

Freedom of Information Act 2000 (FOIA)

Decision notice

Date: 01 October 2012

Public Authority: Medicines and Healthcare Products
Regulatory Agency

Address: 151 Buckingham Palace Road
Victoria, London, SW1W 9SZ

Decision (including any steps ordered)

1. The complainant has requested information relating to the type of catheter used at Green Parks Hospital in April 2009.
2. The Commissioner's decision is that Medicines and Healthcare Products Regulatory Agency (the 'MHRA') has complied with section 1(1) of the FOIA in advising that it did not hold the information requested.
3. The Commissioner does not require the public authority to take any further steps.

Request and response

4. On 15 December 2011, the complainant wrote to the MHRA and requested information in the following terms:

"May I make a consequential request for you to investigate the TYPE of catheter that was in use for the catheterised specimen that was reported to have E Coli on 19 April 2011.

"Have you any information about what catheter was in use at Green Parks House for this sample of 19 April 2011."

"As there is significant concern over the Urinary and Catheter

CQUINS, I am requesting that you find out what specific type of catheter was used in South London Healthcare NHS Trust for [name redacted?]"

5. The MHRA responded on 2 March 2012. It apologised for the oversight in not responding to her request. The MHRA explained that a response to a similar question had been issued in an email dated 7 December 2011 (prior to the FOIA request). It stated that the MHRA does not hold the information requested.
6. Following an internal review the MHRA wrote to the complainant on 29 May 2012. It maintained its original position.

Scope of the case

7. The complainant contacted the Commissioner to complain about the way her request for information had been handled.
8. The Commissioner considers that the scope of this case is to determine the probability of the MHRA holding the requested information.

Reasons for decision

9. Section 1(1)(a) of FOIA states 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"

10. On 6 December 2011 the complainant wrote to a number of organisations and individuals raising a number of concerns about the care of her sister and hospital record keeping. In this email the complainant states *"I now wish to know which precise catheter was used, how many times it has been changed since it was inserted in the PRUH"*

11. The MHRA responded on 7 December 2011 stating that it did not hold information on individual patient care and suggested that the complainant contacted the health care providers directly.
12. On 8 December 2011 the complainant made a request for information relating to occurrences of E-coli diagnosed in 2011. The complainant was aware that on 19 April 2011 there had been a report of E-coli identified in the London Borough of Bromley. This was identified in a catheterised urinary sample.
13. The MHRA advised the complainant that the most likely source for the information requested would be the Health Protection Agency.
14. The complainant wrote to the MHRA on 15 December 2011 making the request detailed in paragraph 4 above.
15. The MHRA did not respond to this request as it believed that the email of 7 December 2011 had addressed the matter.
16. The MHRA subsequently issued a response on 2 March 2012, advising that it did not hold the information requested.
17. In March 2012 the complainant made an Adverse Incident Report to the MHRA regarding the use of a catheter in the previous March.
18. The MHRA stated that due to the time elapsed since the use of the catheter and the Adverse Incident Report being submitted the device had long since been disposed of there was little evidence to support an investigation.
19. The Commissioner notes that it can be difficult for a public authority to "prove" that it does not hold any information on a particular subject.
20. The MHRA have advised that adverse incidents involving medical devices are reported to the MHRA by manufacturers, clinicians and the public. These are logged and recorded on a separate electronic system. This is the MHRA internal database for processing and monitoring medical device adverse incident reports.
21. Adverse incident reports of the type in question are only recorded on this system. Emails and other relevant electronic documents are also held on the system and associated with the initial report.

Reference: FS50452077



22. Searches for the information in question would have been restricted to this system, which is the only place it would have been held.
23. The data can be searched for using a number of criteria, which would include the date, type of device, reporters identity etc. All these, and possibly others would have been used at the time to locate a report.
24. The information would be held electronically. Any relevant documentation produced in hard copy form would be scanned and held on the system electronically in association with the initial report.
25. No relevant information was held regarding the adverse incident until the complainant reported it in March 2012.
26. The MHRA's records management policy states that this type of information would be retained for a minimum of 15 years as it is considered to be safety related data.
27. Having reviewed the evidence, the Commissioner is satisfied that the MHRA conducted a search of its database for the requested information.
28. The Commissioner is satisfied that, on the balance of probabilities, no information is held by the MHRA in relation to the type of catheter in use at Green Parks Hospital on 19 April 2009. Therefore the MHRA has complied with section 1(1)(a) in advising that it did not hold the information.

Right of appeal

29. Either party has the right to appeal against this decision notice to the First-tier Tribunal (Information Rights). Information about the appeals process may be obtained from:

First-tier Tribunal (Information Rights)
GRC & GRP Tribunals,
PO Box 9300,
LEICESTER,
LE1 8DJ

Tel: 0300 1234504

Fax: 0116 249 4253

Email: informationtribunal@hmcts.gsi.gov.uk

Website: www.justice.gov.uk/guidance/courts-and-tribunals/tribunals/information-rights/index.htm

30. 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.
31. Any Notice of Appeal should be served on the Tribunal within 28 (calendar) days of the date on which this decision notice is sent.

Signed

Pamela Clements
Group Manager, Complaints Resolution
Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF