

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 a historical complaint concerning a urine sample collection device. The Medicines and Healthcare Products Regulatory Agency (MHRA) disclosed some information and withheld other information that it said was exempt under section 40(2) (personal data) 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(2) and section 44(1)(a) to the request and he does not require it to take any further steps.

Request and response

3. On 21 March 2014, the complainant wrote to the MHRA and requested information in the following terms:

"1 Kindly advise if the complaint regarding this was made by Jbol Ltd and if not then by whom¹⁷ [sic].

2. Kindly advise what was the substance of the complaint against the RBI container.

3. Kindly advise the outcome of the complaint of the complaint [sic] against the RBI 30 ml container and by outcome we mean the final decision and when it was reached

4. Kindly advise when a decision was reached to take action (or no action) against the RBI container and by whom, and when this decision was made, - by action is meant the decision to pursue the investigation or not and the decision to prosecute or not

- 5. Kindly provide the letters issued to RBI in regard to any such investigation and or prosecution and their replies*
 - 6. Kindly advise which officers of the MHRA dealt with and investigated this complaint of the RBI container*
 - 7. Kindly advise what were the full grounds and reasons to prosecute or not to*
 - 8. Kindly advise when the complaints were closed and the full reasons for closing them*
 - 9. Kindly advise of the evidence taken into consideration to investigate the RBI and when this started and when this period ended*
 - 10. Kindly advise of the evidence taken into consideration to prosecute or not the RBI container and when this started and when this period ended*
 - 11 Kindly advise if the advice of any third parties was sought such as barristers, DOH personal etc and please identify the organisations if this was the case*
 - 12. Kindly provide a full copy of the investigation file”*
4. The MHRA responded on 15 April. It told the complainant that the paper file relating to the complaint that is the subject of his request was closed in 2009 and would have been destroyed, in line with its retention schedule for cases where there is no prosecution raised from an initial investigation. It did not therefore hold the paper file. The information it could disclose was drawn from information the MHRA held on its old computer systems.
 5. The MHRA released information in respect of parts 1, 2, 3, 4, 7, 8 of the request. It said it did not hold information in respect of parts 5 and 11. It withheld information in respect of part 6, citing the exemption under section 40(2) of the FOIA. In respect of parts 9 and 10, the MHRA referred the complainant to its response to part 7 and said it did not hold any additional information. The MHRA released some information in respect of part 12, redacting some information that it said was exempt from disclosure under section 40(2) of the FOIA.
 6. Following an internal review the MHRA wrote to the complainant on 16 May. It now said that, following a search, it had located the paper complaint file in its off-sight storage facility. It apologised, explained how this mistake had happened and detailed the steps it would take to reduce the risk of it happening again.
 7. The MHRA amended its response to the complainant’s request. It largely confirmed or provided more information in relation to parts 1, 2, 3, 4, 6, 7, 8 and 9 of its original response, and maintained its position in regards to the information it had withheld under section 40(2). However, it now said that it holds information in relation to part 5 but

that this is exempt from disclosure under section 44(1)(a) of the FOIA. It said that information it could now confirm it holds in relation to parts 10, 11 and 12 is also exempt under section 44(1)(a).

8. The complainant did not request an internal review of the MHRA's amended response but the MHRA has confirmed to the Commissioner that, in all likelihood, it would have maintained its position that part 6 of the request is exempt from disclosure under section 40(2), and parts 5 and 11, and the remaining withheld information relating to parts 10 and 12 are exempt under section 44(1)(a).

Scope of the case

9. The complainant contacted the Commissioner on 4 August to complain about the way their request for information had been handled. They were dissatisfied that the MHRA had misplaced the paper file and had exempted some of the information they had requested. The complainant also considered that the MHRA's claim that it had destroyed an investigation file had breached section 77 (altering records to prevent disclosure).
10. Having considered the explanation the MHRA provided to the complainant in the course of the initial internal review it undertook, regarding its location of relevant files in offsite storage, the Commissioner is prepared to accept this as an accurate version of events – on the balance of probabilities – and he did not investigate this element further.
11. The Commissioner therefore focussed his investigation on the MHRA's application of section 40(2) to part 6 and section 44(1)(a) to parts 5 and 11 of the request, and the remaining withheld information relating to parts 10 and 12, by virtue of the EA2002.

Reasons for decision

12. **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.
13. The Commissioner therefore first considered whether the information requested in part 6 of the complainant's request is the personal data of a third party.

Is the information personal data?

14. 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.
15. The Commissioner is satisfied that the MHRA officer who investigated the complaint in question is a living individual; that their name 'relates' to them and that they could be identified if their name was to be released. The requested information is therefore their personal data.
16. 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?

17. 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...'.
 18. 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?
 19. 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?

20. The MHRA has confirmed that the 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?

21. Whether a public authority employee could reasonably expect their personal data to be released can depend on their seniority and whether they are in a public facing role.
22. The MHRA has told the Commissioner that the individual concerned is not in a role 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. In addition, the MHRA has also told the Commissioner that it gives a higher degree of protection to its staff who are engaged in investigation and enforcement work, such as the individual in this case. This individual's interaction with the public is also limited to those people that they encounter in the course of a particular investigation – they do not have a generally outward facing role. 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?

23. This request is similar in scope to FS50550588. 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.
24. The dispute goes back to 2009 and the MHRA has told the Commissioner that, to date, the complainant has submitted over 50 FOIA requests to the MHRA, in addition to a large volume of other complaints and correspondence.
25. The complainant has, on occasion, used abusive or aggressive language and terminology about MHRA staff in their long 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.
26. In view of this, the MHRA has argued that disclosing the staff member's name to the complainant risks bringing about circumstances that the staff member 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 member in question is not also targeted with similar accusations.

Balancing the individual's rights and freedoms against the legitimate interest in disclosure

27. Despite the factors above, the requested information may still be disclosed if there is a compelling public interest in doing so.
28. 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 officer that is of such importance that it outweighs the officer's right not to have their personal data disclosed to a third person.
29. The Commissioner accepts the MHRA's arguments and is satisfied that the withheld information is the personal data of a third person 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).
30. **Section 44(1)(a)** of the FOIA says that information is exempt if its disclosure is prohibited by, or under, any enactment.
31. The enactment the MHRA has cited in relation to parts 5, 10, 11 and 12 of the request is the Enterprise Act 2002 ('EA2002'), and specifically section 237(2).
32. 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.
33. 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, continues to exist.

Is the information 'specified' information'?

34. 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."

35. 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?

36. 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.
37. 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.
38. The Commissioner therefore considers that the MHRA has correctly applied the exemption under section 44(1)(a) of the FOIA to parts 5 and 11 of the request, and the remaining withheld information relating to parts 10 and 12, by virtue of the EA2002.

Right of appeal

39. 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

40. 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.
41. 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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