Freedom of Information Act 2000 (Section 50)

Decision Notice

Dated 31 July 2006

Public Authority: **Department for Environment, Food & Rural Affairs (DEFRA)**

Address: **Nobel House**
17 Smith Square
London
SW1P 3JR

Summary Decision and Action Required

The Commissioner's decision in this matter is that the public authority has dealt with the complainant's request in accordance with Part I of the Act except that it has failed to comply fully with its obligations under section 16. The Commissioner regards the authority's offer to provide an additional piece of information as a suitable outcome to a partly justified complaint.

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

1.1 The Information Commissioner (the 'Commissioner') has received an application for a decision whether, in any specified respect, 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 Freedom of Information Act 2000 (the 'Act').

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

- a 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- the application has been withdrawn or abandoned,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 The Veterinary Medicines Directorate (VMD) are an executive agency of the Department for Environment, Food and Rural Affairs (DEFRA). The complainant

has advised that, on 1 November 2004, the following information was requested from the VMD in accordance with section 1 of the Act:
"... full and frank disclosure of ALL data in [their] possession detailing clinical trials and results and adverse reaction reports supplied to [them] as REGULATOR from the License HOLDER Pfizer in the case of RIMADYL [carprofen]."
At the relevant time, Rimadyl was distributed in the UK by Pfizer Limited (Pfizer). The complainant had indicated his interest in information about the safety of Rimadyl in clinical use in dogs.

2.2 VMD replied on 23 November 2004, reminding the complainant that the Act did not come into force until 1 January 2005 and that his request would be considered then. VMD said that they would write to Pfizer to seek their comments on releasing the information requested. They provided the complainant with a copy of their standard summary of product characteristics for Rimadyl.

2.3 The Commissioner has noted this correspondence before the Act come into force on 1 January 2005 but has only based his decision on actions and events after that date.

2.4 The complainant repeated and amplified his request in detail on 1 January 2005. He said that he was seeking: "a full appraisal of the precise DATES, TIMES and SPECIFICS of the Marketing Authorizations applicable to RIMADYL for use in the UK. ... In addition ... a reference catalogue or index which gives a comprehensive listing of information on Marketing Authorizations held by you as the UK Licensing Authority." The complainant also referred to VMD's 'traffic light document' (TLD). The TLD forms part of a memorandum of understanding between the UK veterinary medicines regulatory authorities and the pharmaceutical industry on the release of information under the Act – information is classed as: 'green', to be released; 'amber', to be considered for release; or 'red', not for release.
The complainant asked for the following information about Rimadyl:

- minutes of the Veterinary Medicines Advisory Board [the Veterinary Products Committee may have been intended];
- licensing history of Rimadyl;
- pre-clinical safety data - all published literature and any non published data;
- evidence of animal testing certificate applications: disclosure of adverse drug reactions exhibited in clinical trials, and disclosure of clinical trial results after the grant of Marketing Authorization;
- Pfizer's expert reports &/or common technical document indicating overall safety and efficacy including assessment reports by the authority; correspondence and emails between the authority, Advisory Body and Pfizer; copy of the package leaflet on Rimadyl applicable at 19/7/2000;
- please supply number of suspected adverse reaction reports with reference to Rimadyl. Any periodic safety update reports with regard to Rimadyl, information on adverse reaction reports listed by drug substance [carprofen] ascribed to any other particular products."

2.5 VMD acknowledged the complainant's request on 7 January 2005 and replied in more detail on 28 January refusing the request but not specifying the exemptions upon which they were relying. They enclosed some information, said they needed to extend the time limit for considering the public interest test (but did not list the

qualified exemptions that they considered to be engaged), promised a reply by 28 February, and asked the complainant to narrow down his request. They said that they had not yet written to Pfizer. They provided information about marketing authorisations and the information referred to in the TLD. They said that the incidence of suspected adverse reactions needed to be set in the context of the volume of the product sold. They provided reaction incidence figures for Rimadyl together with an explanation of their significance. VMD also said that there were four other products containing carprofen as the active substance on which they did not yet have information, and promised within 10 working days the licensing history of Rimadyl with the relevant package leaflet.

2.6 The complainant replied by email on 1 February 2005, seeking any information that had come into VMD's possession from the Royal College of Veterinary Surgeons. As regards narrowing down his request, he asked VMD to reply by 28 February at the latest with all the summary of product characteristics and asked for actual numbers of adverse events reported to them for a related product up to and including its withdrawal from the market. He restated his request, coupled with his original request, for access to relevant catalogues and indexes.

2.7 On 4 February 2005 VMD wrote to Pfizer to ask their permission to disclose product safety data to the complainant. Pfizer replied on 18 February, refusing.

2.8 On 11 February 2005 VMD provided the complainant with: the history of four products containing carprofen, a relevant package leaflet and the summary of product characteristics document for Rimadyl that had applied in July 2000.

2.9 On 28 February 2005 VMD wrote again to the complainant. They cited section 43 of the Act and went on to provide the outcome of their consideration of the public interest test and withheld the numbers of suspected adverse reaction reports as sales data could be derived from them. VMD also:

- provided the conclusions of the Veterinary Products Committee's (VPC) consideration of the precursor product in January 1993.
- withheld, citing section 43, pre-clinical safety data and expert reports, periodic safety update reports, animal test certificate applications, the results of clinical trials made following the grant of marketing authorisation and sales data, all of which were classed as red in the TLD (i.e. to be withheld).
- said that section 12, the appropriate limit on the cost of dealing with requests, would now be applied as spending on these enquiries had already totalled £1,500.

2.10 On 3 March 2005, and in more detail on 5 March, the complainant asked for an internal review of the decision to withhold information, telling VMD of his concern that they had failed to comply with the spirit and letter of the Act and with the Secretary of State's Code of Practice issued under section 45 of the Act (the Code of Practice) which they had violated in: not providing advice and assistance especially catalogues and indexes, transferring requests, consulting third parties and confidentiality. He also raised an issue about cyclo-oxygenase isoform COX2 inhibitor safety. VMD sent a holding reply on 8 March, saying that they were carrying out an internal review of his case and were also seeking advice from DCA. They needed to extend the time limit for replying. In a further short letter of 8 April,

VMD said that they were still waiting for advice from DCA who were scrutinising the case.

2.11 On 25 April 2005 VMD provided the outcome of their internal review to the complainant. VMD summarised the actions they had taken in response to the complainant's requests of 1 November 2004 and 1 January 2005. They said they had acted in accordance with the Act since it came into force and had now exceeded the appropriate limit of resources prescribed by regulation, that is resources expended after 1 January 2005 on dealing with requests for information. They added that the cyclo-oxygenase isoform COX2 inhibitor safety issue related to safety in human medicine. On 12 May 2005 the complainant wrote to the Commissioner asking him to investigate whether or not VMD had acted properly in respect of: the public interest test, the Code of Practice, giving help and the expense limits.

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."

Time for compliance with request
Section 10 provides that:
"(1) 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. ...

(3) If, and to the extent that-
(a) section 1(1)(a) would not apply if the condition in section 2(1)(b) were satisfied, or
(b) section 1(1)(b) would not apply if the condition in section 2(2)(b) were satisfied, the public authority need not comply with section 1(1)(a) or (b) until such time as is reasonable in the circumstances; but this subsection does not affect the time by which any notice under section 17(1) must be given."

Cost of compliance
Section 12 provides that:
"(1) Section 1(1) does not oblige a public authority to comply with a request for information if the authority estimates that the cost of complying with the request would exceed the appropriate limit.
...
(5) The Secretary of State may by regulations make provision for the purposes of this section as to the costs to be estimated and as to the manner in which they are to be estimated."

The 'appropriate limit' is set out in the Freedom of Information and Data Protection (Appropriate Limit and Fees) Regulations 2004, S.I.2004/ No. 3244 (the 2004 regulations).

Advice and assistance
Section 16(1) provides that –
"It shall be the duty of a public authority to provide advice and assistance, so far as it would be reasonable to expect the authority to do so, to persons who propose to make, or have made, requests for information to it".

Information provided in confidence
Section 41 provides that -
"(1) Information is exempt information if-

(a) it was obtained by the public authority from any other person (including another public authority), and
(b) the disclosure of the information to the public (otherwise than under this Act) by the public authority holding it would constitute a breach of confidence actionable by that or any other person."

Commercial interests
Section 43 provides that:
"(1) Information is exempt information if it constitutes a trade secret.

(2) Information is exempt information if its disclosure under this Act would, or would be likely to, prejudice the commercial interests of any person (including the public authority holding it)."

Issue of code of practice by Secretary of State
Section 45 provides that:
(1) The Secretary of State shall issue, and may from time to time revise, a code of practice providing guidance to public authorities as to the practice which it would, in his opinion, be desirable for them to follow in connection with the discharge of the authorities' functions under Part I.

4. Review of the case

4.1 The complainant asked the Commissioner to:

- determine if the public interest test had been properly applied by VMD
- ensure that the Code of Practice had been properly interpreted
- determine if the help and assistance expected has been properly applied
- determine if the expense limits have been properly applied.

4.2 On 28 April 2006 VMD wrote to the Commissioner, explaining that the information being withheld was extremely voluminous and suggesting that it be viewed at VMD's offices. VMD drew attention to the TLD and the impact on the market authorisation holder (i.e. Pfizer) of disclosing information they had provided to VMD

in confidence. VMD said that sections 41 and 43 of the Act applied and explained their reasoning in applying the public interest test and the Code of Practice. They explained that so far they had expended some 90 hours of staff time in processing the request, and did not feel justified in spending several hours more in extracting some additional information which was only held in microfiche form.

4.3 A member of the Commissioner's staff visited VMD on 23 May for discussions with VMD staff and noted the volume of material and VMD's reference catalogue for Rimadyl – one of numerous such indexes. VMD confirmed that the information stored on microfiche could only be extracted in paper form. They subsequently provided an analysis of the 90 hours of staff time so far expended on the case and confirmed that in excess of 24 hours of relevant staff time, costed at £25 per hour, had been incurred since 1 January 2005 on activities specified in the 2004 regulations (see section 3 above).

4.4 The Commissioner has noted that VMD have provided the complainant with: the conclusions of the January 1993 Veterinary Products Committee meeting concerning the use of Rimadyl in dogs; a list of four other carprofen products authorised for use in the UK; the detailed licensing history of Rimadyl and a predecessor product; relevant product leaflets; the TLD and memorandum of understanding with the pharmaceutical industry (which the Commissioner has noted); the May 1999 summary of product characteristics for Rimadyl when used for small animal injection (a 10 page document); and the % reaction incidence figures for Rimadyl which had been derived from periodic safety update reports from Pfizer.

VMD are refusing to disclose to the complainant: 37 volumes of dossiers of the pre-clinical trial information that supported the marketing authorisation of Rimadyl; a letter from Pfizer dated 18 February 2005 which was provided in confidence; and numbers of suspected adverse reaction cases which, if combined with the % reaction incidence data already given, could enable commercially sensitive sales data to be calculated.

In withholding the remaining information VMD have relied upon sections 41 and 43 of the Act and the resource limitations set out in section 12.

The public interest test

4.5 Section 41 relates to information which has been provided in confidence by another legal person, the disclosure of which would give rise to an actionable breach of confidence. It is an absolute exemption and so is not subject to a public interest test. However the duty of confidence is not absolute and information may still be disclosed in any of three circumstances: with consent; if required by law; and, where there is an overriding public interest.

By means of a letter to VMD, Pfizer objected to disclosure of the information that VMD are withholding on: pre-clinical safety and expert reports; periodic safety update reports; animal testing certificates; the results of clinical trials after grant of marketing authorisation; and sales data. The Commissioner accepts that the section 41 exemption is engaged and that the owner of this information objects to its release. He further notes that there is no legal requirement for it to be released and, because the information is all known to the VMD who are the responsible

regulatory body, the Commissioner sees no over-riding public interest in its release to the complainant.

4.6 Section 43 relates to the commercial interest of either the public authority or another body. It is a qualified exemption which carries a public interest test and, in section 43(2), a prejudice test. VMD say that much of the information withheld on sales and market share data, as well as product safety, clinical experience and testing, represents a considerable investment by Pfizer and could, if disclosed, offer commercial advantage to other companies and harm the commercial interests of Pfizer. The Commissioner accepts that the exemption is engaged. The complainant told the Commissioner that he was aware of allegations by some other pet owners that their pets had been similarly and adversely affected by reactions to Rimadyl; he saw it as in the public interest for VMD to disclose to pet owners the data in their possession concerning possible adverse reactions to Rimadyl. VMD said that release of the information could affect decisions by pharmaceutical companies to market veterinary medicines in the UK to the detriment of animal welfare. Because the information about alleged serious adverse reactions to Rimadyl is known to VMD (who, as the regulatory body, are under a duty to act in the public interest in this matter), the Commissioner found that the public interest in maintaining the exemption in this instance outweighs that in releasing the information.

The section 45 Code of Practice

4.7 The Secretary of State has, as required by section 45 of the Act, published a Code of Practice which sets out guidance to public authorities on practices that it would, in the his opinion, be desirable for them to follow in exercising their functions under the Act. This covers such matters as the provision of advice and assistance to persons making requests for information, transfers of requests, consultation with third parties, confidentiality obligations and complaints procedures. The complainant asked if the code had been properly interpreted by VMD in their dealings with him. It appeared to the Commissioner that, subject to the matters noted elsewhere in this Notice, VMD followed the Code of Practice.

Refusal Notice

4.8 Section 10 of the Act requires, subject to certain exceptions, the issue of a refusal notice by the authority within 20 working days of the request having been made. VMD's letter of 28 January 2005 refused disclosure of certain information and noted the need for more time to provide a response in respect of the public interest test. However, that letter did not cite the exemptions that VMD were relying upon; this was not done until their letter of 28 February 2005.

Help and assistance

4.9 Section 16 of the Act places a duty on public authorities to provide reasonable advice and assistance to applicants. Further guidance on this is set out in the Code of Practice. Paragraph 10 of the Code of Practice notes that appropriate assistance by public authorities might include outlining different kinds of information which might meet the terms of the request and providing access to detailed catalogues and indexes. VMD asked the complainant to focus more tightly his initial request for: "ALL data in your possession about Rimadyl". This he did, making clear

that his concerns were with the safety of Rimadyl as used in clinical practice in the UK. The Commissioner is satisfied that VMD outlined the kinds of information available in their January and February 2005 letters in a way that was helpful and that they provided some of the information requested on suspected adverse reactions to the drug and the relevant summary of product characteristics.

4.10 VMD did not fully comply with section 1 of the Act in that they did not respond to the complainant's repeated requests for access to their catalogues and indexes listing the information held on marketing authorisations related to Rimadyl. VMD explained to the Commissioner's staff that they held numerous indexes of such authorisations and that each was very technical in nature and of little use to the lay reader without careful interpretation. The Commissioner welcomes VMD's offer to now provide the complainant with the relevant catalogue(s) and index(es) and to assist his understanding of them, and does not require VMD to undertake any further remedial action beyond that.

4.11 VMD repeatedly told the complainant that they would write to Pfizer to seek their comments on releasing information which VMD believed they could not release without Pfizer's consent. VMD were slow to carry out their promises to write but eventually did so on 4 February 2005. Pfizer replied on 18 February, withholding consent on grounds of commercial confidence.

Expense limits

4.12 The 2004 regulations stipulate that the appropriate limit on expenditure on complying with a request is currently set at £600 for central government departments. The activities that can be taken into account in assessing whether the appropriate limit has been met or exceeded are:

- determining whether the authority holds the information;
- locating the information, or a document which may contain the information;
- retrieving the information, or a document which may contain the information, and
- extracting the information from a document containing it.

4.13 The 2004 regulations specify, for the purposes of the "appropriate limit" of cost, that the staff cost to a public authority of extracting, retrieving etc. information is to be calculated at £25 per hour. This means that, if it would take the VMD more than 24 hours (£600 ÷ £25 per hour) to extract information, then the "appropriate limit" would be exceeded and the information need not be provided. The Commissioner has noted the substantial scale of VMD documentation and that they say they have, since 1 January 2005, already expended in excess of £600 on staff time calculated in this way on relevant activities in responding to the complainant's requests. The Commissioner has further noted that additional information is held on microfiche and cannot be extracted electronically but only by printing in hard copy form; he does not require VMD to take any further action on this material that would incur significant additional cost. The Information Commissioner's decision is that the appropriate limit has been reached in this case and that VMD are therefore justified in refusing to do more, by virtue of the exemption at section 12 of the Act, beyond that which they have helpfully offered on the catalogue(s) and index(es).

5. The Commissioner's Decision

5.1 The Commissioner's decision in this matter is that, with the procedural exceptions noted, VMD have dealt with the complainant's request in accordance with the requirements of Part I of the Act. VMD failed to show the complainant their relevant catalogue(s) and index(es) of the information held; the Commissioner regards VMD's offer to provide this information to the complainant now as a suitable outcome to a partly justified complaint.

6. Action Required

6.1 The Commissioner requires VMD to take no action save fulfilling their offer to provide the complainant with a copy of their relevant catalogue and index(es).

7. Right of Appeal

7.1 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

7.2 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 31st day of July 2006

Signed ……..

Phil Boyd
Assistant Commissioner

Information Commissioner
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