Freedom of Information Act 2000 (Section 50)

Decision Notice

Date: 22 August 2011

Public Authority: **Medicines and Healthcare products Regulation Agency (the 'MHRA')**

Address: **10-2 Market Towers**
1 Nine Elms Lane
London
SW8 5NQ

Summary

The complainant requested, under the Freedom of Information Act 2000 (the 'Act'), information from the MHRA about its procedures in set circumstances.

The MHRA provided some information and explained that it did not hold further information. The complainant asked for an internal review and the MHRA upheld its position. The case was referred to the Commissioner.

The Commissioner found one relevant policy and ensured that this was disclosed to the complainant, but finds on the balance of probabilities that the MHRA does not hold any further relevant recorded information in this case.

The Commissioner finds a breach of section 10(1) because the single policy was not provided in twenty working days. However, he does not require any remedial steps to be taken as it has now been provided.

The Commissioner's Role

1. The Commissioner's duty is to decide whether a request for information made to a public authority has been dealt with in accordance with the requirements of Part 1 of the Freedom of Information Act 2000 (the "Act"). This Notice sets out his decision.

Background

2. The complainant has been in a long running dispute with the MHRA about its classification of one of the complainant's devices and one of his competitor's devices.

3. That dispute has been heard in a number of forums and the complainant has made this request in order to understand how the MHRA usually deals with complaints of this nature.

The Request

4. On 19 December 2010 the complainant submitted the following twelve point request to the MHRA:

> [1] *Does the MHRA have a set procedure for a classification dispute between a manufacturer and itself of a medical and or IVD product;*
>
> [2] *If so please provide a copy of this procedure and all of its appeals;*
>
> [3] *Does the MHRA have a set procedure for classification of what can be called borderline medical or IV products*
>
> [4] *If so can it define borderline products and*
>
> [5] *Can it please provide a copy of the is (sic) procedure regarding borderline products;*
>
> [6] *Does the MHRA have a set procedure for a classification dispute between a notified body and itself of a medical and or IVD product;*
>
> [7] *If so please provide a copy of this procedure and all of its appeals;*
>
> [8] [Same as [6] above].
>
> [9] *Does the MHRA have a set procedure for a classification dispute between another EU competent authority and itself of a medical and or IVD product;*
>
> [10] *If so please provide a copy of this procedure and all of its appeals;*

[11] *If there is no MHRA set procedure is there and (sic *an) EU directive or UK national one for 9. and*

[12] *If so what is it – please give chapter and verse as to where it is and the relevant regulations.*

5. The MHRA issued its response on 19 January 2011. It explained that:

- no procedure existed for [1], and so the answer to [2] was no recorded information held;
- the MHRA did have a procedure for [3] contained in its SOP and it provided this information;
- the procedure does not define what a borderline product is and so there is no recorded information is held for [4] or [5];
- there is no procedure for [6] and so there is no recorded information for [7] or [8];
- there is no procedure for [9] and no recorded information held for [10];
- there is no Directive or UK national law for [11] and therefore there is no recorded information held for [12]; and
- it provided links to other relevant guidance that could be found on its website.

6. On the same day, the complainant requested an internal review. He challenged the accuracy of the information.

7. On 28 January 2011 the MHRA communicated the results of its internal review. It explained that the decision about classification disputes was taken on a bespoke basis, that there was no set procedure and that there are different procedures in relation to other matters that were dealt with by the MRHA. Those other procedures are not used for a dispute about the borderline Statement of Practice (SOP).

The Investigation

Scope of the case

8. On 4 February 2011 the complainant contacted the Commissioner to complain about the way his request for information had been handled.

The complainant specifically asked the Commissioner to consider the following points:

1. That the information he had asked for had not been provided;

2. That he believed that the MHRA was vexatious; and

3. That he believed that the Commissioner should consider whether the offence found in section 77 of the Act had occurred in this case.

9. On 27 April 2011 the complainant agreed that the scope of the Commissioner's investigation would be to determine the following four things:

    1. Whether the MHRA holds further recorded information in relation to parts [1] to [7] and [9] to [12] of the request [as part [8] was a duplicate];

    2. If so, whether this information can be provided to the public;

    3. To consider whether the MHRA has complied with its obligations in relation to timeliness; and

    4. To consider whether there is sufficient evidence to make out the criminal offence in this case.

10. The Commissioner is satisfied that the MHRA has provided convincing evidence that it did disclose the SOP for request [3] on 19 January 2011. He has also ensured that the complainant has received another copy of it and will not consider this matter further.

11. The Commissioner also identified a policy entitled *'Exchange of information between Medical Device Competent Authorities'* that he considered was also relevant for request [3]. The MHRA agreed that this information could be disclosed and this was released to the complainant on 13 July 2011. The Commissioner will consider the procedural issues that arose from this information not being provided prior to his investigation, but will obviously focus on whether further relevant recorded information is held in the substantive analysis below.

12. The complainant also raised other issues that are not addressed in this Notice because they are not requirements of Part 1 of the Act.

13. In addition, it is noted above that the complainant asked the Commissioner to consider section 77 of the Act. This is Part VIII of the Act and cannot be considered in this Notice. The Commissioner's

analysis of the complainant's allegations will be contained in a separate letter.

Chronology

14. The chronology below contains only the key exchanges of correspondence in this case.

15. On 5 March 2011 the Commissioner wrote to the MHRA and the complainant to explain that this complaint was eligible.

16. On 27 April 2011 the Commissioner wrote to the complainant to confirm the scope of his investigation. The scope was confirmed on the same day.

17. It was also apparent that there was a dispute about whether the SOP that was relevant for request [3] had been provided to the complainant with the response dated 19 January 2011. The Commissioner ensured that the complainant had received a copy of this information on 5 May 2011.

18. On 12 May 2011 the Commissioner asked the MHRA for its detailed arguments about its position in this case. He received those arguments on 10 June 2011.

19. On 6 July 2011 the Commissioner made further enquiries of the MHRA. He received a response on 12 July 2011. He wrote to the complainant on the next day, to provide his preliminary findings and to ask whether he wanted the investigation to continue. The complainant responded and confirmed that he did want the investigation to continue.

20. On 29 July 2011 and 4 August 2011 the complainant provided further arguments to the Commissioner about why he believed that there was information that was held but not provided.

Findings of fact

21. The MHRA is responsible for ensuring that medicines and medical devices work and are acceptably safe.

22. As part of its role, it must consider what a product is and whether it satisfies the relevant criteria for that kind of product.

Analysis

Substantive Procedural Matters

Is further relevant recorded information held?

23. Section 1[1] provides that any person making a request for information to a public authority is entitled (a) to be informed in writing by the public authority whether it holds information of the description specified in the request and (b) if that is the case, to have that information communicated to him. The MHRA only needs to consider any information it held in recorded form falling within the scope of the request as at the date of the request, namely 19 December 2010.

24. The standard of proof that the Commissioner uses to determine whether relevant recorded information is held was confirmed by the Tribunal in *Linda Bromley & Others v Information Commissioner and Environment Agency* [EA/2006/0072] ('Bromley'). It said that the test for establishing whether information was held by a public authority was not one of certainty, but rather the balance of probabilities.

25. He has also been assisted by the Tribunal's explanation of the application of the 'balance of probabilities' test in *Bromley*. It explained that to determine whether information is held requires a consideration of a number of factors including the quality of the public authority's final analysis of the request, the scope of the search it made on the basis of that analysis and the rigour and efficiency with which the search was then conducted. It also requires considering, where appropriate, any other reasons offered by the public authority to explain why further recorded information is not held.

26. The Commissioner has considered the arguments of both sides and considered the factors specified in *Bromley*.

27. Firstly, it must be noted that the MHRA located the policy entitled *'Exchange of information between Medical Device Competent Authorities'* during the course of his investigation and allowed the Commissioner to provide it to the complainant. The procedural issues will be dealt with below, but at this stage the Commissioner is considering whether further information beyond this policy was held by the MHRA at the date of the request.

[1] All sections of the Act that are cited in this Notice can be found in full in an attached legal annex.

28. The Commissioner has split the requests between those that are domestic (requests [1] to [7]) and those that have a European dimension (requests [9] to [12]). This is because the requests are worded slightly differently and the complainant's arguments as to why he considers the information is held can be divided in the same way.

Requests [1] to [7]

29. The MHRA explained that it read these seven requests as being requests for its own set procedures. The Commissioner accepts that the requests cannot be read to be wider than being requests for MHRA set procedures.

30. The MHRA has explained that it does have a 'classification decision making procedure'. This procedure is found in its SOP that was disclosed on 19 January 2011. The Commissioner provided the complainant with a second copy of it on 5 May 2011. It also had the *'Exchange of information between Medical Device Competent Authorities'* that it uses when it needs European input in making difficult classification decisions and this was disclosed to the complainant on 13 July 2011.

31. However, it also confirmed that it had no procedure over and above the two things noted above. It explained that it did not need anything else because the SOP is comprehensive internally and the European policy stood by itself. It explained that every decision is taken on a bespoke basis with the responsible experts making a decision based on the information provided and their understanding of the law and they will seek legal advice where appropriate. The responsible experts are specialists and the MHRA has confidence that they can do their role without further guidance. Should the case go before a court, then these experts will sign a witness statement.

32. It confirmed to the Commissioner that it had no SOP on how to deal with decision making queries or specifically about borderline classification.

33. It confirmed that it had a set approach that it used for dealing with borderline classification queries. Its experts consider the cases on a bespoke basis considering the facts and the law, getting legal advice where necessary. Discussions are undertaken between staff to ensure that the position is consistent. If there is an internal difference of opinion the matter is referred to the Head of Regulatory Affairs or to Europe for further discussion in line with the policy discussed in paragraph 11 above.

34. It also has a set regulatory approach. It explained that it adopted the Hampton principles to work with the manufacturer to ensure compliance. If the manufacturer is unhappy they can apply for judicial review and in some circumstances the MHRA will prosecute a

manufacturer and the issue will be decided by a court. For the sake of clarity, the Hampton principles are not its own set procedures and thus did not fall within the scope of the requests.

35. It explained that it had also considered checking through every case file, but this would be too expensive and unnecessary because it uses the same procedure in every case. It carefully considered whether there would be lead cases that could be flagged, but considered that the lead cases would not provide any further information about its procedures that are constant.

36. The MHRA also stated that the case files provide a useful reference source to ensure consistency of decision making, but they do not constitute a procedure and thus do not fall inside the request.

37. The MHRA also explained the relationship between it and Notified Bodies (for requests [6] and [7]). Notified bodies are independent third party organisations that are designated to verify manufacturer's compliance under the relevant conformity assessment procedure. The MHRA's role is to audit the UK based Notified bodies to ensure they are capable of fulfilling their job. It explained that the Directive provides a procedure for the MHRA to intervene in a dispute between a manufacturer and a Notified body. The MHRA can disagree with a Notified body and this would be resolved through negotiation. However, the MHRA has confirmed that it holds no set procedure that outlines what will happen in this situation.

38. The complainant argued that there must be more procedures for these seven requests and he raised the following three arguments (which the Commissioner has paraphrased):

    1. That there must be a procedure in relation to question one because the consequences to the manufacturer are great if their product is not accepted. This can include criminal prosecutions. He has explained that it would appear sensible for this issue to be resolved by the MHRA rather than the court.

    2. The SOP explains that a decision stands until it is overturned by DPERA Business Head (DPERA is the technical name for the SOP). The SOP appears to be silent about whether there is any review or complaints procedure that would lead to this occurrence. This means that the information provided is not complete.

    3. Without a review procedure, the situation appears inconsistent with the MHRA's general approach when it decides that products are not unacceptable. This general approach appears to offer the manufacturer a chance to appeal to an Independent Review

Panel[2] and that it would be logical for both approaches to be consistent.

39. The Commissioner invited the MHRA to address these arguments. It explained that:

    1. The MHRA does not have any procedure outside the SOP. The consequences of disagreement are known (and are outlined in paragraph 31 above) and as there is understanding about the procedure there is no need to have any further written procedures.

    2. The MHRA explained that as every decision was bespoke there was no set review or complaints procedure. This was because it trusted its experts in relation to this matter.

    3. The MHRA explained that the situation was inconsistent because the legislative regimes for medical devices and medicines are different. In the past there were two different Regulators: one considered medical devices (the Medical Devices Agency) and one considered medicines (the Medicines Control Agency). They were merged to form the MHRA, but the differences in legislation remain and different departments deal with these different responsibilities.

40. The Commissioner has considered the SOP and the arguments of both sides. Given the arguments that he has received, he is satisfied on the balance of probabilities that there is no further recorded information held by the MHRA that is relevant to requests **[1]** to **[7]**.

Requests [9] to [12]

41. The MHRA has explained that these requests were drafted more narrowly. They are asking for a MHRA set procedure that it would use when there is a classification dispute between itself and another EU competent authority.

42. The MHRA has confirmed that it holds no such set procedure. It does have a procedure it uses when it requires input from other Member States about making a classification decision (noted in paragraph 11 above). However, this does not fall within the scope of the request.

43. It explained that it would know if it had a set procedure because it would be required to have drafted it and would use it for its business. In

[2] See page 17 of the policy found at the following link: http://www.mhra.gov.uk/home/groups/is-lic/documents/publication/con007544.pdf

addition, it does not require any other procedure in relation to the circumstances in which it is involved in Europe.

44. The complainant presented the following three arguments about why he believed that the MHRA would hold information for these requests (the Commissioner has paraphrased them):

    1. The SOP explains that where there is not unanimity and/or there is uncertainty about Member States views the case would be passed through to the Medical Devices Expert Group's (MDEG) Borderline and Classification working group.

    2. He is aware of (1) The Compliance and Enforcement Group (COEN); (2) The IVD Technical Group; and (3) the NB Med Groups which appear to have roles when determining similar issues and believes that one or more must be involved.

    3. He believes that for [9] there must be a procedure. He believes this because his product has been accepted as being an IVD by the Irish regulatory body (the IMB), but not by the MHRA and believes there must be a procedure to deal with this sort of situation.

45. The Commissioner asked the MHRA to respond to these arguments and it responded as follows:

    1. There is a procedure where the MHRA seeks European input about the classification of devices through MDEG. However, this is outside the scope of this request (although has now been provided as part of request [3] – see paragraph 11 above).

    2. These three groups do not consider classification disputes between itself and another EU competent authority and are not relevant to the request for information. In addition, there is no other group that does.

    3. It explained that there was no set procedure whereby one Member State accepts a registration that may be disputed by another Member State. It explained that generally they would communicate to try to resolve the issue. It also explained that it must be understood that the majority of Member States do not do an assessment of registration on receipt and the MHRA's opening letter specifically states that this is so. Instead, they may wait until issues arise that raise concerns about the product's eligibility.

46. The Commissioner has considered the SOP and the arguments of both sides. Given the arguments that he has received, he is satisfied on the

balance of probabilities that there is no further relevant recorded information held by the MHRA that constitutes a procedure and so is relevant to requests [9] and [10].

47. Requests [11] and [12] are drafted so that they are slightly wider in scope. They ask for a national or EU procedure that applies when there is a classification dispute between another EU competent authority and the MHRA in respect of a medical and or IVD product. Firstly, it must be noted that there is no obligation to generate new information in response to a request for information. The only obligation on the MHRA is to locate the information that it holds that is relevant to the request.

48. The MHRA explained that there was no such procedure for these situations. It explained that it would know of these procedures if they existed because they would be required to use them in their every day business. In addition, if there needed to be a national procedure then the responsibility of creating one would have been likely to have been delegated to it and it could confirm that it had produced no such procedure. It explained that all in all it could be confident that there was no further recorded information held within the scope of requests [11] and [12].

49. The complainant has not offered satisfactory arguments why the MHRA does hold this information and the Commissioner finds the MHRA's arguments convincing in this matter.

50. It follows that the Commissioner has considered the arguments of both sides and is satisfied that on the balance of probabilities there is no further relevant recorded information held by the MHRA that is relevant to requests [11] and [12].

Procedural Requirements

Section 1(1)(b)

51. Section 1(1)(b) requires that the public authority provides relevant recorded information where it is not exempt.

52. In this case, the MHRA failed to provide one policy that was within the scope of request [3] before the Commissioner's investigation and so breached section 1(1)(b).

Section 10(1)

53. The complainant also explained that he was unhappy with the time taken by the MHRA and required a formal decision in order to record this failure.

54. Section 10(1) states that:

'Subject to subsections (2) and (3), a public authority must comply with section 1(1) promptly and in any event not later than the twentieth working day following the date of receipt'..

55. In this case for the reasons outlined above, the MHRA failed to comply with its section 1(1)(b) obligations in twenty working days and therefore breached section 10(1) of the Act.

The Decision

56. The Commissioner's decision is that the public authority dealt with the following elements of the request in accordance with the requirements of the Act:

- He is satisfied that on the balance of probabilities it does not hold any further relevant recorded information in this case.

57. However, the Commissioner has also decided that the following elements of the request were not dealt with in accordance with the Act:

- It failed to comply with section 1(1)(b) in 20 working days in relation to the policy that it subsequently provided. This was a breach of section 10(1).

Steps Required

58. The Commissioner requires no steps to be taken.

Right of Appeal

59. 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,
Arnhem House,
31, Waterloo Way,
LEICESTER,
LE1 8DJ

Tel: 0300 1234504
Fax: 0116 249 4253
Email: informationtribunal@hmcts.gsi.gov.uk
Website: www.justice.gov.uk/guidance/courts-and-tribunals/tribunals/information-rights/index.htm

60. 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.

61. Any Notice of Appeal should be served on the Tribunal within 28 (calendar) days of the date on which this Decision Notice is sent.

Dated the 22nd day of August 2011

Signed ……

Pamela Clements
Group Manager, Complaints Resolution
Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF

Legal Annex

Section 1 - General Right of Access

Section 1 of the Act provides that:

(1) Any person making a request for information to a public authority is entitled –

(a) to be informed in writing by the public authority whether it holds information of the description specified in the request, and

(b) if that is the case, to have that information communicated to him.

(2) Subsection (1) has the effect subject to the following provisions of this section and to the provisions of sections 2, 9, 12 and 14."

...

Section 10(1) - Time for Compliance

Section 10(1) provides that:

Subject to subsections (2) and (3), a public authority must comply with section 1(1) promptly and in any event not later than the twentieth working day following the date of receipt.