commissioner requires no steps to be taken.

## Other matters

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33. Although it does not form part of this Decision Notice the Commissioner wishes to highlight the following matter of concern.
34. The Commissioner believes that the incomplete indexing of the public authority’s records was a significant contributing factor to the appropriate limit being exceeded in this case. The Commissioner is aware that the public authority now uses electronic records management tools and considers that the age of some of the records and the type of filing systems involved contributed to the reliance on section 12. Whilst recognising these as legacy issues, and acknowledging that not all of the public 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.

## Right of Appeal

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35. 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@dca.gsi.gov.uk](mailto:informationtribunal@dca.gsi.gov.uk)

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 29<sup>th</sup> day of November 2006**

**Signed .....**

**Richard Thomas  
Information Commissioner**

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