Decision 34/2005 Mr John G Young and the Scottish Executive

Request for information about the "Myodil" disclaimers and meaning of "service product"

Applicant: Mr John G Young
Authority: Scottish Executive
Case No: 200501900
Decision Date: 7 October 2005

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Decision 34/2005 – Mr John G Young and the Scottish Executive

Request for information about the Myodil "disclaimers" and the meaning of "service product" – who holds this information – information not held under section 17(1)(b)

Facts

Mr Young asked the Scottish Executive who held information in England or Scotland on the Myodil "disclaimers" 1951 and 1971 and information about Myodil being made a "Service product " in February 1971. Mr Young also asked for the meaning of "Service Product". He asked to be provided with copies of any information held. The Scottish Executive indicated that it did not hold the information requested by Mr Young. The Executive advised that it had sought advice from its legal advisers who were unfamiliar with the term "service product", had carried out a records management search and sought comments from the Medicines and Healthcare Products Regulatory Agency (MHRA). Mr Young was dissatisfied with this response and the result of the subsequent review and applied to the Scottish Information Commissioner for a decision.

Outcome

The Commissioner found that the Scottish Executive had complied with Part 1 of the Freedom of Information (Scotland) Act 2002 (FOISA). The Commissioner was satisfied that the Scottish Executive had carried out all reasonable steps to determine that it did not hold the information requested by Mr Young under section 17(1)(b) of FOISA.

Appeal

Should either the Scottish Executive or Mr Young wish to appeal against this decision, there is a right to appeal to the Court of Session on a point of law only. Any such appeal must be made within 42 days of receipt of this notice.

Background

1. On 28 February 2005, Mr Young sent a letter to the First Minister asking for the following information:

   - Who holds the information in England or Scotland on the Myodil Disclaimers 1951 and 1971?
   - Who holds the information on Myodil being made a "Service Product" in 1971?
   - What is a "Service Product?"
   - Can you gain access and copies of this information for me?

2. The Scottish Executive (the Executive) responded to Mr Young's request on 24 March 2005. It indicated that it did not hold the information requested. The Executive advised that the licensing and safety of medicines was a reserved matter and was the responsibility of the Medicines and Healthcare Products Regulatory Agency (MHRA).

3. The Executive indicated that the MHRA had advised that it did not hold any information on Myodil being made a "Service Product" and did not hold any information on the Myodil Disclaimers to which Mr Young had referred. The MHRA had advised that it was not aware of who might hold such information.

4. The Executive reported that the term "Service Product" was not familiar to the MHRA and had not been mentioned in any of the papers the Agency held concerning the licensing of Myodil.

5. The MHRA had suggested that Glaxo might be able to assist Mr Young.

6. Mr Young was unhappy with the response from the Executive and requested a review by letter dated 4 April 2005.

7. On 12 April 2005 the Executive acknowledged Mr Young's request for review and indicated that it would respond within 20 working days.

8. The Executive responded to Mr Young's request for review on 28 April 2005. It concluded that its original response to Mr Young's request should be upheld.

9. Mr Young contacted my office on 30 May 2005 requesting an investigation into the matter. The case was then allocated to an investigating officer.

10. When Mr Young supplied all correspondence to my office for the purposes of this investigation he included a letter dated 19 January 2005 addressed to the First Minister which was identical to his subsequent letter of 28 February 2005. The Executive advised me that it has no knowledge of a letter dated 19 January 2005 and had treated the letter of 28 February 2005 as Mr Young's original request for information.

Investigation

11. Mr Young's appeal was validated by establishing that he had made a request to a Scottish public authority, and had appealed to me only after asking the authority to review its response to his request.

12. The investigating officer contacted the Executive on 15 June 2005 giving notice that an appeal had been received and that an investigation into the matter had begun. The Executive was asked to comment on the issues raised by Mr Young's case and to provide supporting documentation for the purposes of the investigation.

13. In particular, the Executive was asked to specify the steps it had taken to determine whether or not it held the information requested by the applicant. The Executive was asked whether it held information about the licensing of specific medicines. The Executive was also asked to provide information about how its review was carried out and for copies of any internal correspondence relating to consideration of this request.

Submissions from the Scottish Executive

14. In its response to the letter of 15 June 2005 from my office the Executive made the following submissions.

15. It advised that Mr Young had written to the Executive on three prior occasions in 2003 and 2004 requesting similar information. Copies of this correspondence were supplied to my Office. At that time, the Executive had consulted its solicitors on the definition of "Service Product". They had advised that they held no information on a definition and were not familiar with the term.

16. The Executive had also consulted on product disclaimers and how these disclaimers would be recorded, issued and accessed. Their solicitors had advised that the Executive did not hold this information.

17. The Executive advised that on receipt of Mr Young's request for information dated 28 February 2005, the Executive had re-examined its papers relating to Mr Young's previous correspondence. The Executive had again consulted the MHRA who had advised that their position had not changed.

18. The Executive advised that it had conducted an internal Records Management database search, and a National Archive of Scotland (NAS) database search which established that it held no relevant information.

19. In subsequent correspondence with the Executive I asked to see the correspondence with the MHRA or telephone note relating to Mr Young's most recent request. I sought further information about the records searches that had been carried by the Executive and sought information about the dissemination of licensed product information in Scotland.

Submissions from Mr Young

20. During the course of the investigation Mr Young supplied my Office with copies of correspondence relevant to his request for information. Mr Young has been in contact with a range of organisations and individuals over the years in his efforts to locate the information requested on this occasion from the Executive.

21. Mr Young has been in contact with the Executive on three occasions prior to his request made in February 2005. He has also been in contact with the NHS Purchasing and Supply Agency, John Reid MP, the Legal Services Commission and the Department of Health and Human Services at the Food and Drug Administration in the United States. In addition, Mr Young has been in contact with the MHRA on a number of occasions, most recently on 4 March 2005.

22. Mr Young also enclosed extracts from a generic opinion on Myodil litigation signed by Augustus Ullstein QC dated 3 May 1994 and a copy of settlement advice in the Myodil litigation signed by Daniel Brennan QC and Augustus Ullstein QC dated 12 July 1995. These documents refer to the Myodil disclaimers and Myodil being made a service product in 1971. The extracts supplied to me provide no further information.

23. In a subsequent submission, Mr Young indicated that there was a Class Action against the Myodil manufacturers, Glaxo, in Scotland with the full knowledge and participation of the Executive. He considered that there was something amiss if the Executive did not hold this information given the Executive's involvement in the Class Action in Scotland on Myodil.

Analysis and findings

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24. I have looked through all of the correspondence supplied by Mr Young as well the extracts from the settlement advice and generic opinion. I have also looked at the correspondence and information supplied by the Executive.

25. I have seen the correspondence between the Executive and MHRA on this particular request for information and note that the MHRA has advised Mr Young on a number of occasions over the last few years that it does not hold the information he has requested.

26. I have also undertaken my own research into the information requested by Mr Young in an attempt to ascertain who might hold this information.

27. While I accept that the licensing of medicines is a reserved matter and falls under the control of the MHRA, it seemed to me that information about licensed medicines would, out of necessity, be distributed to health bodies in Scotland. I therefore asked the Executive a series of questions relating to the dissemination of this kind of information in Scotland.

28. I wanted to understand the normal practice in relation to the distribution of licensed products by the MHRA, for example, whether this kind of information was routinely distributed to the Executive and health boards. I recognised that the position might differ pre- and post-devolution. Mr Young's request refers to Myodil disclaimers dated 1951 and 1971.

29. When a product is licensed by the MHRA the Executive advised that individual bodies in Scotland are not sent the information as such. Instead the MHRA puts the information on its website for anyone to access as necessary. The Executive advised that it is not a case of notifying any particular bodies.

30. Likewise, where a company applies to vary a licence the process is as it would be if applying for a licence. The information would be published on the MHRA website for general consumption, and not notified to any particular bodies.

31. Where the MHRA had concerns about a particular licensed product, the Executive advised that the MHRA would advise the Executive, and the Executive would disseminate the information to health boards, who in turn would advise GPs, pharmacists and other NHS contractors, as appropriate.

32. I also enquired about product information (such as disclaimers) and who would be notified in the event that this information changed. The Executive advised that changes in product information were a matter between the pharmaceutical company and the MHRA and that this information would not be disseminated to bodies in Scotland.

33. I understand from this that the occasions when the Executive receives information on licensed medicinal products are limited to cases where the MHRA has concerns about a particular product.

34. However, the MHRA has advised that it does not hold the information requested.

35. I also asked the Executive about its involvement in the Myodil litigation in Scotland as this had been raised by Mr Young in his submissions. The Executive advised that it was not involved in the Myodil litigation in Scotland. It indicated that it held a small amount of information related to the litigation which was generated in the course of dealing with a Ministerial Correspondence case at the time. The Executive advised that it had had no direct involvement, however, and the information held arose due to correspondence received by the Executive from a member of the public and was settlement related.

36. I understand that Mr Young is trying every possible avenue to find out information about the reference to the Myodil "disclaimers" and to Myodil being made a service product in 1951 and 1971. His attempts have led him to contact many organisations.

37. While I am sympathetic to Mr Young's pursuit of this information, my powers are limited in such a matter.

38. In this case I can only investigate the Executive's statement that it does not hold the information requested by Mr Young. FOISA does not oblige an authority to create new information. Only information held by an authority at the time the information is requested is covered by FOISA.

39. I do not have the power to investigate whether any body, other than the Executive, holds this information. In particular, I do not have the power to investigate whether the MHRA holds this information, although the applicant will be able to take his request to the MHRA further under the Freedom of Information 2000, if he so wishes, and appeal to the Information Commissioner based in Wilmslow.

40. I am also unable to comment on whether the Executive should hold this information.

41. I enquired about the records management and national archives searches that were carried out by the Executive when it received this request for information. The Executive advised that both the National Archives of Scotland (NAS) database (http://www.dswebhosting.info/nas/), and the Executive's own internal records management database search utilise a keyword search facility. On inputting the keyword 'myodil' NAS returns no files and the Executive's internal database returned two files, neither of which holds any information on Myodil disclaimers or on Myodil being made a 'Service Product".

42. Having considered all correspondence and information supplied to me by both Mr Young and the Scottish Executive in this case, I am satisfied that the Executive has taken all reasonable steps to determine whether it holds the information requested by Mr Young.

Decision

I find that the Scottish Executive dealt with Mr Young's requests for information in accordance with Part 1 of the Freedom of Information (Scotland) Act 2002 (FOISA).

Kevin Dunion
Scottish Information Commissioner
7 October 2005