Freedom of Information Act 2000 (FOIA)

Decision notice

Date: 18 January 2021

Public Authority: Medicines and Healthcare Products Regulatory Agency

Address: 10 South Colonnade
Canary Wharf
London
E14 4PU

Decision (including any steps ordered)

1. The complainant requested from the Medicines and Healthcare Products Regulatory Agency ("MHRA") information in relation to two specific devices. The MHRA refused to comply with the complainant's request citing section 44(1) (prohibition on disclosure) of the FOIA as its basis for this refusal.

2. The Commissioner's decision is that the MHRA has correctly applied section 44(1) of the FOIA to the information requested.

3. The Commissioner does not require the MHRA to take any steps.

Request and response

4. On 11 February 2020 the complainant wrote two separate letters to the MHRA to request information in the following terms:

> *"From the date 1 March 2016 to the present, please provide me with copies of all emails in which the word lifevac is part of the email address of the sender or the recipient. If your search system differentiates capital and lower case letter, please also search: LifeVac and Lifevac"*

"From the date 1 March 2016 to the present, please provide me with copies of all emails in which the word dechoker is part of the email address of the sender or the recipient. If your search system differentiates capital and lower case letters, please also search: Dechoker"

5. On 5 March 2020, the MHRA responded to provide an update on the actions undertaken by their Compliance Unit in connection with the specified products, but it did not provide the complainant with the actual copies of the emails requested. In this reply the MHRA did not cite any legal basis for refusing to comply with the information request.

6. Remaining dissatisfied with the response received, on 6 March 2020 the complainant requested an internal review from the MHRA.

7. On 7 April 2020, the MHRA provided the complainant with the outcome of its internal review. It upheld its initial position to refuse to disclose the emails requested, but this time quoted section 44(1)(b) of the FOIA as its basis for this refusal.

Scope of the case

8. The complainant contacted the Commissioner on 29 April 2020 to complain about the way his request for information had been handled.

9. The Commissioner is aware that the MHRA, when it dealt with the request and also when it communicated with the Commissioner, cited section 44(1)(b) as its basis for refusing to provide the information requested. However, she believes that the MHRA should have cited section 44(1)(a), for the reasons provided below.

10. Therefore, the scope of this case and the following analysis is to consider whether section 44(1)(a) of the FOIA was engaged in this case.

Reasons for decision

Section 44 - Prohibitions on disclosure

11. Section 44 provides that:

"(1) Information is exempt if its disclosure (otherwise than under this Act) by the public authority holding it—

(a) is prohibited by or under any enactment,

(b) is incompatible with any EU obligation, or

(c) would constitute or be punishable as a contempt of court."

12. The MHRA is the regulator for medical devices and works under the Medical Devices Regulations 2002[1] ("MDR2002") which implement several European Directives - Directive 90/385[2], Directive 93/42[3] and Directive 98/79[4].

13. Article 20 of Directive 93/42 places a confidentiality obligation on the MHRA in relation to its duties when considering medical devices. It provides that all the parties involved in the application of this Directive are bound to observe confidentiality regarding all information obtained in carrying out their tasks.

14. This is also echoed in Article 15 of Directive 90/385 and Article 19 of Directive 98/79.

15. The EU confidentiality provisions are implemented in UK law via section 237(2) of the Enterprise Act 2002 ("EA2002"). This section applies to specified information and provides that:

"(2) Such information must not be disclosed:

(a) during the lifetime of the individual, or

(b) *while the undertaking continues to exist."*

16. The above provision prevents the disclosure of "specified information" that relates to the affairs of an individual or undertaking which a public authority has obtained in connection with the performance of certain functions. Specified information must not be disclosed during the lifetime of the individual or while the undertaking continues to exist

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[1] https://www.legislation.gov.uk/uksi/2002/618/contents/made

[2] https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:31990L0385&qid=1477564355940&from=en

[3] https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1993L0042:20071011:EN:PDF

[4] https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:31998L0079&from=en

unless the disclosure is permitted under sections 239 to 243 of the EA 2002.

17. Section 238 of the EA 2002 defines specified information as information that has come to a public authority in connection with the exercise of any function it has under or by virtue of:

    a. Part 1,3,4,6,7 or 8 of the Enterprise Act 2002;
    b. An enactment listed in Schedule 14 of the Enterprise Act 2002; or
    c. Such subordinate legislation as the Secretary of State may by order specify for the purposes of this subsection.

18. The MHRA told the Commissioner that, in line with its statutory obligations under Article 20 Directive 93/42, it treats all correspondence with economic operators (manufacturers, authorised representatives and distributors) as confidential to the parties involved. It added that *"This is further emphasised for correspondence relating to compliance and enforcement investigations conducted by the Agency, due to the legal and evidential implications for such correspondence should investigations lead to prosecution or legal decision in Court."*

19. The MHRA stated that in the present case the information requests sought data that would *"specifically capture correspondence between MHRA and manufacturers within the context of our ongoing compliance investigation".*

20. The MHRA explained that the withheld information in this case would cover all correspondence between MHRA and the manufacturers as part of its compliance investigation, which at this stage has been ongoing for over 4 years. It added that to collate all the withheld information would produce in excess of 100 emails.

21. The MHRA provided the Commissioner with a sample of 10 pieces of email correspondence, that are part of the withheld information, to indicate the nature of the information that the complainant requested and the MHRA refused to disclose.

22. The Commissioner has previously dealt with complaints of similar nature. In her decision notice in case FS50616856[5], the Commissioner

[5] https://ico.org.uk/media/action-weve-taken/decision-notices/2016/1625338/fs50616856.pdf

recognised that the MHRA is the regulator for medical devices and works under the MDR2002 which implement several European Directives, including the EU Medical Device Directive 93/42. In this case she found that Article 20 of this Directive places an obligation on the MHRA to keep "'all information" confidential when it is "'obtained in carrying out their tasks"'.

23. In the Commissioner's decision in case FS50697988[6], she concluded that the MHRA was correct to apply section 44(1)(a) of FOIA when it decided to withhold information requested based on the obligation imposed by Article 20 of the EU Medical Device Directive 93/42.

24. Furthermore, the Information Tribunal, in its decision in case EA/2015/0055-7[7] stated that the MHRA is entitled (indeed obliged) by virtue of section 44(1)(a) FOIA to withhold information received in connection with its function of enforcing the MDR2002.

25. Having examined the submissions of both parties, including the samples of withheld information provided by the MHRA, the Commissioner is satisfied that the information that has been withheld was obtained by the MHRA in carrying out its tasks. It follows that an obligation of confidentiality is placed upon the MHRA in relation to this information.

26. In conclusion, the Commissioner has found that the MHRA was entitled to withhold the information but in this instance the relevant exemption is section 44(1)(a) rather than section 44(1)(b) as relied upon by the MHRA.

27. In his complaint letter to the Commissioner, the Complainant stated that *"since lives may be at risk as a result of the MHRA's decision, the requested information is unquestionably a matter of public interest."*

28. The Commissioner reiterated that , by virtue of section 2(3) of FOIA, the exemption in section 44(1) is absolute. The only issue the Commissioner can consider is whether disclosure of the withheld information was: prohibited by or under any enactment, incompatible with any Community obligation or would constitute or would be punishable as a contempt of court. There is no public interest test.

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[6] https://ico.org.uk/media/action-weve-taken/decision-notices/2017/2172813/fs50697988.pdf

[7] http://informationrights.decisions.tribunals.gov.uk/DBFiles/Decision/i1667/EA-2015-0055-0057_03-11-2015.pdf

29. As the Commissioner is satisfied that disclosure is incompatible with the EA 2002, her conclusion is that the MHRA was entitled to withhold the requested information under section 44(1)(a).

Right of appeal

30. 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

31. 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.

32. 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 ……

Ben Tomes
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