Freedom of Information Act 2000 (FOIA)

Decision notice

Date: 24 February 2015

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 on whether the NHS hospitals are still using a particular type of hip replacement. The Medicine and Healthcare Products Regulatory Agency (MHRA) informed the complainant that it did not hold the information.

2. The Commissioner's decision is that the MHRA is correct when it says it does not hold the requested information and has therefore complied with its obligations under section 1 of FOIA.

3. The Commissioner does not require the public authority to take any further action in this matter.

Request and response

4. On 5 June 2014 the complainant wrote to the MHRA and requested information in the following terms:

> "Further to the NICE recommendation and National press release can you please tell me if the Zimmer Durom metal on metal hip prosthesis has now stopped being implanted in all NHS Hospitals in the UK"

5. The MHRA responded on 3 July 2014. It stated that it did not hold the requested information on whether that particular type of hip replacement was still being used within the NHS.

6. The complainant requested an internal review on 26 July 2014 at which time he slightly rephrased his request and now asked:

> "If the Zimmer Durom Metal on Metal (MoM) hip prosthesis has now been stopped for implanting in all NHS Hospitals in the UK".

7. This caused the MHRA to rethink its interpretation of the request. It now considered whether the complainant was asking whether the use of that particular hip replacement had stopped as a result of action taken by the MHRA, ie whether the MHRA had effectively banned the use of the Zimmer Durom Metal on Metal hip replacements.

8. Following an internal review the MHRA wrote to the complainant on 8 August 2014. In respect of how the request had been originally phrased, the MHRA explained that hospitals were not obliged to inform it which implants they were using, nor was there any obligation on the MHRA to collect this information. Therefore it had no way of knowing whether the particular hip replacement was still being used. In respect of how the request was phrased at the internal review stage, the MHRA said that it had "… taken no specific safety action in respect of …" that particular hip implant.

Scope of the case

9. The complainant contacted the Commissioner on 1 September 2014 to complain about the way his request for information had been handled.

10. In his attempts to find out whether metal on metal (MoM) hip replacements were still being implanted, and in particular whether the Zimmer Durom implant was still being used, the complainant had previously contacted NHS England. NHS England had said that it did not hold any relevant information and had directed him to the MHRA. This, quite reasonably, leads him to believe that the MHRA would hold the requested information.

11. At the start of his investigation the Commissioner attempted to clarify the intended meaning of the request, ie whether the complainant was interested in any information on whether the particular hip implant was still being fitted, or whether he was really asking if the MHRA had banned the use of that product. The complainant responded that he was seeking a decision in respect of how his request was originally phrased. The Commissioner understands from this that the complainant is not seeking confirmation of whether MHRA has imposed a ban but is seeking information on whether the Zimmer Duron MoM hip replacement is still being used by NHS hospitals.

12. Therefore the matter to be decided is whether the MHRA holds any information which would enable it to answer the request as originally phrased, ie whether it holds information on whether the particular hip replacement is still being fitted.

Background

13. Over recent years it has come to light that some patients have experienced problems with MoM hip replacements. The problem is caused by soft tissue reactions to the wear debris from the artificial joint. In 2012 MHRA issued a Medical Device Alert which advised hospitals to check MoM hip implants on an annual basis. In February 2014 NICE issued new guidance that only prosthetic hips which have a revision rate (ie require replacing or further surgery) of 5% or less after 10 years should be used. This was stricter than previous guidance. Although the Commissioner has not identified any particular press coverage from February 2014 relating to the publication of the new guidance, he is aware of earlier press reports and campaigns which anticipated the guidance and said its implementation would effectively ban the use of MoM hip implants.

14. In notes to the press release which accompanied NICE's new guidance, it makes it very clear that the guidance does not ban the use of implants which fail to meet the new standards. The new guidance simply means that the NHS must make sure it has hip implants which meet the new standard, available as a treatment option.

Reasons for decision

15. Section 1 of FOIA states that someone making a request to a public authority is entitled to be told whether the public authority holds that information and, if it is held, to have that information communicated to them, subject of course to a number of exemptions.

16. The complainant has been advised by NHS England that the MHRA is the body that would be responsible for issuing safety alerts or guidance on stopping the use of MoM devices. It is therefore understandable that he would expect the MHRA to monitor the use of joint replacements including the fitting of MoM hip implants. Certainly he would expect the MHRA to be able to inform him whether it had imposed a ban on the use of such implants which would have resulted in them no longer being used.

17. In light of this the Commissioner's investigation has focussed on the MHRA's role and whether it has a business need to hold the requested information.

18. The MHRA has explained to the Commissioner that its role focusses on the supply of medical devices such as hip implants. Legislation exists which places an obligation on manufacturers to ensure their medical devices are safe and fit for purpose. It is the MHRA's role to ensure that all medical devices placed on the UK market comply with that legislation. It performs this role by overseeing the work of 'designated bodies' within the UK. It is these designated bodies which actually certify a medical device is safe. For a manufacturer's product to be certified it must demonstrate to the appropriate designated body that the product conforms to all the necessary safety standards. Once a manufacturer has had its product certified it can be marketed in the UK and throughout the European Union. By overseeing the work of the designated bodies the MHRA ensures the products supplied to the NHS meet current safety standards.

19. However there is always a need to monitor how devices perform in practice. The Commissioner asked the MHRA directly how it gathers intelligence on the performance of these devices and how they are alerted to any problems. It explained that manufacturers are legally obliged to have in place a means of monitoring the performance of their products and to report any incidents involving their devices which might lead to serious injury. The reports are submitted to the MHRA's adverse incident centre. Although doctors and clinicians are not obliged by law to submit adverse incident reports they do so as a matter of good practice. The MHRA has explained that it has a very good communication network with clinicians. The MHRA also works closely with the National Joint Registry (NJR) which monitors the performance of hips, knees, ankles and shoulders. The NJR alerts the MHRA to any products that are underperforming.

20. The monitoring procedures described above are used to identify any problems that arise. When they do, the MHRA has a range of regulatory measures it can use. This could include prosecuting a manufacturer for noncompliance with relevant legislation, or stopping the supply of a product. It can also issue Medical Device Alerts. One such Medical Advice Alert was issued in respect of MoM hip replacements in June 2012. Clinicians were advised to have follow up consultations with patients on an annual basis to check there was no problem with their hip replacement. However such alerts are advice only and the MHRA does not have the power to oblige the NHS to follow its advice.

21. The Commissioner accepts that the MHRA's explanation of how it monitors the performance of medical devices such as hip implants.

These procedures do not collect information on every hip replacement that is carried out, rather they are designed to collect information on when things go wrong. In response to a direct question, MHRA has confirmed that NHS hospitals are not obliged by law to inform it what implants they are using. Good practice means that clinicians report adverse incidents, but this is very different from routinely informing the MHRA of every device that is fitted. This explanation is consistent with the MHRA's internal review response to the complainant when it informed him that, there is no obligation on hospitals to inform the agency when they implant or what they implant. Furthermore there is no obligation for the agency to collect that information from the hospitals.

22. In light of this the Commissioner is satisfied that MHRA did not gather statistics on what hip implants were being used at the time of the request. It follows that the MHRA was not in a position to say whether MoM hip implants were still being used.

23. Furthermore the MHRA has stated categorically that it has not taken any action in respect to Zimmer Durom MoM hip prosthesis. It therefore has no grounds for supposing that hospitals were not still implanting that particular model.

24. The Commissioner is satisfied that the MHRA does not hold the requested information and has complied with its obligations under section1 of FOIA. The MHRA is not required to take any further action in this matter.

Right of appeal

25. 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

26. 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.

27. 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 .....

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