

Freedom of Information Act 2000 (Section 50)

Decision Notice

Date: 18 February 2010

Public Authority: Medicines and Healthcare Regulatory Authority
Address: Market Towers
1 Nine Elms Lane
London
SW8 5NQ

Summary

The complainant made a request under the Freedom of Information Act 2000 (the "Act") to the Medicines and Healthcare Regulatory Authority (MHRA) for information it had redacted from pages 9 to 31 of an Assessment Report setting out the findings of a study conducted on the issue of mortality rates in Linezolid treated patients. The MHRA refused to disclose the requested information upon reliance of the exemptions contained at sections 40(2) and 41(1) of the Act. The Commissioner considers that the MHRA correctly applied the exemption contained at section 41(1) of the Act to withhold the requested information. As the Commissioner found that section 41(1) of the Act was correctly engaged he did not go on to consider the MHRA's application of section 40(2) of the Act. The Commissioner does however consider that the MHRA breached sections 1(1)(a) and (b), section 10(1) and section 17(1) in its handling of this request.

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. The complainant made a request on 16 September 2008 to the MHRA. The complainant asked the MHRA to provide her with information surrounding the missing pages 9 to 31 of an Assessment Report

setting out the findings of a study conducted on the issue of mortality rates in Linezolid treated patients, as well as asking for a copy of those missing pages. On 6 November 2008 the MHRA answered all of the complainant's questions surrounding the missing pages but did not at that stage provide the complainant with the missing pages. On 10 December 2008 the MHRA provided the complainant with pages 9 to 31 of the Assessment Report however had made a number of redactions under section 40(2) of the Act.

3. The complainant requested an internal review in January 2009. The MHRA upheld the redactions that it had made, however explained that the exemption contained at section 41(1) of the Act was also applicable to the redactions it had made. It did however highlight that section 40(2) had been incorrectly applied to some of the redactions made.

The Investigation

Scope of the case

4. As the complainant was dissatisfied with the redactions made to pages 9 to 31 of the Assessment Report she made a formal complaint to the Information Commissioner's Office regarding this on 2 March 2009.
5. The Commissioner has therefore considered whether or not the MHRA made the redactions to pages 9 to 31 of the Assessment Report in accordance with the Act.

Chronology

6. On 2 October 2009 the Commissioner wrote to the MHRA to ask for further arguments in support of its application of section 40(2) and section 41(1) to the redactions to pages 9 to 31 of the Assessment Report. He also asked for an unredacted copy of pages 9 to 31 of the Assessment Report along with an explanation as to the redactions which were made and under which exemption.
7. On 23 October 2009 the MHRA responded to the Commissioner. It confirmed what information it had redacted from pages 9 to 31 of the Assessment Report and which exemption it had applied to those redactions. It provided further arguments in support of its application of the exemptions contained at sections 40(2) and 41(1) of the Act to the various redactions made.

Analysis

Exemptions

Section 41(1)

8. Information is exempt under section 41(1) if it was obtained by a public authority from another person and the disclosure of the information outside of the Act would constitute an actionable breach of confidence.
9. The information redacted from pages 9 to 31 of the Assessment Report, contains information about the patients who took part in the study conducted on the issue of mortality rates in Linezolid treated patients , including their patient identification number, their age and gender as well as information about their symptoms, diagnosis, treatment and treatment outcome.
10. There are two components to section 41(1), firstly the information must have been obtained by the public authority from another person and secondly disclosure of the information would have to give rise to an actionable breach of confidence. A person may be an individual, a company, a public authority or any other legal entity.

Was the information obtained by the MHRA from another person?

11. In deciding whether information has been 'obtained from another person' the Commissioner will focus on the content of the information rather than the mechanism by which it was imparted and recorded.
12. The MHRA has explained that the redacted information was provided to it by the pharmaceutical company conducting the study. The redacted information was obtained by the practitioner treating the patients who were taking part in the study. This information was then passed to the pharmaceutical company conducting the study who ultimately provided it to the MHRA.
13. The Commissioner is satisfied that the redacted information was provided to the MHRA by the patients who took part in the study through the practitioners and pharmaceutical company which conducted the study. He therefore considers that it falls within the definition of information obtained by a public authority as contemplated by section 41 (1).

Would disclosure give rise to an actionable breach of confidence?

14. When considering whether or not a breach of confidence is itself actionable in this case, the Commissioner has decided that it is appropriate to follow the test set out by Megarry J in *Coco v A N Clark (Engineers) Limited* (1968) FSR 415 and cited by the Information

Tribunal in *Bluck v the Information Commissioner & Epsom St. Helier University NHS Trust* (EA/2006/0090). Megarry J stated that:

'...three elements are normally required, if apart from contract, a case of breach of confidence is to succeed. First, the information itself must have the necessary quality of confidence about it. Secondly, that information must have been imparted in circumstances importing an obligation of confidence. Thirdly, there must be an unauthorised use of the information to the detriment of the party communicating it...'

15. The Commissioner will therefore consider whether these three factors can be met in this case in order to determine whether disclosure would give rise to an actionable breach of confidence.

Was the information imparted in circumstances importing an obligation of confidence?

16. The MHRA has explained that the redacted information was originally communicated between patient and practitioner. The MHRA stated that this "carries a well recognised and de-facto obligation of confidence, and is certainly tacit where a written understanding does not exist."
17. The Commissioner notes that although there is no absolute test of what constitutes a circumstance giving rise to an obligation of confidence, in *Coco v Clark*, it was suggested that the 'reasonable person' test may be a useful one, "If the circumstances are such that any reasonable man standing in the shoes of the recipient of the information would have realised that upon reasonable grounds the information was being given to him in confidence, then this should suffice to impose upon him the equitable obligation of confidence."
18. The Commissioner also notes that an obligation of confidentiality may be expressed explicitly, or implicitly. Whether or not there is an implied obligation of confidence may depend on the nature of the information itself, and the relationship between the parties.
19. The Commissioner has not been made aware that confidentiality was expressed in this case, however due to the nature of the relationship between a practitioner and a patient and the nature of the information itself, he is satisfied that confidentiality was implied.
20. The Commissioner therefore considers that the redacted information was imparted to the MHRA by the patients in circumstances that imported an obligation of confidence.

Does the information itself have the necessary quality of confidence about it?

21. Information will have the necessary quality of confidence if it is not otherwise accessible, in other words if it is not already in the public

domain, and if it is more than trivial. According to Megarry J in *Coco v Clark*, “however confidential the circumstances of communication, there can be no breach of confidence in revealing something to others which is already common knowledge.”

22. The redacted information is personal information relating to the patients involved in the study and their medical symptoms, diagnosis, treatment and outcome. Bearing in mind the nature of the information concerned, the Commissioner is satisfied that the information possesses the necessary quality of confidence, as he is satisfied that it is not information which is already in the public domain nor is it trivial.

Would unauthorised use of the redacted information cause detriment to the patients?

23. The MHRA stated that this is difficult to quantify, but suggested that it would not be unreasonable to assume that unauthorised disclosure of information, which was considered to have been imparted confidentially, is likely to cause distress to the patients who took part in the study (or next-of-kin where the patient has since deceased) where details of medical conditions are concerned. The Commissioner therefore considers the real consequence of disclosing the information would be that it would be an infringement of the patients privacy and dignity as the disclosure would be to the public at large and not just to the patients, their families and/ or next of kin.
24. The Commissioner also notes that this is supported by the fact that in *Attorney General v Guardian Newspapers [1990] 1AC 109*, Lord Keith of Kinkel stated that:

‘.....I would think it a sufficient detriment to the confider that information given in confidence is not to be disclosed to persons to whom he would prefer not to know of it, even though the disclosure would not be harmful to him in any positive way.’ (Cited at paragraph 8, *Bluck v Information Commissioner & Epsom St. Helier University NHS Trust*)
25. The Commissioner considers that as medical information constitutes information of a personal nature there is no need for there to be any detriment to the confider, in terms of any tangible loss, in order for it to be protected by the law of confidence and therefore it is not necessary to consider this further.
26. Further to the above, Article 8 of the Human Rights Act 1998 (the ‘HRA’) recognises the importance to individuals to have the privacy of the affairs respected and in line with this an invasion of privacy would be a sufficient detriment to the confider

Would the public authority have a defence to a breach of confidence claim because the public interest in disclosure would outweigh the public interest in maintaining the duty of confidentiality

27. Although section 41 is an absolute exemption, the law of confidence does contain its own inbuilt public interest in that one defence to an action for breach of confidence is that the disclosure is in the public interest. The Commissioner therefore also considered whether the public authority could rely on a public interest defence so that a breach of confidence in the event of disclosure would not be actionable. However the Commissioner takes the view that a duty of confidence should not be overridden lightly, particularly in the context of a duty owed to an individual. Disclosure of any confidential information undermines the principle of confidentiality itself which depends on a relationship of trust between the confider and the confidant.
28. Although the public authority did not provide any public interest arguments in this case, the Commissioner would concur with the comments of the Information Tribunal in *Bluck v the Information Commissioner & Epsom St Helier University NHS Trust* (EA/2006/0090) that it is in the interest of *“patients to have confidence that medical staff will not disclose sensitive medical data before they divulge full details of their medical history and lifestyle. Without that assurance patients may be deterred from seeking advice and without adequate information doctors cannot properly diagnose or treat patients.”* The Commissioner has not been presented with any compelling argument as to a particular public interest in disclosure into the public domain in this case sufficient to outweigh the considerable public interest in maintaining the confidentiality of medical information. He therefore considers the Trust would not have a public interest defence for breaching the confidence in this case.

Does the breach remain actionable after the death of the confider?

29. In this case the MHRA has confirmed that some of the patients who took part in the study are now deceased.
30. In *Bluck* the Tribunal confirmed the ICO's position, that even though the person to whom the information relates may have died; action for a breach of confidence could be taken by the personal representative of that person, and that therefore the exemption continues to apply. The Tribunal stated that;

“In these circumstances we conclude that a duty of confidence is capable of surviving death of the confider “
31. The Commissioner considers that in the circumstances of this case the duty of confidence is similarly capable of surviving the death of the confider. It is the Commissioner's view that in determining whether disclosure would constitute an actionable breach of confidence, it is not

necessary to establish that, as a matter of fact, the deceased person has a personal representative who would take action.

Conclusion

32. Having considered the various elements required to satisfy the application of section 41(1) in this case the Commissioner considers that the exemption was correctly engaged in this case in relation to all of the redacted information.
33. The Commissioner notes that some of the withheld information relates to living individuals and may therefore constitute their personal data. However as the Commissioner has concluded all the withheld information is exempt on the basis of section 41(1) he has not gone to reach a decision in relation to the application of section 40(2).

Procedural Matters

Section 1(1)(b)

34. Section 1(1) of the Act 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, and
(b) if that is the case, to have that information communicated to him.”*

35. In this case the MHRA did not confirm what information it held relevant to the scope of the request and furthermore it did not disclose information it held which was not exempt within the statutory time for compliance. The Commissioner therefore considers that the MHRA breached section 1(1)(a) and (b) in its handling of this request.

Section 10(1)

36. Section 10(1) of the Act 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.”

37. The Commissioner has considered whether or not the MHRA complied with section 10(1) of the Act.
38. As the MHRA did not comply with its obligations under section 1(1)(a) and (b) within the statutory time for compliance, it breached section 10(1) in its handling of the request.

Section 17

39. Section 17(1) states 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.”*

40. The Commissioner will find a PA in breach of s17(1) if any element of the refusal notice relating to the application of exemptions, which is being relied upon at the completion of the internal review or the time for statutory compliance, is introduced outside of the 20 working day period.

The Decision

- 41. The Commissioner’s decision is that the MHRA correctly applied section 41 (1) in order to withhold the information redacted from pages 9 to 31 of the Assessment Report.
- 42. The Commissioner does however find that the MHRA breached section 1(1)(a) and (b), section 10(1) and section 17(1) in the handling of this request.

Steps Required

- 43. The Commissioner requires no steps to be taken.

Right of Appeal

44. 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,
Arnhem House,
31, Waterloo Way,
LEICESTER,
LE1 8DJ

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 18th day of February 2010

Signed

**Lisa Adshead
Senior FOI Policy Manager**

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

Legal Annex

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.”