

Freedom of Information Act 2000 (FOIA)

Decision notice

Date: 3 February 2015

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 about an investigation into two products: urine sample collection devices. The Medicines and Healthcare Products Regulatory Agency (MHRA) disclosed some information and withheld other information that it said was exempt under section 40 (personal data), section 41 (information provided in confidence) and section 44(1)(a) (prohibitions on disclosure) of the FOIA.
2. The Commissioner's decision is that the MHRA has correctly applied section 40, section 41 and section 44(1)(a) to the request and he does not require it to take any further steps.

Request and response

3. On 20 March 2014, the complainant wrote to the MHRA and requested information in the following terms:
 1. *around January 2010 the MHRA launched a compliance investigation against two products of the Firm Jbol Ltd Whiz Midstream and Whiz Freedom - the latter was settled we believe by arbitration and the former was dismissed as an abuse of process with costs in the magistrates court. Kindly provide us with the full investigation file regarding this matter. In this regard we attach a letter of agreement from the firm Jbol Ltd to release this information and a letter from [Named Individual] who was also prosecuted by the MHRA personally (also dismissed as an abuse of process by the courts). Signed hard copies of these have been posted to the MHRA.*

- 2. Kindly advise if the complaint regarding this was made by [Named Organisation] in relation to the Whiz midstream and if not then who made the complaint.*
 - 3. Kindly [sic] confirm that no complaint was made against the Whiz freedom*
 - 4. Kindly advise what was the substance of the complaint against the Whiz Midstream and the Whiz freedom.*
 - 5. Kindly advise the outcome of the complaint of the complaint [sic] against the Whiz midstream and by outcome we mean the final decision and when it was reached regarding the Whiz midstream.*
 - 6. Kindly advise when a decision was reached to take action against Jbol Ltd and [Named Individual] and by whom, and when this decision was made, - by action is meant the decision to pursue the action and the decision to prosecute.*
 - 7. Kindly provide the letters issued to [Named Individual and or Jbol Ltd in regard to any such prosecution and their replies*
 - 8. Kindly advise which officers of the MHRA dealt with and investigated this complaint of the whiz midstream*
 - 9. Kindly advise what were the full grounds and reasons to prosecute*
 - 10. Kindly advise when the complaints were closed and the full reasons for closing them*
 - 11. Kindly advise of the evidence taken into consideration to investigate both products and when this started and when this period ended*
 - 12. Kindly advise of the evidence taken into consideration to prosecute both products and when this started and when this period ended*
 - 13. Kindly provide a full copy of the investigation file given that permission for its release has been obtained from Jbol Ltd and [Named Individual]*
 - 14. Kindly make no redactions from the file as full permission for its release has been given*
 - 15. Kindly confirm in writing that nothing has been deleted from the file, erased altered etc.*
4. This request is similar in scope to FS50551392. Both requests form part of a long standing dispute between the complainant and the MHRA. The dispute concerns various classification and enforcement matters to do

with products the complainant has designed, and those of other manufacturers.

5. The MHRA responded to FS50550588 on 16 April. It released information in respect of parts 5, 6 and 7 and said that:
 - information relating to part 2 of the request was exempt from disclosure under section 41 and section 44(1)(a) of the FOIA
 - information relating to parts 3 and 4 of the request was also exempt under section 44(1)(a)
 - that information relating to part 8 was exempt under section 40
 - information relating to parts 9 and 10 had been provided in its response to other parts of the request
 - some information relating to parts 11 and 12 had been provided in its response to other parts of the request and some of the information in these parts was exempt under section 44(1)(a)
 - it had already provided the complainant with information relating to parts 13 and 14 in response to a separate request.
6. Following an internal review the MHRA wrote to the complainant on 16 May. The MHRA:
 - clarified that, as with parts 13 and 14 of the request, information requested at part 1 had already been provided to the complainant.
 - maintained its position regarding parts 3, 4, 10, 11, 12 and 14
 - clarified its application of the exemptions it had cited in relation to part 2 (section 41 and 44) and part 8 (section 40)
 - now said that parts 5, 6, 7 and 9 of the request are differences of opinion on the MHRA's decision and are therefore outside the scope of the FOIA
 - noted where its original response might have been clearer, including the fact that it could have cited section 21 of the FOIA (information available by other means) in relation to part 13; and
 - said it would provide a response to point 15 within 10 working days.
7. On 24 May, the MHRA provided a further response in relation to part 2 and part 9 of the request. In relation to part 15 of the request, it also confirmed that no information had been deleted, erased or altered.

Scope of the case

8. The complainant contacted the Commissioner on 10 July to complain about the way his request for information had been handled.
9. In addition to the exemptions applied to this request, the complainant maintains that the MHRA has also breached section 77 (altering records to prevent disclosure). However, the Commissioner has seen no evidence to support this position and he has not included section 77 in his investigation into the MHRA's handling of the request.
10. The Commissioner focussed his investigation on the MHRA's application of section 40 to part 8 of the request, its application of section 41 to part 2 of the request (the MHRA also considers section 40 and section 30(2)(b) [investigations and proceedings] may apply to this part) and its application of section 44(1)(a) to parts 2, 3, 4, and the remaining withheld information relating to parts 11 and 12.

Reasons for decision

11. **Section 40(2)** of the FOIA says information is exempt from disclosure if it is the personal data of a third party (ie someone other than the applicant) and the conditions under either section 40(3) or 40(4) are also satisfied.
12. The Commissioner therefore first considered whether the information requested in part 8 of the complainant's request is the personal data of a third party.

Is the information personal data?

13. The Data Protection Act (DPA) says that for data to constitute personal data, it must relate to a living individual, and that individual must be identifiable.
14. The Commissioner is satisfied that the MHRA officers who investigated the complaint in question are living individuals; that their names 'relate' to them and that they could be identified if their names were to be released. The requested information is therefore their personal data.
15. Having decided that the requested information is third party personal data, the Commissioner then turned his attention to the conditions under section 40(3).

Are the conditions under section 40(3) satisfied?

16. The first condition under section 40(3)(a)(i) says that personal data is exempt from disclosure to a member of the public if doing so would contravene one of the data protection principles set out in Schedule 1 of the DPA. The Commissioner has considered whether the MHRA is correct when it argued in its submission to him that disclosing the information would breach the first data protection principle: that personal data 'shall be processed fairly and lawfully...'.
 17. When considering whether disclosure would be unfair, and so breach the first principle, the Commissioner took three factors into account:
 - Have the individuals concerned (ie the data subjects) given their consent to disclosure?
 - What reasonable expectation do the individuals have about what will happen to their personal data?
 - What might be the likely consequences resulting from disclosure?
 18. Assessing fairness however, also involves balancing the individuals' rights and freedoms against the legitimate interest in disclosure to the public. It may still be fair to disclose the information if there is an overriding legitimate interest in doing so (condition 6 in Schedule 2 of the Data Protection Act). The Commissioner therefore also finally considered these interests.

Has the individual given their consent to disclosure?

19. The MHRA has told the Commissioner that one of the individuals concerned has left the organisation but is unlikely to have given permission for their name to be disclosed. The MHRA has confirmed that the second individual concerned has not consented to the disclosure of their personal data.

What reasonable expectation do the individuals have about what will happen to their personal data?

20. Whether public authority employees could reasonably expect their personal data to be released can depend on their seniority and whether they are in a public facing role.
21. The MHRA has told the Commissioner that the individuals concerned are not in roles that the MHRA considers especially senior and that it is not usual for the MHRA to disclose the names of officers below the grade of Senior Civil Servant. These individuals' interactions with the public are limited to those people that they encounter in the course of particular

investigations – they do not have generally outward facing roles. As such, they would have a reduced expectation that their personal data would be made publicly available.

What might be the likely consequences resulting from disclosure?

22. As discussed at paragraph 4, the request is part of a long standing dispute that goes back to 2009. The MHRA has told the Commissioner that, to date, the complainant has submitted over 50 FOIA requests, in addition to a large volume of other complaints and correspondence.
23. The complainant has, on occasion, used abusive or aggressive language and terminology about MHRA staff in his long running correspondence with the MHRA, for example references to Nazism, anti-Semitism and comparing individuals with people involved in the 'Baby P' case. The complainant has also made other unsubstantiated accusations of criminality and corruption against MHRA staff.
24. In view of this, the MHRA has argued that disclosing the staff members' names to the complainant risks bringing about circumstances that the staff members would find distressing. The MHRA says that it is aware that when the complainant finds out the identity of an individual, he often adds them to his list of contacts – it is keen that the staff members in question are not also targeted with similar accusations.

Balancing the individuals' rights and freedoms against the legitimate interest in disclosure

25. Despite the factors above, the requested information may still be disclosed if there is a compelling public interest in doing so.
26. The MHRA recognises the general need for public authorities to be accountable and transparent and it ensures the professionalism and probity of its staff through performance reviews and external audits. Given this, and the fact that the complaint case that is the subject of this request was closed a number of years ago, the Commissioner can see no public interest reason for disclosing the name of the complaint's investigating officers that is of such importance that it outweighs the officers' right not to have their personal data disclosed to a third person.
27. The Commissioner accepts the MHRA's arguments and is satisfied that the withheld information is the personal data of third persons and that releasing it would contravene one of the conditions under section 40(3)(a)(i). He considers it would be unfair to do so, would breach the first data protection principle and there is no legitimate public interest in its disclosure. It has not been necessary to go on to consider the conditions under section 40(4).

28. **Section 44(1)(a)** of the FOIA says that that information is exempt if its disclosure is prohibited by, or under, any enactment.
29. The enactment the MHRA has cited in relation to parts 2, 3 and 4 of the request and the remaining withheld information in relation to parts 11 and 12 is the Enterprise Act 2002 ('EA2002'), and specifically section 237(2).
30. Section 237 of the EA2002 makes it an offence to disclose "specified information" which relates to the affairs of an individual [(1)(a)], or business of an undertaking [(1)(b)], during the lifetime of the individual [(2)(a)] or while the undertaking continues to exist [(2)(b)]. Section 238 clarifies that information is specified information if it comes to a public authority in connection with the exercise of its functions.
31. The Information Tribunal has previously been asked to consider the use of section 237 as a statutory prohibition on disclosure and it has concluded it can be used in this way. The Commissioner has therefore gone on to consider whether the requested information is "specified information" and whether the undertaking; in this case the organisation that submitted the complaint to the MHRA (the 'Named Organisation' in the request), continues to exist.

Is the information 'specified' information'?

32. The Commissioner considers that the requested information is 'specified information' as defined under the EA2002, section 238(1)(c). This is because it has come to the MHRA in connection with the exercise of a function it has under, or by virtue of, "such subordinate legislation as the Secretary of State may by order specify for the purposes of this subsection."
33. As the regulating authority responsible for medicines and healthcare products, the function the MHRA is exercising is consumer protection, under the Consumer Protection Act 1987. This falls within category (b) of section 238(1) of the EA2002: an enactment specified in Schedule 14.

Does the undertaking continue to exist?

34. The 'undertaking' refers to the related individual or business entity. The Commissioner is satisfied that the organisation that submitted the complaint to the MHRA is currently in existence and consequently he is also satisfied that section 237(2)(b) applies.
35. Sections 239 to 243 of the EA2002 provide for certain gateways for the disclosure of information. These gateways do not compel the MHRA to disclose information, but do allow it to do so for the purposes set out in these sections, or in accordance with the requirements they stipulate.

The MHRA's position is that none of these gateways apply to the requested information.

36. The Commissioner therefore considers that the MHRA has correctly applied the exemption under section 44(1)(a) of the FOIA to parts 2, 3 and 4 of the request and the remaining withheld information in relation to parts 11 and 12, by virtue of the EA2002.
37. Although the Commissioner accepts that section 44(1)(a) applies to part 2 of the request, MHRA has also cited section 41 in relation to part 2, the Commissioner has in this particular case gone on to also consider the application of section 41.
38. **Section 41** of the FOIA says that information is exempt from disclosure if it was provided to a public authority by another person and disclosing it would be an 'actionable' breach of confidence (ie the aggrieved party would have the right to take the authority to court as a result of the disclosure). Although section 41 is an absolute exemption and is therefore not subject to a public interest test under the FOIA, the common law duty of confidence contains an inherent public interest test. The Commissioner has therefore also considered this in order to decide if the information is exempt.
39. The MHRA applied this exemption to part 2 of the information request - who made the particular complaint about one of the complainant's products.

Was the information provided by another person?

40. The MHRA has told the Commissioner that a third person provided it with the requested information and he is satisfied that this is the case.

Would disclosing the information be a breach of confidence?

41. When considering whether disclosing information would be a breach of confidence, the Commissioner takes into account whether:
 - the information has the necessary quality of confidence
 - the information was imparted in circumstances importing an obligation of confidence; and
 - whether disclosure would be an unauthorised use of the information to the detriment of the confider.

Does the information have the necessary quality of confidence?

42. The MHRA has told the Commissioner that the information in question is not accessible other than through disclosure and that, being about an

investigation, it is important to the confider and not trivial. The Commissioner accepts this and is satisfied that the information consequently has the necessary quality of confidence.

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

43. In support of its position, the MHRA says that the nature of the relationship between the confider, the confidant (MHRA as investigator in this case) and the investigated (the complainant) clearly implies a duty of confidentiality.
44. The Commissioner agrees that the conditions inherent in this relationship, although not explicitly stated, are obvious from the circumstances. An investigator would not need to tell the investigated who had complained about them – this is simply understood.

Would disclosure be an unauthorised use of the information to the detriment of the confider?

45. The MHRA acknowledges that specific detriment is difficult to identify. However, it maintains that disclosing information such as this would be an infringement of the confider's privacy and refers to the Commissioner's own guidance which says '*an invasion of an individual's privacy can be viewed as a detriment in its own right*'. As a regulator, the MHRA needs to be able to reassure confiders that it will respect confidences. Otherwise, there is a risk that it will not receive information about potential breaches and other wrongdoings that are not picked up through its routine monitoring and inspections.
46. From the arguments provided by the MHRA, the Commissioner is satisfied that disclosing the information in question would be a breach of the confidence that the confider has a right to, and would expect.
47. As noted at paragraph 38, the common law duty of confidence contains an inherent public interest test. This test assumes that information should be withheld unless the public interest in disclosure outweighs the public interest in maintaining the duty of confidence (and is the reverse of that normally applied under the FOIA).
48. The MHRA has confirmed that no questions of propriety have arisen regarding the investigation that is the subject of this request; neither are there broader public health issues to be considered or a need to reassure the public. The MHRA therefore argues that there is no public interest in disclosing this particular information about the investigation in question. The Commissioner is convinced of the merits of this argument and has concluded that the public interest in withholding the

information, as summarised at paragraph 47, outweighs any interest in disclosing it.

49. Since the Commissioner is satisfied that the information requested at part 2 of the wider request is exempt from disclosure under both sections 41 and 44 of the FOIA, he has not gone on to consider the MHRA's additional possible application of section 40 and section 30 to this element of the request.

Right of appeal

50. 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: 0870 739 5836

Email: GRC@hmcts.gsi.gov.uk

Website: www.justice.gov.uk/tribunals/general-regulatory-chamber

51. 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.
52. 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

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