

## Freedom of Information Act 2000 (Section 50)

### Decision Notice

Date: 4 January 2012

**Public Authority:** Medicines and Healthcare Products Regulatory Agency  
**Address:** Market Towers  
London SW8 5NQ

### Summary

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The complainant requested information about a specific clinical drug trial. The Medicines and Healthcare Products Regulatory Agency withheld the information under sections 40, 43 and 38. Subsequently the complainant confirmed that he did not want the information withheld under sections 38 and 40. The Commissioner's view is that the Medicines and Healthcare Products Regulatory Agency has not engaged section 43 and therefore the information withheld only under section 43 should be disclosed to the complainant. He also finds a breach of section 10 for a late response.

### 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

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2. A clinical drug trial was carried out in 2006 to test a drug known as TGN1412. Eight volunteers took part in the trial and the six volunteers who received TGN1412 rather than a placebo, suffered multiple organ failure. The Medicines and Healthcare Products Regulatory Agency ("MHRA") published some information about the trial but withheld other information.

## The Request

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3. The Commissioner notes that under the Act the MHRA is not a public authority itself, but is an executive agency of the Department of Health which is responsible for the MHRA. Therefore, the public authority in this case is actually the Department of Health not the MHRA. However, for the sake of clarity, this decision notice refers to the MHRA as if it were the public authority.

4. On 23 August 2010 the complainant submitted the following request:

*'This is a request under the Freedom of Information Act in relation to the incidents which occurred on 13 March 2006 at Northwick Park hospital during the clinical trials of TGN1412. As you may be aware, the MHRA released to the public its interim report together with a number of documents relating to TGN1412. One of our clients, injured in the TGN1412 drug trial, has instructed us to request that the documents be disclosed in an un-redacted form. These documents are:*

*1. Clinical Trial: Assessment Report: Pharmaceutical Data*

*2. Investigator's Brochure*

*3. Investigational Medicinal Product Dossier*

*4. Clinical Trial: Protocol.'*

5. On 11 October 2011 the MHRA responded. It withheld the requested information citing sections 40, 43 and 38.

6. On 13 October 2010 the complainant requested an internal review.

7. On 3 November 2010 the MHRA confirmed it had carried out its internal review and was withholding the information on the same grounds.

## The Investigation

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### Scope of the case

8. On 23 December 2010 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:

- The MHRA had not applied any of the exemptions correctly.
  - The MHRA had not considered the public interest in relation to sections 43 and 38 appropriately.
9. During the Commissioner's investigation, the complainant explained that he was not looking for the information withheld under sections 38 and 40. Therefore the Commissioner will only consider the application of section 43 by the MHRA.

## **Chronology**

10. There was correspondence between the Commissioner and the MHRA. The Commissioner explained that he would need a copy of the withheld information, clearly marked to show which specific information the various exemptions were being applied to. The MHRA explained that initially it had not been able to identify the new owners of the drug, but that subsequently, although it had in fact contacted them and explained the situation, they had not responded. The Commissioner also asked the MHRA to reconsider the withheld information in light of the passage of time.

## **Analysis**

### **Exemption**

#### **Section 43 (Commercial interests)**

11. 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.

#### The applicable interest

12. The MHRA stated that the relevant commercial interests are those of the new owners of TGN1412.

#### The nature of the prejudice

13. The withheld information is about the clinical drug trial of TGN1412. It includes information about the structure of the drug, medical conditions it could be used to treat, the manufacturing process, safety trials and criteria for safety evaluation.
14. The MHRA informed the Commissioner that TGN1412 had been bought by new owners. It also explained that it had tried to contact the new

owners about the request. Initially the new owners could not be traced but subsequently the MHRA contacted lawyers who were acting for them. The MHRA provided the Commissioner with copies of emails in which the lawyers acknowledged that they would pass the MHRA's concerns to the new owners; however the MHRA explained that neither the new owners nor their representatives have responded to it. The MHRA went on to explain that it felt that disclosure would prejudice the commercial interests of the new owners.

15. It is the Commissioner's view that in some cases it may be that, due to time constraints for responding to requests, arguments are formulated and argued by a public authority, based on its prior knowledge of the third party's concerns. The Commissioner accepts that these may be valid arguments and that where a public authority can provide evidence that they genuinely reflect the concerns of the third party involved then they may be taken into account.
16. The MHRA sent the Commissioner the arguments that the original owners put forward in 2006 in response to a request for the information withheld under the commercial interest exemption.
17. The MHRA explained that in its opinion these arguments reflected the concerns that the new owners may have about disclosure of the commercial information. It is the Commissioner's view that the concerns of the original owners who initially manufactured the drug, could be taken into account as they could reflect the concerns of the present company.

Would prejudice be likely to occur?

18. The original owners argued that in response to a previous request for information it considered that the information was a trade secret for the purposes of section 43(1) although it did not explain why this was the case. It also argued that disclosure of the information would or would be likely to prejudice its commercial interests although it did not specify the level of prejudice that would occur. Therefore the Commissioner has considered whether disclosure of the information would be likely to prejudice the new owner's commercial interests.
19. The original owners also argued that the requester involved in the previous request had accepted that information about the preclinical testing undertaken in relation to TGN1412 was commercially sensitive. It also went on to say that disclosure to a competitor would almost certainly cause real harm to it.
20. The original owners also explained that the requester had argued that it was unlikely that any company (including the original owners) would

wish to pursue the development of TGN1412 or a similar product. The original owners went on to explain that this assumption was overly simplistic and wholly speculative. It explained that its commercial interests were dependant upon its ability to build on the knowledge gained as a result of the preclinical product development undertaken to date.

21. The original owners went on to argue that if the requester did not believe that such products would be developed, the requested information would be of little interest to them. It also argued that it was evident that not only was the information important to its own commercial interests but that disclosure would mean the information would be exploited by competitors; this in turn would prejudice its commercial interests.
22. The MHRA also explained that it considered that there may be other companies researching similar products. It argued that these companies would find the withheld information useful in order to fast-track their products through the research and development stages. It acknowledged that it could not be sure that this was the case but felt that it was a reasonable assumption given that TGN1412 has been purchased.
23. The Commissioner has considered all of the arguments from the original owners and the MHRA. He notes that the MHRA has not been able to provide evidence to support its assertion that disclosure of the requested information would be likely to prejudice the commercial interests of the new owners.
24. The Commissioner also notes that the arguments put forward by the MHRA relate to the original owner's concerns in 2006. He further notes that TGN1412 has now been sold to another company which has not in fact objected to the disclosure. As explained in paragraph 14, although the MHRA managed to contact lawyers representing the new owners, neither the new owners nor their representatives have contacted the MHRA to raise any concerns about disclosure of the requested information. The Commissioner further notes that although the MHRA has argued that disclosure would prejudice the new owners commercial interests, it has only been able to speculate about this.
25. The Commissioner's view is that the MHRA has not demonstrated that disclosure would or would be likely to prejudice the new owner's commercial interests. It is therefore his view that the section 43 exemption has not been engaged, so the public interest arguments do not require consideration.

## **Procedural Requirements**

26. Section 10 of the Act provides that a public authority must respond to a request for information promptly and not later than the twentieth working day following the date of receipt.
27. The Commissioner notes that the public authority received the request for information on 23 August 2010 but failed to respond until 11 October 2010. Therefore the Commissioner find the MHRA is in breach of section 10.

## **The Decision**

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28. The Commissioner's decision is that the public authority did not deal with the request for information in accordance with the Act.

## **Steps Required**

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29. The Commissioner requires the public authority to take the following steps to ensure compliance with the Act:
  - Disclose the withheld information under section 43 only.
30. The public authority must take the steps required by this notice within 35 calendar days of the date of this notice.

## **Failure to comply**

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31. Failure to comply with the steps described above 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.

## Right of Appeal

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32. 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: [informationtribunal@hmcts.gsi.gov.uk](mailto:informationtribunal@hmcts.gsi.gov.uk)

Website: [www.justice.gov.uk/guidance/courts-and-tribunals/tribunals/information-rights/index.htm](http://www.justice.gov.uk/guidance/courts-and-tribunals/tribunals/information-rights/index.htm)

33. 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.
34. 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** .....

**Graham Smith**  
**Deputy Commissioner**  
**Information Commissioner's Office**  
**Wycliffe House**  
**Water Lane**  
**Wilmslow**  
**Cheshire**  
**SK9 5AF**