

Freedom of Information Act 2000 (Section 50)

Decision Notice

Date: 21 December 2009

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

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

Summary

The complainant requested details of whether the public authority had issued a caution under the Medicines Act 1968 to a named clinic. The public authority refused to confirm or deny whether it held information falling within the scope of the request. During the course of the Commissioner's investigation the public authority sought to rely on sections 30(3), 40(5) and 43(3) of the Act. The Commissioner subsequently determined that the public authority was correct to rely on section 30(3) to refuse to confirm or deny whether it held any relevant information.

The Commissioner also identified some procedural breaches of the Act by the public authority related to a failure to initially identify that it was relying on sections 30(3), 40(5) and 43(3) to neither confirm nor deny whether it held the requested information.

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.

Background

2. The Medicines and Healthcare Products Regulatory Agency (the "MHRA") is the regulatory body for medicinal and medical products that are placed on the UK market. It has statutory responsibility for, among other matters, responding to and investigating, and where appropriate taking criminal proceedings, in relation to

alleged breaches of the regulations governing the marketing, sale and supply of medicinal products.

3. The Commissioner notes that under the Act the MHRA is not a public authority itself, but is actually an executive agency of the Department of Health which is responsible for it. The public authority in this case is therefore the Department of Health, not the MHRA. However, for the sake of clarity, this decision notice refers to the MHRA as if it were the public authority.

The Request

4. On 19 June 2008 the complainant emailed the public authority and asked it to confirm the following:-
 1. whether the MHRA has issued any caution of any kind against the Norton Clinic Limited in relation to illegally supplying the general public with prescription medicines and the date of any caution issued.
 2. the position within the Norton Clinic Limited of the person or persons issued with a caution of any kind of an offence of illegally supplying the general public with prescription medicines.
5. On 24 June 2008 the public authority informed the complainant that its policy was to neither confirm nor deny in all cases whether an individual or individual company is, or has been, the subject of any investigation.
6. On 20 July 2008 the complainant asked the public authority to carry out an internal review of its decision.
7. On 26 August 2008 the public authority informed the complainant that the outcome of the internal review was to uphold its original decision.

The Investigation

Scope of the case

8. On 1 September 2008 the complainant wrote to the Commissioner to complain about the public authority's refusal to disclose the information he had requested.

Chronology

9. On 24 June 2009 the Commissioner wrote to the public authority to ask it to provide him with details of any information that might have been withheld. He also asked it to provide him with a full explanation as to why it believed that it was entitled to refuse to confirm or deny whether any information was held, including details of the exemption or exemptions that it was relying on.

10. On 3 August 2009 the public authority provided the Commissioner with detailed arguments as to why it believed it was entitled to refuse to confirm or deny whether information was held. It confirmed that it was relying on section 30(3) of the Act.
11. On 6 August 2009 the Commissioner sought further explanation from the public authority as to the harm that it believed might arise from confirming or denying whether the requested information was held.
12. On 20 August, 7 September and 10 September 2009 the public authority provided the Commissioner with further information in support of its contention that it was entitled to neither confirm nor deny whether information was held. It informed the Commissioner that, in addition to section 30(3), it believed that sections 40(5) and 43(3) were also applicable. It identified a previous decision of the Commissioner, involving the Department of Business, Enterprise and Regulatory Reform (FS50128245 issued on 1 April 2009), which it suggested raised similar issues to the current case and supported the view that it had taken.

Analysis

Exemptions

Section 30 – Investigations and proceedings conducted by public authority

13. Section 30(1) provides that

“Information held by a public authority is exempt information if it has at any time been held by the authority for the purposes of-

(a) any investigation which the public authority has a duty to conduct with a view to it being ascertained-

- (i) whether a person should be charged with an offence, or*
- (ii) whether a person charged with an offence is guilty of it,*

(b) any investigation which is conducted by the authority and in the circumstances may lead to a decision by the authority to institute criminal proceedings which the authority has power to conduct, or

(c) any criminal proceedings which the authority has power to conduct.”

14. Section 30(3) goes on to state that

“The duty to confirm or deny does not arise in relation to information which is (or if it were held by the public authority would be) exempt information by virtue of subsection (1) or (2).”

15. The public authority explained that section 108 of the Medicines Act 1968 required the Secretary of State for Health to enforce, or secure the enforcement of, the provisions of the Act and regulations made under it. This duty was delegated to certain MHRA officials who were authorised by the Secretary of State to carry it out on his/her behalf. As a result, authorised officers had a right to conduct investigations in order to establish whether there had been any contravention of the Medicines Act or the regulations made under it and determine whether to institute criminal proceedings.
16. The Commissioner is satisfied that any information falling within the scope of the request that may have been held by the public authority would have been held for the purposes of an investigation conducted by the public authority and which may have lead to a decision to institute criminal proceedings which it had power to conduct. He is therefore of the view that section 30(1) is engaged and that, consequently, section 30(3) is also engaged.
17. As section 30 is a qualified exemption the Commissioner proceeded to consider whether, 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 public authority holds any information falling within the scope of the request.

Public interest arguments in favour of confirming or denying whether the requested information is held

18. The Commissioner acknowledges that there is a general public interest in promoting transparency and accountability in relation to the operation of public authorities. The disclosure of whether or not a caution had been issued in relation to the clinic identified by the complainant would have provided some information about the workings of the public authority with regard to its enforcement of the regulations governing the marketing, sale or supply of medicinal products and whether it discharged its powers effectively and appropriately. The Commissioner considers that the disclosure of whether or not a caution had been issued in relation to a particular company would, in itself, provide relatively limited information in terms of assisting public engagement in a meaningful debate over the investigations carried out by the public authority in this area. However, it is also his understanding that there is very little information in the public domain about whether MHRA has carried out an investigation, save for in those instances where proceedings have resulted. Therefore, whilst limited, the confirmation or denial in this case would add to the public's knowledge in this area and this argument has consequently been given some weight. The Commissioner has not been provided with, nor is he aware of, any evidence to show that there is particular concern amongst the public about MHRA's actions in respect of the

company named in the request which may have warranted giving this argument further weight.

19. Given that investigations carried out by the public authority relate to the provision of medicinal products, there is a public interest in revealing whether or not the regulator has sufficient concerns about possible breaches of the relevant regulations by specific companies or people to issue a caution. The public authority informed the Commissioner that it issues a caution where it believes that a criminal offence has been committed but is satisfied that it does not merit a criminal prosecution as the matter is not sufficiently serious or the potential or actual risk to public health is relatively minor. Therefore whilst the Commissioner considers this argument to have some merit, in his view it is of limited weight because the alleged offence is likely to be of a relatively minor nature.
20. In addition the public authority informed the Commissioner that, whilst it did not publish details of cautions that it had issued, it did publish details of all the criminal prosecutions it had brought. It believed that this, to some extent, fulfilled the public interest in demonstrating that it took appropriate action against companies or individuals who endangered the public health by serious breaches of the Medicines Act.

Public interest arguments in favour of maintaining the exclusion of the duty to confirm or deny

21. The public interest inherent in maintaining the exemption is preserving the ability of public authorities to carry out any investigation to which the information relates and to decide whether proceedings are necessary. It also protects the investigative process so far as disclosure would result in a detriment to future investigations.
22. The public authority informed the Commissioner that under section 112 of the Medicines Act it had the power to require the production of any books or documents in connection with an investigation involving medicines. However, it argued that the process of carrying out its investigations under the Act, including the gathering of relevant information, was greatly facilitated by the cooperation of the companies and individuals that were the subject of an investigation.
23. The Commissioner was also informed by the public authority that it needed the consent of a company or individual that was under investigation before it could issue a caution. It could not impose one without the agreement of the relevant party. The public authority confirmed that it did not disclose to the public whether or not a caution had been issued and believed that the companies and individuals that it investigated would be aware of this fact. It stated that a caution was normally issued against an individual and only exceptionally, if at all, against a company.
24. The public authority was of the view that if it disclosed that a caution had been issued to a particular person or body, the individuals and companies that came within its area of regulation would be much less willing to accept a caution in future. They would argue that as the fact that a caution had been issued would be

placed in the public domain, which would be likely to have an adverse effect on their reputation and hence their business, they might as well refuse to accept the caution and challenge the public authority to prosecute them or take no further action.

25. In addition, if the details of the companies or individuals who had received cautions were to be made public, the public authority believed that it would result in it receiving far less voluntary cooperation during the course of future investigations. It was likely to result in companies and individuals adopting an adversarial approach from the outset of investigations in order to avoid the stigma of a criminal prosecution and potentially conviction. This would hamper its ability to carry out effective investigations.
26. The public authority stated that the issuing of a caution gave the relevant party notice that, although it was not minded to prosecute on that occasion, it took a serious view of the offence committed and would use the fact of the caution as a factor in considering future prosecution were the offence (or a similar offence) to be repeated. In accepting the caution the individual or company acknowledged that they had committed an offence and, implicitly, accepted that they need to change their behaviour.
27. It was contended by the public authority that if it was unable to issue cautions, this would impact on its enforcement strategy as it would be faced with the prospect of either undertaking a potentially costly criminal prosecution through the courts or taking the very limited step of issuing a verbal warning. In practice this would mean that many offenders would only receive a verbal warning as it would not have sufficient resources to bring criminal prosecutions for all potential offences of which it becomes aware.
28. The public authority believed that the issuing of cautions was a proven and effective way of dealing with minor breaches and, if it was required to disclose whether or not a caution had been issued, there would be no incentive in cases where they were deemed appropriate for offenders to agree to accept them. This would adversely affect its ability to carry out its enforcement activities in a proportionate and flexible way and would hamper its efforts to concentrate its enforcement resources where they, in its view, could make real benefits to public health by concentrating on serious or repeated wrongdoing.

Balance of the public interest arguments

29. The Commissioner is of the view that there is a limited public interest in the public authority confirming or denying whether the information that was requested is held. He believes that this public interest in maintaining the exclusion from the duty to confirm or deny outweighs the public interest in revealing whether information is held in order to ensure the cooperation of companies and individuals in its investigations and to preserve the ability of the public authority to continue to adopt a flexible and proportionate approach in enforcing the legislation for which it is responsible. He has therefore decided that it was correct to apply section 30(3).

Section 40(5) – Duty to confirm or deny in relation personal data and section 43(3) – Duty to confirm or deny in relation to prejudice to commercial interests

30. The public authority also argued that the duty to confirm or deny whether information was held did not arise because of sections 40(5) in relation to personal data and 43(3) in relation to the potential prejudice to commercial interests. As the Commissioner determined that section 30(3) was applicable, he did not proceed to make a determination with regard to these other exemptions which the public authority had applied.

Procedural Requirements

31. Section 17(1) of the Act requires that, where a public authority is relying on a claim that an exemption in Part II of the Act is applicable to the information requested, it should in its refusal notice:-

- (a) state that fact,
- (b) specify the exemption in question,
- (c) state why the exemption applies.

32. In this case, by failing to inform the complainant within 20 working days of the date of the request that it was relying on sections 30(3), 40(5) and 43(3) and explain why they applied, the public authority breached section 17(1). By failing to state that it was relying on sections 30(3), 40(5) and 43(3) and explain why they applied by the time of the completion of the internal review, it breached section 17(1)(b) and (c).

The Decision

33. 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 applied section 30(3) to the request.

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

- it breached section 17(1)(b) and (c) by not stating within 20 working days of the request or by the time of the completion of the internal review that it was relying on sections 30(3), 40(5) and 43(3), nor explaining why they applied.

Steps Required

35. The Commissioner requires no steps to be taken.

Other matters

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

37. If a similar request to the one under consideration in this notice were made to the public authority in future and it was of the view that it was appropriate to neither confirm nor deny whether the requested information was held, the Commissioner believes that it would be appropriate to provide the requester with a clear explanation as to why it had come to that conclusion.

Right of Appeal

38. 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 21st day of December 2009

Signed

**Jo Pedder
Senior Policy Manager**

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

Legal Annex

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.”

Investigations and proceedings conducted by public authorities.

Section 30(1) provides that –

“Information held by a public authority is exempt information if it has at any time been held by the authority for the purposes of-

- (a) any investigation which the public authority has a duty to conduct with a view to it being ascertained-
 - (i) whether a person should be charged with an offence, or
 - (ii) whether a person charged with an offence is guilty of it,
- (b) any investigation which is conducted by the authority and in the circumstances may lead to a decision by the authority to institute criminal proceedings which the authority has power to conduct, or
- (c) any criminal proceedings which the authority has power to conduct.”

Section 30(2) provides that –

“Information held by a public authority is exempt information if-

- (a) it was obtained or recorded by the authority for the purposes of its functions relating to-
 - (i) investigations falling within subsection (1)(a) or (b),
 - (ii) criminal proceedings which the authority has power to conduct,
 - (iii) investigations (other than investigations falling within subsection (1)(a) or (b)) which are conducted by the authority for any of the purposes specified in section 31(2) and either by virtue of Her Majesty's prerogative or by virtue of powers conferred by or under any enactment, or

- (iv) civil proceedings which are brought by or on behalf of the authority and arise out of such investigations, and
- (b) it relates to the obtaining of information from confidential sources.”

Section 30(3) provides that –

“The duty to confirm or deny does not arise in relation to information which is (or if it were held by the public authority would be) exempt information by virtue of subsection (1) or (2).”

Section 30(4) provides that –

“In relation to the institution or conduct of criminal proceedings or the power to conduct them, references in subsection (1)(b) or (c) and subsection (2)(a) to the public authority include references-

- (a) to any officer of the authority,
- (b) in the case of a government department other than a Northern Ireland department, to the Minister of the Crown in charge of the department, and
- (c) in the case of a Northern Ireland department, to the Northern Ireland Minister in charge of the department.”

Section 30(5) provides that –

“In this section-

"criminal proceedings" includes-

- (a) proceedings before a court-martial constituted under the Army Act 1955, the Air Force Act 1955 or the Naval Discipline Act 1957 or a disciplinary court constituted under section 52G of the Act of 1957,
- (b) proceedings on dealing summarily with a charge under the Army Act 1955 or the Air Force Act 1955 or on summary trial under the Naval Discipline Act 1957,
- (c) proceedings before a court established by section 83ZA of the Army Act 1955, section 83ZA of the Air Force Act 1955 or section 52FF of the Naval Discipline Act 1957 (summary appeal courts),
- (d) proceedings before the Courts-Martial Appeal Court, and
- (e) proceedings before a Standing Civilian Court;

"offence" includes any offence under the Army Act 1955, the Air Force Act 1955 or the Naval Discipline Act 1957.”

Personal information.

Section 40(1) provides that –

“Any information to which a request for information relates is exempt information if it constitutes personal data of which the applicant is the data subject.”

Section 40(2) provides that –

“Any information to which a request for information relates is also exempt information if-

- (a) it constitutes personal data which do not fall within subsection (1), and
- (b) either the first or the second condition below is satisfied.”

Section 40(3) provides that –

“The first condition is-

- (a) in a case where the information falls within any of paragraphs (a) to (d) of the definition of "data" in section 1(1) of the Data Protection Act 1998, that the disclosure of the information to a member of the public otherwise than under this Act would contravene-
 - (i) any of the data protection principles, or
 - (ii) section 10 of that Act (right to prevent processing likely to cause damage or distress), and
- (b) in any other case, that the disclosure of the information to a member of the public otherwise than under this Act would contravene any of the data protection principles if the exemptions in section 33A(1) of the Data Protection Act 1998 (which relate to manual data held by public authorities) were disregarded.”

Section 40(4) provides that –

“The second condition is that by virtue of any provision of Part IV of the Data Protection Act 1998 the information is exempt from section 7(1)(c) of that Act (data subject's right of access to personal data).”

Section 40(5) provides that –

“The duty to confirm or deny-

- (a) does not arise in relation to information which is (or if it were held by the public authority would be) exempt information by virtue of subsection (1), and
- (b) does not arise in relation to other information if or to the extent that either-
 - (i) he giving to a member of the public of the confirmation or denial that would have to be given to comply with section 1(1)(a) would (apart from this Act) contravene any of the data protection principles or section 10 of the Data Protection Act 1998 or would do so if the exemptions in section 33A(1) of that Act were disregarded, or
 - (ii) by virtue of any provision of Part IV of the Data Protection Act 1998 the information is exempt from section 7(1)(a) of that Act (data subject's right to be informed whether personal data being processed).”

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).”