

## **Freedom of Information Act 2000 (FOIA)**

### **Decision notice**

**Date:** 11 February 2014

**Public Authority:** Medicines and Healthcare Products Regulatory Agency

**Address:** 151 Buckingham Palace Road  
Victoria  
London  
SW1W 9SZ

#### **Decision (including any steps ordered)**

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1. The complainant has requested information concerning the MLX364 consultation for proposed regulation of nicotine containing products (NCPs).
2. The Commissioner's decision is that the Medicines and Healthcare Products Regulatory Agency (MHRA) has correctly applied section 12.
3. The Commissioner requires the public authority to take no steps.

#### **Request and response**

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4. On 28 March 2013, the complainant submitted a request for information to the MHRA. The MHRA responded on 29 April 2013 and explained that section 12(2) applied. However, under section 16, the MHRA provided advice and assistance to the complainant. It advised that if it were to narrow its request by requesting less information or specifying a time period, then it may be able to comply with the request.
5. Subsequently on 3 May 2013, the complainant wrote to MHRA and requested information in the following terms:
  1. *Information confirming when MHRA currently expects to announce its decision on whether to regulate NCPs as 'medicinal products' – a simple statement of the current status, which must be known to the*

*MHRA officials in charges of the consultation and decision making process*

- 2. Information setting out the legal advice MHRA has received, the effect of which is that NCPs 'which appreciably affect metabolism' may come within the scope of the medicines legislation because of their pharmacological effect (see MHRA's consultation letter of 1 February 2010) – if it assists in saving time and costs, a copy of the advice itself could be disclosed to us, assuming it has been relayed to the MHRA has referred to its existence in its own consultation paper*
- 3. Confirmation of that particular piece of legislation MHRA is referring to in response Q17 in its March 2011 "Q&A" document, published on MHRA's MLX364 website, which is said to support MHRA's view that NCPs containing tobacco should be excluded from the consultation - this is a straightforward request which could be made of the person responsible for drafting the Q&A document and who presumably is aware of the specific piece of legislation relied on. Again, this information is obviously known and does exist, because MHRA has referred to the existence of legislation in its own consultation papers.*
- 4. Information which confirms the steps MHRA has taken to satisfy its March 2011 terms of reference for the further scientific and market research, which is intended to provide further evidence on the pharmacological effects of nicotine and the impact of regulation on business and consumers – a short and simple chronology will suffice; as the exercise is still ongoing or is very recently concluded, presumably a documentary summary of the steps taken already exists and could be disclosed to us.*
- 5. Information which explains how MHRA has met its commitment to measure the impact of regulation on consumers and business, and ensure that it pursues its objectives in the least burdensome manner possible – again, this should not be time-consuming exercise given the ongoing/recently active nature of the exercise; documentation summarising this may already exist and could be disclosed to us.*
- 6. Confirmation as to whether MHRA is now awaiting the outcome of the EU Commissioner's proposed Tobacco Products Directive prior to making its own decision on the regulation of NCPs as medicines – as with request 1, this requires a simple statement of the current status which must be known to the MHRA officials in charge of the process.*

6. The MHRA responded on 4 June 2013. It stated that although the complainant had narrowed their request, section 12(2) still applied. It explained that it would take more than 24 staff hours to conduct a search to ascertain whether or not it holds the information specified in the requests. The MHRA explained that over 800 documents would need to be considered. The MHRA further explained that although it is likely to hold the information, it was unable to confirm or deny whether it did in fact hold it.
7. The complainant subsequently asked for an internal review to be carried out on 7 June 2013. During the period between the internal review request and the internal review response, the MHRA issued a press release on 12 June 2013 which effectively answered a number of the complainant's requests.
8. Following the internal review request the MHRA wrote to the complainant on 9 July 2013. It stated that it had correctly relied upon section 12(2).

### **Scope of the case**

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9. The complainant contacted the Commissioner on 16 August 2013 to complain about the way the requests for information had been handled. Specifically the complainant asked the Commissioner to consider whether the MHRA had failed to correctly apply the exemption under section 12.
10. The Commissioner has had to consider whether the MHRA were correct to rely upon section 12.

### **Reasons for decision**

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11. Section 12(2) of FOIA states that a public authority does not have to confirm or deny whether it holds the requested information if the estimated cost of complying with paragraph 1 of section 1(1) alone would exceed the appropriate limit.
12. It is important to note that during the Commissioner's investigation, he asked the MHRA to consider whether section 12(1) was a more appropriate exemption to rely on. The Commissioner's understanding is that to rely on section 12(2), the MHRA must have no idea it holds the requested information. In this case, the MHRA is involved in the proposed regulation of NCPs and therefore it would seem likely that it would hold the requested information. Subsequently, the MHRA

confirmed that it had cited the wrong subsection of section 12, and in fact section 12(1) applied to the requested information.

13. Section 12(1) allows a public authority to refuse to comply with a request for information if the authority estimates that the cost of compliance would exceed the 'appropriate limit', as defined by the Freedom of Information and Data Protection (Appropriate Limit and Fees) Regulations 2004 (the Regulations.)
14. This limit is set in the fees regulations at £600 for central government departments and £450 for all other public authorities. The fees regulations also specify that the cost of complying with a request must be calculated at the rate of £25 per hour, meaning that section 12(1) effectively imposes a time limit of 24 hours in this case.
15. In estimating whether complying with a request would exceed the appropriate limit, Regulation 4(3) states that an authority can only take into account the costs it reasonably expects to incur in:
  - a. determining whether it holds the information;
  - b. locating a document containing the information;
  - c. retrieving a document containing the information; and
  - d. extracting the information from a document containing it.
16. The four activities are sequential, covering the retrieval process of the information by the public authority.
17. Furthermore, a public authority is able to aggregate requests where they fall 'to any extent' under the same over-arching theme. In the Commissioner's view, the requests under consideration are clearly inter-related so can be considered together.
18. The MHRA explained that in accordance with the Commissioner's guidance, it had set out to substantiate that it had arrived at a sensible and realistic estimate of the task by undertaking a sampling exercise.
19. It explained the sampling exercise was conducted on a relevant work folder in the shared drive of one of the business areas involved in the consultation, using the word 'nicotine' as the chosen search term.
20. From the sampling exercise the MHRA concluded that it found 484 documents, each one it assumed it would need five minutes to view the document in order to locate the information within the scope of the request. It subsequently confirmed that if five minutes were used to assess the document to consider whether any part of it was within the

scope, it worked out to take 2420 minutes or 40.3 hours to comply with the request and therefore it fell under section 12.

21. The MHRA carried out a further search this time including the Documentum system. It explained that this search revealed a similar number of documents to the original search. There were 8 folders which contained around 30 documents each, approximately 240 in total. It further explained that a similar number of documents were held on a shared drive covering the production of papers for a committee and its expert group which had been considering the issues raised in the request resulting in a further 500 documents that would need to be considered as part of the request. The MHRA used its original estimate that five minutes would be needed to assess the document resulting in a calculation of 66.6 hours in total. The MHRA made clear that these 800 documents represented only a sample and not the entirety of what is believed to be held.
22. Although the Commissioner accepted that the sampling exercise was done in accordance with his guidance, he questioned whether the information requested had already been located and extracted due to the close proximity between the request of 3 May 2013 and the press release of 12 June 2013. The MHRA addressed the Commissioner's questioning by the response given below:

*"...some material relating to points 2, 4, 5 and 6 of [redacted name] request of the 3rd May is contained in documents attached to a press release of 12th June. However, that material is contained within scientific and regulatory summary papers which had been considered by the Commission on Human Medicines and is not, as demonstrated by the sampling exercises, all the information available and falling for consideration under the FOIA request. Preparation for publication of the press release required only the collation, inspection and redaction of those papers along with drafted new documents (a public summary and a question and answer document.) Also, preparation of the documents for publication took place mostly during the first working week in June (3 - 8 June) i.e. little of this would anyway have been collated before the response to FOI went out on 4 June".*

23. It further explained:

*"The nature and extent of the work involved in preparing the release was therefore not analogous to that involved in collating or inspecting the far greater number of documents concerned to furnish an adequate response to the FOIA request contained in the letter of 3rd May. Releasing only that data attached to the press release would not have provided a full response to the FOIA request and we believed it was not appropriate under the Act for the Agency to only locate some of the*

*relevant information when responding to an FOIA request. The totality of available information held by MHRA which fell within the scope of the request has not been released”.*

24. The Commissioner will now consider each request in turn below.

### **Requests 1, 3 and 6**

25. With respect to requests 1 and 3, the MHRA explained that these requests could not be answered under the terms of the Act at the time it was received as the information requested was not held in recorded form. However, it further explained that in order to be helpful in its dealings with the requestor, it provided a response to these points in parallel correspondence outside of the Act. The MHRA also explained that request 6 has subsequently been answered in the press release on 12 June 2013.

### **Request 2**

26. The MHRA explained that although it is known that legal advice is held, it did not consider the time it would take to locate and extract this information as by aggregation of the requests it did not need to consider this.

### **Request 4**

27. The MHRA considered that it was request 4 that exceeded the appropriate limit and therefore by aggregation, did not need to consider the other requests. The subsequent paragraphs will therefore take into consideration the MHRA's application of section 12.

28. The Commissioner had some initial concerns regarding the scope of the request. The Commissioner understood the request to be asking for information concerning steps taken to satisfy the MHRA's March 2011 terms of reference for the further identified scientific and market research. However, in order to be of some assistance and enabling the Commissioner to have a better understanding of the request, the MHRA explained that the Terms of Reference encompasses several strands of research. It explained that the research took place between 2011 – 2013 and consisted of hundreds of scientific papers, research and background emails which informed the final decision that was announced publically on 12 June 2013. The MHRA rephrased the request for the Commissioner to illustrate the broad scope. It explained that the request seeks the following information:

*“Information that confirms the steps MHRA has taken to research the:*



- *Investigation of the levels of nicotine which have a significant physiological effect through its pharmacological action*
- *The nature, quality and safety of unlicensed NCP's*
- *The actual use of unlicensed NCPs (excluding tobacco products) in the market place*
- *The efficacy of unlicensed NCPs in smoking cessation*
- *Modelling of the potential impact of bringing these products into medicines regulation public health outcomes*

*In order to inform a decision on bringing NCPs into medicines regulation”.*

29. The MHRA confirmed that it did hold information electronically within the scope of request 4. The Commissioner therefore asked whether there was a specific folder which contained the information sought under the request. It explained that there are specific folders for NCPs on the shared drives and Documentum which would contain documents. However, it explained that the information was not held in a single folder due to the wide scope of the request.
30. During his investigation the Commissioner questioned whether the search term used was the most appropriate one to locate the relevant information within the scope of each request. He asked the MHRA to clarify why it considered the search term 'nicotine' to be the most appropriate and the most likely to locate the requested information. He also asked it to clarify whether it had considered narrower search terms and if so, why they were rejected. The MHRA subsequently explained that the search term 'terms of reference' would not have returned many results as the research and other documents would not consistently refer to the 'terms of reference'. The MHRA therefore felt it was appropriate to use the search term 'nicotine' because of the high level of probability that relevant results for every bullet point would be returned.
31. It explained that if it searched for any of the words used in the rephrased request at paragraph 29, the search would have returned a certain number of documents for each one. There would consequently be a possibility that a number of different search terms could have been used instead of 'nicotine'. However, the MHRA explain that each individual search term would have returned an unquantified number of the same document for consideration which would add a layer of delay in having to determine which parts of the document fell within each bullet point of the terms of reference.
32. It therefore concluded that 'nicotine' was the most appropriate search term to use. Although it admitted that it was likely to return a high

number of results, it felt like a broad search term would return results for all areas of the request and was therefore the quickest overall method. The MHRA subsequently relied upon its sampling exercise described in paragraphs 20 and 21.

33. The Commissioner further asked if there was a business purpose for which the requested information should be held. He also asked that if there was business purpose, the MHRA needed to explain why the information is not easily accessible. The MHRA explained that there is a business purpose for which the information is held. However, due to the broad scope of information which falls under the request, it would have difficulty retrieving the information.

### **Request 5**

34. The MHRA confirmed that it does hold information within the scope of the request. Similarly to request 4, the MHRA confirmed that there was not a specific folder that held this information. However as explained at paragraph 30, it explained that there were specific folders for NCPs which would include documents pertaining to that issue.
35. When addressing why the search term 'nicotine' was used for request 5, the MHRA explained that *"as the information requested under request 4 was already believed to have taken the request beyond the appropriate limit, and 'nicotine' still deemed a relevant search term in respect of request 5"*.
36. For these reasons the Commissioner has decided that the request would exceed the appropriate limit and that therefore it was correct to refuse the request under section 12 of FOIA.

### **Section 16 – advice and assistance**

37. The Commissioner notes that in the MHRA original response to the complainant's information request, it failed to adequately explain how it arrived at its decision that section 12 applied. However, the MHRA did address this failure in its internal review response. The Commissioner also notes that the MHRA did advise the complainant that:

*"In accordance with our duty to advise and assist those making requests for information, if you are able to narrow your request by requesting less information, or specifying a time period, we may be able to comply with the duty to inform you whether or not we hold information within the cost limit. Of course, further refinement would not necessarily bring the request under the appropriate limit, and it is still necessary to consider if any further exemptions apply to the information within the scope of such a narrowed request and you should not assume we will be able to disclose it to you"*.



38. However the MHRA has subsequently confirmed that it does hold the information within the scope of request 2 and that it would be quick to locate, nevertheless due to aggregation of the requests, it did not consider request 2. The Commissioner notes that the complainant may want to submit a new request for the information sought in request 2. The MHRA has explained that this information contained within request 2 would be exempt from disclosure under section 42 (Legal Professional Privilege). However this is not within the scope of this decision notice.

## **Conclusion**

39. In reaching his decision the Commissioner is mindful that the complainant's request is broad and would clearly capture a significant number of documents from various areas across the MHRA that would then have to be searched to determine if they contain information falling within the scope of the request. In his view the MHRA has made a reasonable estimate that the request would exceed the appropriate limit and in doing so only took into account relevant costs. The estimate is not a mere assertion but was instead based on a sampling exercise of the information it held and relied on the quickest method of gathering the requested information – i.e. electronic databases were used to search for relevant information.
40. The Commissioner is therefore satisfied that the MHRA has correctly relied upon section 12.

## **Right of appeal**

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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](mailto:GRC@hmcts.gsi.gov.uk)

Website: [www.justice.gov.uk/tribunals/general-regulatory-chamber](http://www.justice.gov.uk/tribunals/general-regulatory-chamber)

41. 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.
42. 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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