

Freedom of Information Act 2000 (FOIA)

Decision notice

Date: 22 November 2017

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 all records associated with the Medicines and Healthcare Products Regulatory Agency ("MHRA") Reference Number device CA014885.
2. The Commissioner's decision is that the MHRA has correctly applied section 44 (1)(a) (statutory prohibition) of the FOIA to the information.
3. The Commissioner does not require the council to take any steps.

Request and response

4. On 26 July 2017, the complainant wrote to the MHRA and requested information in the following terms:

To whom it may concern:

This is a request for information under the Freedom of Information Act. Please confirm receipt.

Please provide me with any and all records associated with the MHRA Reference Number device CA014885. Records should include but not be limited to applications and correspondence.

If possible, please provide the records in digital format via e-mail. If your office wishes to correspond with me, please feel free to do so via e-mail.

I'm requesting these records for an article I'm reporting on my blog, therefore this is to request that I be categorized as a member of the news media. Further, I have no financial interest in the records, therefore this is to request that any fees be waived. If the fee for completing my request exceeds US\$5, please obtain my written approval prior to completing this request.

If my request is denied in whole or part, I ask that you justify all deletions and redactions by reference to specific exemptions of the FOI Act. I also expect you to release all segregable portions of otherwise exempt material".

5. The MHRA responded on 14 August 2017. It applied section 44(1)(a) (statutory prohibition) of the FOIA to the requested information.
6. Following an internal review, the MHRA wrote to the complainant on 24 August 2017. It maintained its position that the information is exempt under section 44 by way of section 237 of the Enterprise Act 2002.

Scope of the case

7. The complainant contacted the Commissioner on 29 August 2017 to complain about the way his request for information had been handled.
8. The Commissioner considers that the scope of the case has been to consider whether the MHRA dealt with this request correctly in accordance with section 44 of the FOIA.

Background

9. In case reference **FS50616856**, the Commissioner decided that the MHRA was entitled by virtue of section 44(1)(a) of the FOIA to withhold information coming to it in connection with its function of enforcing the Medical Devices Regulations 2002 ("MDR2002").
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Reasons for decision

Section 44- Prohibitions on disclosure

10. Section 44(1)(a) of the FOIA provides that information is exempt information if its disclosure is prohibited by or under any enactment. This is commonly known as a statutory bar to disclosure. In this case, the MHRA argues that section 237 of the Enterprise Act 2002 provides a statutory bar to a disclosure of the requested information.
11. The MHRA is the regulator for medical devices and works under the MDR2002 which implement several European Directives- Directive 90/385, Directive 93/42 and Directive 98/79.
12. Article 20 of Directive 93/42 places the following obligation on the MHRA in relation to its duties when considering medical devices:

"Member States shall ensure that all the Parties involved in the application of this Directive are bound to observe confidentiality with regard to all information obtained in carrying out their tasks."
13. This is also echoed in Article 15 of Directive 90/385 and Article 19 of Directive 98/79.
14. The Commissioner is satisfied that Article 20 places an obligation on the MHRA to keep 'all information' confidential when it is 'obtained in carrying out their tasks'.
15. The Commissioner is also satisfied the information that is subject to this exemption is information that would have been obtained by the MHRA as part of the discharge of its functions under the MDR2002.
16. As the MHRA outlined in its arguments to the Commissioner, the above confidentiality provisions are implemented in UK law via section 237(2) of the Enterprise Act 2002.
17. Section 237 of the Enterprise Act 2002 prevents the disclosure of 'specified information' that relates to the affairs of an individual or business 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 business continues to exist unless the disclosure is permitted under sections 239 to 243 of the Enterprise Act 2002.
18. Section 238 of the Enterprise Act 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.
19. The Commissioner understands that the MHRA receives information regarding adverse incidents involving medical devices from a number of sources.
 20. These are the manufacturer of the devices or the authorised representative in the country where the device is placed on the market, healthcare professions (in the NHS and private healthcare organisations), and members of the public. Of these, only the manufacturer or their authorised representative are legally obliged to report adverse incidents that fall under the criteria of vigilance, as defined in the medical Device Directives. The MHRA has explained that this information may only be shared with other Competent Authorities across the EU where it is necessary to protect the public's health and safety.
 21. As stated, the Commissioner is satisfied that the requested information would have come to the MHRA as a result of its functions under the MDR2002 and therefore it constitutes 'specified' information for the purposes of the Enterprise Act 2002.
 22. Once it has been established that the requested is specified information, the second question that the Enterprise Act 2002 raises is whether the information relates to the affairs of an individual or any business of an undertaking. The Commissioner also has to consider whether the individual is still alive or if the undertaking is still in existence.
 23. If a company continues to file accounts and maintain its registration at Companies House then it should be deemed to still be in existence, even if it no longer actively trades.
 24. The request in this case refers to the affairs of [redacted name], which continues to exist. The Commissioner is therefore satisfied that the aforementioned conditions are met.
 25. A failure to observe the confidentiality of a manufacturer's information on the part of the MHRA would amount to a breach of the Enterprise Act 2002 and the Medical Directives Regulations 2002 which is upheld by the European Union.
 26. The MHRA considers that a breach of section 44 of the Enterprise Act 2002 would possibly lead to the reluctance to report adverse incidents in

the future, by that company, and this would ultimately impact on the MHRA's duty to protect public health and discharge its obligations as the Competent Authority for medical devices in the UK.

Conclusion

27. 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.
28. The Commissioner has noted that the obligation is qualified in that it does not apply in limited circumstances specified in the last sentence of Article 20. This sentence is limited to when the MHRA needs to disclose the information for their purposes. It does not allow disclosure to the public outside those limited circumstances. She notes that the wording of section 44(1) explicitly requires the disclosure to be considered without consideration of the FOIA (for it states 'otherwise than under this Act').
29. In conclusion, the Commissioner has found that the MHRA was entitled to rely on section 44(1)(a) to withhold from providing the requested information.
30. By virtue of section 2(3) of FOIA, the exemption in section 44(1)(a) is absolute. The only issue the Commissioner can consider is whether disclosure of the withheld information was incompatible with any Community obligation. There is no public interest test.
31. As she is satisfied that the statutory bar applies, the MHRA was entitled to withhold this information and the Commissioner upholds its position.

Right of appeal

32. 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

33. 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.
34. 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

Alun Johnson
Team Manager
Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF