Freedom of Information Act 2000 (FOIA)

Decision notice

Date: 18 December 2013

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 relating to 'PIP' breast implants (Poly Implant Prosthese).

2. The Commissioner's decision is that the Medicines and Healthcare Products Regulatory Agency (MHRA) has correctly applied section 44(1)(b) of the FOIA.

3. The Commissioner does not require any steps to be taken as a result of this decision.

Request and response

4. On 23 June 2013 the complainant wrote to MHRA as follows:

"I have a friend who was fitted with PIP implants in 2004 who has reported some adverse effects including inflammation and strange lumps.

I have read through Lord Howe's recent report on the MHRA's response to the PIP case but could not see the detailed information on problem reports from doctors to the MHRA.

I have read that Dr Quaba in Scotland reported problems with PIP implants to the MHRA in 2005 and 2006 and stopped using PIP implants in 2007. Dr Quaba carried out I believe around 300 to 350 operations.

Out of the 40,000+ PIP implants carried out in the UK I see that Harley

Medical Group carried out about 13,000. Please can you confirm if their surgeons reported any problems to the MHRA and what the date was of these reports?"

5. The MHRA responded on 24 June 2013 and advised it was unable to confirm whether a specific surgeon organisation had submitted an adverse incident report. It further stated that the expert group's report into PIP breast implants, which was led by Sir Bruce Keogh, gives more information about specific clinical findings and how long PIP breast implants last by comparison with those from other manufacturers stated.

6. The complainant responded on the same day stating that he had read the report but it did not provide the information he was interested in. He therefore made a request under the FOIA in the following terms:

"I presume you do have the reports from Dr Quaba (which he has written about) and others surgeons on adverse incidents with PIP. Will it be possible to access these through the Freedom of Information Act?"

7. On 16 August 2013 the MHRA responded. It provided some information within the scope of the request, but refused to provide the remainder citing section 44(1)(a) of the FOIA as its basis for doing so.

8. Following an internal review the MHRA wrote to the complainant on 28 August 2013, maintaining its position.

Scope of the case

9. The complainant contacted the Commissioner on 4 September 2013 to complain about the way his request for information had been handled.

10. The Commissioner considers the scope of this case to be to determine if the MHRA has correctly applied section 44 of the FOIA to the withheld information.

Reasons for decision

11. During the course of the Commissioner's investigation, the MHRA clarified that it had quoted the wrong provision within section 44 in its response to the complainant. It should have quoted section 44(1)(b).

12. Section 44(1)(b) of the FOIA states that

'Information is exemption information if its disclosure (otherwise than under this Act) by the public authority holding it –
…
(b) is incompatible with any Community obligation.'

13. Section 44(1)(b) is an absolute exemption, so if the statutory bar applies then the information is exempt and no public interest test is necessary.

14. In its response to the Commissioner, the MHRA identified Article 20 of the European Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (MDD).

Council Directive 93/42/EEC of 14 June 1993 concerning Medical Devices

15. Article 1 of the Directive (http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1993L0042:20071011:en:PDF) provides the definition of what constitutes a Medical Device.

16. Article 20 places the following obligation on the MHRA in relation to its duties when considering Medical Devices:

'Without prejudice to the existing national provisions and practices on medical secrets, 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. This does not affect the obligation of Member States and notified bodies with regard to mutual information and the dissemination of warnings, nor the obligations of the persons concerned to provide information under criminal law.'

17. As noted above, the MHRA are the body who decides whether a device is a Medical Device, or is something else. The Commissioner considers it is appropriate to defer to the expertise of the MHRA in relation to the classification of such devices. It follows that the Commissioner is satisfied that the legislation that he should consider is Council Directive 93/42/EEC and Article 20 of that Directive.

18. 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'.

19. 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.

20. The Commissioner is also satisfied that any investigation that may have been undertaken was part of the MHRA's tasks as Regulator of Medical Devices.

21. He is satisfied that the information that has been withheld under section 44(1)(b) constitutes information that 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.

22. 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. He 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').

23. In conclusion, the Commissioner has found that the MHRA was entitled to rely on section 44(1)(b) in respect of the all the withheld information that fell within the scope of the request.

24. 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 prohibited by or under the statutory bar. There is no public interest component.

25. As he is satisfied that the statutory bar applies, the MHRA was entitled to withhold the information from the public and the Commissioner upholds its position.

Other matters

Section 17(1)(b)

26. Section 17(1)(b) explains that a public authority must explain what exemption it is relying on. In the Commissioner's view this means that it must state the exemption down to its subsection.

27. In this case, the MHRA did not state the correct subsection it was applying to the request in either its refusal notice or internal review. In the Commissioner's view this was a breach of section 17(1)(b).

28. The Commissioner notes that the MHRA has recognised these procedural breaches occurred.

Right of appeal

29. 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: 0116 249 4253
    Email: GRC@hmcts.gsi.gov.uk
    Website: http://www.justice.gov.uk/tribunals/general-regulatory-chamber

30. 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.

31. 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 .....

Pamela Clements
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