Freedom of Information Act 2000 (FOIA)

Decision notice

Date: 3 November 2016

Public Authority: Medicines & Healthcare Products Regulatory Agency (MHRA)

Address: 151 Buckingham Palace Road
London
SW1W 9SZ

Decision (including any steps ordered)

1. The complainant has requested a range of information taken from voluntary reports of adverse incidents involving medical devices. The MHRA agreed to disclose some information but considered that model, manufacturer, catalogue, serial and batch numbers, and date of incidences of adverse incidents was exempt on the basis of section 41, 43 and 44 of the FOIA. In addition to this, the MHRA also considered that section 43 applied to the request for reference numbers.

2. The Commissioner's decision is that the MHRA has correctly withheld the information request at parts 2, 3, 4, 5, 6 and 10 of the request on the basis of section 44. However, she does not consider that the MHRA has sufficiently demonstrated that section 43 is engaged in relation to the information requested at part 16 of the request.

3. The Commissioner requires the public authority to take the following steps to ensure compliance with the legislation.

    - Disclose the information requested at part 16 of the request – MHRA reference numbers for all voluntary reports of adverse incidents received since 1 April 2003

4. The public authority must take these steps within 35 calendar days of the date of this decision notice. Failure to comply may result in the Commissioner making written certification of this fact to the High Court pursuant to section 54 of the Act and may be dealt with as a contempt of court.

Request and response

5. The complainant made a request to the MHRA on 30 June 2014. The MHRA responded to this request, initially citing section 12 of the FOIA as a basis for refusing to comply. This was later amended and sections 41, 43 and 44 were instead relied upon by the MHRA. The complainant sent a complaint to the ICO about this response from the MHRA but the Commissioner was unable to look at this due to the length of time that had passed between the refusal of the request and the matter being brought to her attention.

6. The complainant subsequently made a new, slightly refined, request to the MHRA on 17 September 2015 for the following information:

"From your AITS database, please provide in CSV format the following information for all voluntary reports of adverse incidents received since 1 April 2003:

(1) Type of device

(2) Model

(3) Manufacturer name

(4) Catalogue number

(5) Serial number

(6) Lot or batch number

(7) Date of manufacture

(8) Expiry date

(9) Quantity defective

(10) Date of incident

(11) Type of injury

(12) Details of incident/nature of device defect

(13) Details of injury (to patient, carer or healthcare professional)

(14) Action taken (includes any action by patient or healthcare professional or by the manufacturer or supplier)

(15) Date report submitted

(16) MHRA reference number"

7. The MHRA responded on 14 October 2015 stating that as the request was almost identical to the earlier request that was refused under section 12 and then later under sections 41 and 44 it would again rely on these exemptions to refuse this request.

8. The complainant asked for an internal review of this decision on the same day and the MHRA responded on 16 October 2015 asking the complainant to explain why he did not agree with the use of sections 41 and 44. The complainant responded on 20 October but did not provide any substantial detail on this.

9. The internal review was completed on 17 November 2015 and stated that the arguments for the use of section 41 and 44 were the same as when responding to the first request. In addition to this the MHRA cited section 43.

10. However, the MHRA sought to rely firstly on section 14 to refuse the request on the basis that it engaged both 14(1) and 14(2). This was explained as being because the request was substantially similar to the earlier request, the request was obsessive as the internal review request was submitted within 24 minutes of the refusal, the request was designed to cause disruption, annoyance and a burden as the internal review was requested despite the complainant knowing the likely outcome, and the complainant was unlikely to be satisfied whatever response he received as he had submitted a nearly identical request.

11. The Commissioner contacted the MHRA on receipt of a complaint from the complainant and explained the reasons for the request appearing to be repeated. The Commissioner explained that the complainant was simply seeking to submit a complaint to her office that would be eligible for consideration of the MHRAs use of the substantive exemptions – sections 41, 43 and 44 to withhold the requested information. Unfortunately as the earlier complaint was not eligible the complainant had submitted what appeared to the MHRA to be a repeated request.

12. The MHRA accepted this explanation and agreed to withdraw its reliance on sections 14(1) and 14(2) of the FOIA. However, it argued that section 12(1) would apply in the alternative due to the burdensome nature of the extraction and redaction process. That being said, in any event, the MHRA still maintained that sections 41, 43, and 44 applied to various parts of the request.

Scope of the case

13. The complainant contacted the Commissioner on 15 February 2016 to complain about the way his request for information had been handled.

14. The Commissioner wrote to the MHRA to establish the scope of the request and to make some preliminary observations regarding the use of the exemptions by the MHRA. The MHRA offered to make some limited disclosures to the complainant for some of the categories of information and confirmed some information was present in the routine extract. This was as follows:

    (1) Type of device – offered a generic description

    (7) Date of manufacture - not present in routine extract

    (8) Expiry date – not present in routine extract

    (9) Quantity defective – agreed to provide the information

    (11) Type of injury – offered to provide this scored as death/serious/minor/none

    (12) Details of incident/nature of device defect – offered a coded field describing type of event but not full text description

    (13) Details of injury – offered a coded field describing nature of injury e.g. bleeding/infection, but not full text description

    (14) Action taken – offered coded field describing actions taken by manufacturer, healthcare establishment and MHRA but not full text

    (15) Date report submitted – offered this by calendar year and quarter

15. After some discussions the complainant deemed these offers and explanations to be acceptable and agreed that the focus of the Commissioner's investigation would be to determine if the MHRA had correctly applied the substantive exemptions – 41, 43 and 44 – to the remaining parts of the request. These are set out below:

    (2) Model – withheld under sections 41, 43 and/or 44

    (3) Manufacturer name - withheld under sections 41, 43 and/or 44

    (4) Catalogue number - withheld under sections 41, 43 and/or 44

    (5) Serial number - withheld under sections 41, 43 and/or 44

(6) Lot or batch number - withheld under sections 41, 43 and/or 44

(10) Date of incident - withheld under sections 41, 43 and/or 44

(16) MHRA reference number - withheld under section 43

Reasons for decision

Section 44 - Prohibitions on disclosure

16. The Commissioner has firstly considered the use of the section 44 exemption to withhold the information requested in parts (2), (3), (4), (5), (6) and (10) of the request.

17. 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 Community obligation, or

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

18. In its responses to the Commissioner, the MHRA has cited section 44(1)(a) but she believes this to be incorrect and the MHRA should in fact have cited section 44(1)(b) and the investigation has focused on whether disclosing the model, manufacturer, catalogue, serial and batch numbers, and date of incidences of adverse incidents involving medical devices would be incompatible with any Community obligation.

19. The MHRA is the regulator for medical devices and works under the Medical Devices Regulation 2002[1] ("MDR2002") which implement

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

several European Directives – Directive 90/385[2], Directive 93/42[3] and Directive 98/79[4].

20. 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."

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

22. 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'.

23. She 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.

24. The complainant has argued though that this confidentiality requirement set out in Article 20 is not applicable to information obtained voluntarily by the MHRA. The Commissioner recognises that the information in this case is information which was obtained by the voluntary reporting of adverse incidents involving medical devices so has gone on to consider this point further.

25. The complainant points to Article 8 of Directive 90/385, Article 10 of Directive 93/42 and Article 11 of Directive 90/79 which all state:

"Where a Member State ***requires medical practitioners or the medical institutions to inform the competent authorities of any incidents*** *referred to in paragraph 1, it shall take the necessary steps to ensure that the manufacturer of the device concerned, or his authorised representative, is also informed of the incident."*

---

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

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

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

26. The complainant argues that there is no requirement in the UK for medical practitioners or medical institutions to report incidents to the MHRA. Therefore, he argues that reports of incidents to the MHRA made by anyone other than the manufacturer of the device, their authorised representative or a notified body do not fall under the provisions of the Directives as they have been made voluntarily and not through requirement, and the confidentiality requirements do not apply.

27. The MHRA have countered these arguments by highlighting that all of the Articles in the Directives refer to "***all*** *parties"* and *"with regard to* ***all*** *information obtained"* and there is therefore no differentiation made between information obtained voluntarily or by requirement. The MHRA argues further that if the intention was to make a distinction between voluntarily provided and provided by requirement then this would have been stated.

28. The Commissioner understands that the MHRA operates a compulsory reporting system for use by medical device manufacturers to report faults. This works in parallel with the voluntary reporting system for adverse incidents where faults can be reported by patients, members of the public, medical practitioners and medical institutions. The voluntary reports are logged and sent to the medical device manufacturers for them to investigate and the MHRA will monitor the progress of this investigation.

29. In making a decision on this point, the Commissioner has referred back to earlier decisions made[5]. In these cases, the Commissioner considered this issue in relation to different requests to the MHRA. She noted that:

    "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'.

    The Commissioner is satisfied that 'obtained' should be given its natural meaning and refer both to information which the MHRA proactively obtains as part of its investigations and information supplied by those wishing the MHRA to carry out an investigation."

30. Taking this into account; the Commissioner sees no reason to alter her view on this matter and would accept that information obtained by the MHRA, both voluntarily and proactively, is subject to the obligation of confidence set out in Article 20 of Directive.

[5] ICO case FS50384738 & FS50511627

31. Furthermore, the Information Tribunal[6] has also adjudicated on a request involving the MHRA and made the following comment of some relevance to this case:

"there can be no doubt that the MHRA is entitled (indeed obliged) by virtue of section 44(1)(a) FOIA to withhold information coming to in connection with its function of enforcing the Medical Devices Regulations 2002 … any question as to whether a particular device comes properly under European Directive 93/42 or 98/79 (or is even a medical device at all) is beside the point, as is the particular wording of any provision in the directives relating to non-disclosure of information by enforcing authorities."

32. The Commissioner notes that this comment from the Tribunal was in relation to the use of section 44(1)(a) by the MHRA and concerned the statutory prohibition on disclosure provided by the Enterprise Act and the MDR2002. Nevertheless it is still relevant here and the salient point is that the wording of the provisions of the directives is not as important as the fundamental fact that the MHRA is entitled to withhold information that comes to it in connection with its function of enforcing the MDR2002.

33. On this point, the Commissioner is in no doubt that the collection of voluntary reports of adverse incidents is an example of the MHRA discharging its function under the MRD2002 as there is a clear obligation in the Directives, for example Article 7 of Directive 90/385, on the MHRA to ensure that any products which do not comply with the Directive are withdrawn from the market. The Directives, as already stated, are interpreted by the MDR2002 and the collection of incident reports on medical devices, both voluntarily and by requirement, is a key tool used by the MHRA in detecting devices that do not comply with the Directives and should be removed from the market.

34. The Commissioner is therefore satisfied that the information that has been withheld under section 44(1)(b) –the model, manufacturer, catalogue, serial and batch numbers, and date of incidences of adverse incidents involving medical devices – 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.

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

35. 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 Act (for it states 'otherwise than under this Act').

36. In conclusion, the Commissioner has found that the MHRA was entitled to rely on section 44(1)(b) in respect of the information requested at parts (2), (3), (4), (5), (6) and (10) of the request.

37. By virtue of section 2(3) of FOIA, the exemption in section 44(1)(b) 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.

38. As she is satisfied that the statutory bar applies, the MHRA was entitled to withhold this information and the Commissioner upholds its position.

Section 43 – prejudice to commercial interests

39. The remaining items of information to consider are the MHRA reference numbers from part (16) of the request. The Commissioner notes the only exemption cited in relation to this information is section 43.

40. Section 43 provides that if the disclosure of information would prejudice the commercial interests of any person including the public authority who holds the information, then the information is exempt from disclosure. This prejudice-based exemption is subject to the public interest test.

41. When presenting arguments in support of the use of section 43(2), the MHRA has indicated it considered the relevant commercial interests to be that of the manufacturers of the medical devices.

42. The MHRA considered section 43(2) to apply to not only its reference numbers but also to the model, catalogue number, serial number, and lot or batch number of the devices. This information, it stated, could be used to identify the manufacturer and the specific device, leading to commercial prejudice. The MHRA believed that releasing the manufacturer name and other details which could be linked to the manufacturer would be likely to prejudice the commercial interests of the manufacturers as it could damage the reputation of the brand/company, particularly as the adverse incident reports may contain information which can be misinterpreted or that on further investigation turns out to be misguided or false.

43. However, the Commissioner has already found that the MHRA has correctly withheld details of the manufacturer and the specifics of the devices under section 44 of the FOIA. Therefore, the only information that she is considering in relation to this exemption is the MHRA reference number associated with each report.

44. The arguments given by the MHRA all relate to the idea that disclosing information which would specifically identify the device and manufacturer would cause commercial detriment. The Commissioner is not convinced that disclosing the MHRA's reference number, even alongside the information the MHRA has agreed to disclose, would identify manufacturer's or the specific devices. It is therefore difficult to see how disclosing the MHRA's reference number could have the stated prejudice on the commercial interests of the manufacturers.

45. Without any further arguments from the MHRA to show a clear link between the disclosure of reference numbers and the alleged prejudice to the commercial interests of the manufacturer, she has concluded that the MHRA has not demonstrated that the prejudice would be likely to occur. It is therefore her view that the section 43 exemption has not been engaged in relation to the information at part (16) of the request.

46. The Commissioner therefore requires the MHRA to now disclose this information.

Right of appeal

47. 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

48. 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.

49. 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 ……

Jill Hulley
Senior Case Officer
Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF