Ref: FS50072939

Information Commissioner's Office
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Freedom of Information Act 2000 (Section 50)

Decision Notice

Dated 12 June 2006

Public Authority: **Medicines and Healthcare Products Regulatory Agency (an executive agency of the Department of Health)**

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

Summary Decision

The Information Commissioner's (the "Commissioner") decision in this matter is that he is satisfied that the Medicines and Healthcare Regulatory Agency ("the Agency") has dealt with the Complainant's request for information in accordance with the requirements of Part 1 of the Freedom of Information Act 2000 ("the Act").

In particular, the Complainant specified that he wanted the Commissioner to consider whether the Agency was entitled to withhold some of the information requested by virtue of section 38 (health and safety) and section 36 of the Act (prejudice to the effective conduct of public affairs). The Commissioner's decision about this is that, in this case, the Agency was justified in withholding information revealing the names of individuals in a way that links them to a specific product, inspection or investigation.

In view of the matters referred to above the Commissioner does not require any steps to be taken by the Agency.

1. Freedom of Information Act 2000 (the 'Act') – Applications for a Decision and the Duty of the Commissioner

1.1 The Commissioner has received an application for a decision whether the Complainant's request for information made to the Public Authority has been dealt with in accordance with the requirements of Part I of the Act.

1.2 Where a complainant has made an application for a decision, unless:

- the Complainant has failed to exhaust a local complaints procedure, or
- the application is frivolous or vexatious, or
- the application has been subject to undue delay, or

- the application has been withdrawn or abandoned,

the Commissioner is under a duty to make a decision.

1.3 The Commissioner shall either notify the Complainant that he has not made a decision (and his grounds for not doing so) or shall serve a notice of his decision on both the complainant and the public authority

2. The Complaint

2.1 On 5 January 2005 the Complainant requested the following information from the Agency in accordance with s.1 of the Act:

"I wish to request the following information from the MHRA and precursor agencies, the CSM and other bodies within the agency, under the 2000 Freedom of Information Act.

(a) Any staff or consultant medical, pharmacological or statistical review, analysis or report, or more substantial record containing such, on the efficacy and general safety of rofecoxib, prior or subsequent to licensure.
(b) Any staff or consultant medical, pharmacological or statistical review, analysis or report, or more substantial record containing such, on the cardiovascular (CV)effects and safety of rofecoxib, prior or subsequent to licensure.
(c) Any staff or consultant medical, pharmacological or statistical review, analysis or report, or more substantial record containing such, on the gastrointestinal (GI)effects and safety of rofecoxib, prior or subsequent to licensure.
(d) Any staff or consultant medical, pharmacological or statistical review, analysis or report, or more substantial record containing such, which discuss outcomes of the following clinical trials of rofecoxib: 029,033,040,034,035,044,045,058,044C and 069,prior or subsequent to licensure (nb, these are likely to be, but may not be, grouped together, and probably in documents requested in (a) – (c).
(e) Records or details, in reasonable summary form, of promotional and/or advertising material on rofecoxib products (Vioxx) received by the agency.

2.2 On 3 June 2005 the Agency issued a Refusal Notice. It disclosed some of the requested information but considered the remainder of the information was exempt under sections 27 (international relations), 40 (personal information) and 43 (commercial interests) of the Act. Additional redacted documents were sent to the Complainant on 6 June 2005.

2.3 The Complainant contacted the Commissioner on the 22 April 2005. He complained about what he considered to be the Agency's general failure to comply with its obligations under the Act. This followed a number of requests he had made

to the Agency seeking identical information about various products. The Commissioner contacted the Agency and the Complainant to ascertain the current status of his various requests and to clarify the nature of his complaint.

2.4 The Complainant specified that his complaint now solely concerned the redaction of the identities of staff and/or external experts, reviewers or analysts, whose names appear in documents of the Agency about rofecoxib. The Agency confirmed to the Commissioner on the 25th October 2005 that only the s.40 exemption was being applied to justify withholding this part of the requested information.

2.5 An agreement was reached between the Complainant and the Agency that the right to an internal review would be waived. This was because other requests for the identities of individuals linked with specific products had already gone through the Agency's internal review process. These reviews all resulted in the Agency upholding its original decision. The Commissioner therefore decided to consider this Complaint even though an internal review had not been carried out.

2.6 In the course of correspondence with the Commissioner the Agency advised that it in fact wanted to rely on the exemptions at s.36 (prejudice to effective conduct of public affairs) and s.38 (health and safety) of the Act. It confirmed that it no longer wished to rely on s.40 as its basis for withholding this part of the requested information.

3. Relevant Statutory Obligations under the Act

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."

4. Review of the case

4.1 As explained above, the Complainant first contacted the Commissioner on the 22 April 2005. On 17 October 2005 the Commissioner wrote to the Agency requesting more information about its decision to use the exemption at s.40 of the Act as its basis for withholding information identifying its staff. In particular he was keen to understand the nature of the risks that apparently face individuals working for the Agency.

4.2 On 14 November 2005 the Agency replied to the Commissioner. It explained that on further consideration of this case it should have cited the s.36 and s.38 exemptions alongside, or instead of, s.40. It confirmed that it therefore intended to seek evidence of its Minister's opinion that disclosure of the requested information would, or would be likely, to prejudice the effective conduct of public affairs.

4.3 The Agency expanded on the risks to personal safety apparently facing its employees and advisors. It described examples of incidents involving Agency staff and the particular risks posed by animal rights activists. It also explained that a core responsibility of the Agency is the assessment of applications for Marketing Authorisations (licences to supply a product in the UK market). Before a licence is granted the Agency must be satisfied that the product meets stringent criteria relating to efficacy, safety and quality. Agency assessors are routinely involved in assessing products that have been tested on animals, and many Agency staff may have undertaken such experimentation in a professional capacity before they joined the Agency. It therefore considers that it is a clear target for animal rights activists who oppose animal testing. This targeting is not limited to those directly involved in animal experimentation but may also extend to those organisations or individuals who appear to be connected to, or in acceptance of, this activity.

4.4 The Agency also explained that, for audit and administrative convenience, it nominates an appropriate lead assessor of a product. This person is identified as the author on the final report. However, in reality assessment reports are corporate documents so that although one name may appear on the report, the final decision on the licensing of a product or an assessment of safety issues will be as a result of extensive in-put from medical, pharmaceutical, scientific, statistical and in many cases other specialist professionals within the Agency. This means that the signatory of the report is acting in a corporate capacity rather than in an individual one. The Agency believes, apparently from experience, that this is not a distinction that is understood by many members of the public, who may then attack an individual's professional credibility, often using the media.

4.5 The Agency explained that its functions are not limited to licensing applications. It also has enforcement powers and employs staff to investigate alleged breaches of the Medicines Act 1968. It also has an Intelligence Unit whose function is to obtain evidence about actual or potential criminal activity. The Agency does not think it should release the names of these staff in a way that links them to specific investigations. It considers that to do so would put their personal safety at risk (and potentially that of their families).

4.6 The Commissioner wrote again to the Agency on 15 December 2005. He requested more information about the health and safety risk to individuals, and about the nature of the corporate decision making process used by the Agency.

4.7 On 28 March 2006 the Agency advised that it had received confirmation of its Minister's opinion that disclosure of the requested information would, or would be likely, to prejudice the effective conduct of public affairs. The Agency clarified that it now intended to rely on s.36 and s.38 as its basis for withholding the information.

4.8 The Commissioner's investigation has therefore focused on whether the requested information is exempt from disclosure by virtue of the exemptions at s.36 and s.38 of the Act. He has considered specifically whether the Agency was justified in withholding the names of individuals linked to decisions taken in relation to specific products, inspections or investigations.

5. The Commissioner's Decision

Section 36 (Prejudice to the Effective Conduct of Public Affairs)

5.1 The Agency invoked Section 36 (2) (b) and (c)) as grounds for withholding the information. This states:

"Information to which this exemption applies is exempt information if, in the reasonable opinion of a qualified person, disclosure of the information under this Act –

(b) would, or would be likely to, inhibit-
(i) the free and frank provision of advice, or
(ii) the free and frank exchange of views for the purposes of deliberation, or
(c) would otherwise prejudice, or would be likely otherwise to prejudice, the effective conduct of public affairs."

5.2 The Minister responsible for the Agency, in her capacity as the qualified person, expressed her opinion that disclosure of the information that the Agency had withheld from the Complainant would, or would be likely, to prejudice the effective conduct of public affairs.

The Commissioner has not had sight of any documents confirming the qualified person's opinion. However, he is satisfied that the Agency's qualified person does hold this opinion, and that it is a reasonable opinion for her to hold. The Commissioner would normally expect to be presented with some firm evidence that the opinion is held.

5.3 However in view of the fact that the Commissioner considers the most appropriate exemption in this case to be s.38 he has not considered the application of s.36 any further in this Decision Notice.

Section 38 (Health and Safety)

Section 38 (1) (a) and (b) was also applied by the Agency as its basis for withholding the information. This states that:

> "Information is exempt information if its disclosure under this Act would, or would be likely to-
> (a) endanger the physical or mental health of any individual, or
> (b) endanger the safety of any individual"

The Agency believes that the health and safety of individuals will be put at risk if their identities are disclosed. This is because those who are opposed to the testing of medicines and other products on animals have targeted and continue to target, sometimes violently, those organisations or institutions involved in, or connected with, animal testing. The Agency suggested that not only those directly involved in animal research have been targeted, but also their relatives and other organisations and individuals who have merely supplied products or services to those more directly involved in the testing. The Agency has provided the Commissioner with compelling evidence of Agency staff being targeted. The Commissioner is satisfied that individuals are facing real risks.

The Commissioner has decided that the requested information does fall within the scope of the exemption provided by section 38. There is clear evidence that organisations and individuals involved in animal research have been targeted, and their health and safety put at risk, by militant anti-vivisection groups. The Commissioner is satisfied that disclosing the names of staff in a manner which links them to a specific product, investigation or inspection would, or would be likely, to endanger their health or safety.

The public interest test

The Commissioner considered the arguments put forward by the Agency in favour of withholding the information and also the arguments in favour of disclosure.

The Agency put forward the following public interest arguments in favour of disclosure:

1. The regulation of medicines is clearly a matter of significant public interest and scrutiny. There is a public interest in disclosing information on how the Agency reaches its decisions.

2. Disclosure of the names of individuals may highlight whether a particular individual has a propensity to make errors of judgment. Disclosure would

give the public grounds to question the decision and so subject the Agency's decision making process to strict scrutiny.

In addition the Commissioner has identified other public interest arguments in favour of disclosure:

1. Disclosure of this information would promote greater openness and transparency within the Agency. There is a public interest in ensuring the impartiality of Agency staff involved in the regulation and licensing of medicines. Disclosure of this information could allow any commercial or financial conflict of interest to be detected.

2. The Agency has a key public health responsibility. Individuals making a decision to grant a licence should therefore be accountable for their actions.

3. There are probably only around 10 individuals across the UK who are prepared to adopt direct action against individuals or institutions connected in any way to animal research. A high proportion of these activists are apparently in prison. Since there are hundreds of organisations and institutions, employing tens of thousands of people, it seems unlikely that up to 10 people could cause fear, alarm or physical harm to the Agency. Direct action is in any event more likely to be focused on institutions or organisations actually carrying out the animal testing. However, a single activist, or small group of activists, could cause harm to particular individuals or organisations.

4. Calls for more openness are now more persuasive given that the police have new powers and new legislation which make it easier to punish animal rights extremists. These powers, and the introduction of a police team dedicated to combating domestic extremism (National Extremism Tactical Co-ordinating Unit - NETCU), should reassure individuals and their families.

The Agency put forward the following public interest arguments against disclosure:

1. Identifying individuals connected with specific products will increase the risk of them being subjected to violence and intimidation by the animal rights activists. It is not in the public interest to subject individuals to this risk.

2. The activities of a small number of animal rights extremists make it necessary to protect the identity of individuals. This protection extends to their families and others associated with them, from potential harassment and harm. Even if the risk of attack was adjudged to be low, the actuality of an attack could have serious consequences for the individual involved. It

therefore argues that the need to protect individuals from harm outweighs the public interest in disclosure of the information requested.

3. The threat the Agency faces is not just from animal rights activists. It explained that Agency staff can encounter persistent lobbying, correspondence and abusive phone calls from the public (including aggrieved patients and their relatives) who perceive a regulatory decision in relation to a particular medicinal product or range of products to have been incorrect. An individual member of staff may then be considered personally responsible for that decision. The Commissioner has noted that the particular product which the complainant is seeking information about has been withdrawn due to the possible health risks associated with its use and the pharmaceutical company involved is facing lawsuits against it. Disclosing the identities of individuals linked to the granting of the licence for this product could lead to individuals being wrongly held personally responsible for the licensing of this product by aggrieved individuals. It is not in the public interest to jeopardise the safety of staff involved in the regulation of medicines.

4. Disclosure would also harm the Agency's ability to investigate, and where appropriate prosecute, breaches of the law which would not be in the public interest.

5. It is not in the public interest for those officials and commissioned experts to have to undertake their work against a background of anxiety as to how their professional background or advice might endanger their personal health, safety or reputation.

6. The Agency accepts there is a public interest in disclosing information on how it reaches regulatory decisions. However it has stressed that decisions do not rest with one individual alone. Any propensity for individuals to make errors of judgment or suggestions of improper conduct would therefore become apparent through its quality assurance processes and its peer review and not simply as a result of disclosure of names to the public.

7. The public interest in transparency and openness is already met by its policy to disclose the names of officials wherever possible. Names of Agency staff and other specialist professionals can be found on its website, in its Annual report, and when writing to the public or other stakeholders. The names of staff and specialist professionals attending its Committee on the Safety of Medicines (CSM) meetings will also be disclosed provided this does not link them with a specific product, investigation or inspection and in particular, where there is any discussion of toxicology tests carried out on animals. There is therefore no detriment to the public and no reduction in the Agency's accountability for its decisions and actions by the withholding of

names. It is a corporate decision making process often involving many individuals.

In addition the Commissioner has identified another possible public interest argument against disclosure:

1. The key public interest is in ensuring that prior to and subsequent to licensure the Agency has acted properly and in accordance with its rules and regulations when granting and reviewing the licensing of a product, and not in knowing the name of the individual attached to the product. The Agency believes its present disclosure policy fulfils this public interest. Since 30 October 2005 assessment reports on the licensing of products are now publicly available. The names of individual assessors and experts are however deleted.

The Commissioner has considered the competing public interest arguments. Some relate more closely to the section 36 exemption which has not been considered here. In respect of section 38, some - on both sides of the equation - are more compelling than others. Overall, the Commissioner has concluded that in all the circumstances of this case, the public interest in maintaining the section 38 exemption outweighs the public interest in disclosure.

6. Summary of the Commissioner's decision

The Commissioner accepts that the regulation and safety of medicines is a matter of significant public interest and must be subject to proper scrutiny. There is clearly a need to ensure that there is no financial or commercial conflict of interest in respect of officials involved in the licensing of medicines and other products. He recognises that disclosure of the requested information may reassure the public about the integrity of Agency staff, or allow any lack of integrity to be detected.

However he notes that the Agency does have a policy on the disclosure of information. It makes assessment reports on the licensing of products publicly available and also discloses the minutes of the CSM meetings. He is persuaded that this should be enough to inform and reassure the public about the integrity and accountability of the activities of the Agency.

He has also carefully considered the health and safety risks of disclosing the identity of individuals in a way that links them to specific products, inspections and investigations. He recognises that the disclosure of individuals' identities may ultimately undermine support for animal activists and reduce the risks facing individuals involved in, or connected to, animal experimentation. However, in this case, the Commissioner is satisfied that the disclosure of the requested information would, or would be likely, to endanger the health or safety of individuals. Given this, there would have to be an extremely strong counter argument for the disclosure of

the requested information to be in the public interest. Given, in particular, the collective manner in which the Agency carries out its approvals, and the steps it already takes to ensure the transparency of its activities, the Commissioner's decision is that the public interest in maintaining the exemption outweighs the public interest in disclosing the requested information.

7. Action Required

In view of these matters the Commissioner hereby gives notice that in exercise of his powers under section 50 of the Act he does not require any remedial steps to be taken by the public authority.

8. Right of Appeal

8.1 Either party has the right to appeal against this Decision Notice to the Information Tribunal (the "Tribunal").Information about the appeals process may be obtained from:

Information Tribunal
Arnhem House Support Centre
PO Box 6987
Leicester
LE1 6ZX

Tel: 0845 600 0877
Fax: 0116 249 4253
Email: informationtribunal@dca.gsi.gov.uk

8.2 Any Notice of Appeal should be served on the Tribunal within 28 days of the date on which this Decision Notice is served.

Dated the 12th day of June 2006

Signed ……..

Information Commissioner's Office
Promoting public access to official information
and protecting your personal information

Richard Thomas
Information Commissioner

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