

Freedom of Information Act 2000 (FOIA)

Decision notice

Date: 6 June 2024

Public Authority: Medicines & Healthcare Products Regulatory Agency

Address: 10 South Colonnade
Canary Wharf
London
E14 4PU

Decision

1. The complainant has requested information from the Medicines and Healthcare Products Regulatory Agency (MHRA). The Commissioner's decision is that the MHRA is entitled to rely on section 41(2) of FOIA to neither confirm nor deny it holds the requested information.

Request and response

2. The complainant made the following information request to the MHRA on 25 December 2023:

"I would like to request you the information under Freedom of Information Act 2000. [personal data redacted] reported about Bristol Laboratories Limited in 2017. Then one of the MHRA inspectors called [personal data redacted] Inspection, Enforcement and Standards Division (I, E & S) and Medicines, Healthcare and Products Regulatory Agency (MHRA).

I would like to know what is MHRA action in response to the data integrity complaint [personal data redacted]. And is that MHRA can confirm that they do consider or not consider the investigation report

into the Bristol laboratories which is [personal data redacted]. If consider what is the basis for that and if not what action you took to protect the victim. I believe same time they do take [personal data redacted] signature for QC department, does MHRA know what happened to him?

I believe MHRA failed to comply Modern Slavery Act 2015, part 5, 52, Duty to notify Secretary of State about suspected victims of slavery or human trafficking.”

3. The MHRA responded on 25 January 2024. It refused to confirm or deny whether it held the requested information, citing the exemptions as set out at sections 40(5) and 41(2) of FOIA as a basis for neither confirming nor denying (NCND) whether it held the information.
4. The complainant sought an internal review of the MHRA’s decision on 31 January 2024. The MHRA provided its internal review response on 22 February 2024. The reviewer upheld the original decision.

Reasons for decision

5. This reasoning covers the MHRA’s reliance on section 41(2) of FOIA.
6. Section 1 of FOIA places an obligation on a public authority to confirm whether it holds information that has been requested – ‘the duty to confirm or deny’.
7. Under section 41(1), a public authority is entitled to withhold information it has confirmed it holds if (a) the information was obtained from another person and (b) disclosure would constitute a breach of confidence.
8. However, a public authority can rely on section 41(2) in cases where even to confirm or deny that the public authority holds the requested information would constitute a breach of confidence.
9. In this case, the complainant has requested information about action taken regarding a complaint submitted to the MHRA.
10. With regard to section 41(1)(a), if the MHRA held information within the scope of the request, it would have obtained it from another person or persons, i.e. statements and evidence submitted in respect of the complaint, investigation report etc.
11. With regard to section 41(1)(b), if held the information would have the necessary quality of confidence as it is not trivial or otherwise available;

would have been imparted in circumstances importing an obligation of confidence and finally, disclosing the information would be contrary to the confider(s) reasonable expectations and therefore cause a detriment to them.

12. To summarise, if the MHRA were to confirm or deny it holds the requested information it would, in effect, be confirming to the world at large that a specific complaint had either been submitted or not submitted and that it had or had not taken action on it. It could also, if it confirmed that the information was held, reveal the personal data of the individual(s) who allegedly submitted the complaint and other individuals such as the alleged subject of the complaint and those who would have provided substantiating evidence e.g. witness statements if the complaint was made.
13. Section 41 is an absolute exemption not subject to the public interest test. However the common law duty of confidence contains an inherent public interest test. With regard to section 41(2), this test assumes that a public authority should not confirm or deny it holds the information unless the public interest in confirming or denying outweighs the public interest in maintaining the duty of confidence.
14. From their complaint to him, the Commissioner appreciates that the information, if held, is of interest to them. However, the information, if held, does not have sufficient wider public interest such that it would warrant the MHRA breaking the obligation of confidence to confirm or deny it holds the information.
15. The Commissioner is therefore satisfied that, if held, the requested information would meet the conditions under section 41(1) and that the MHRA is therefore entitled to rely on section 41(2) to neither confirm nor deny it holds the information.
16. As the Commissioner considers that section 41(2) covers the entirety of the requested information, he has not gone on to consider the MHRA's application of section 40(5) of FOIA.

Right of appeal

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

18. 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.
19. Any Notice of Appeal should be served on the Tribunal within 28 (calendar) days of the date on which this decision notice is sent.

Name: Deirdre Collins
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