



Tribunals Service
Information Tribunal

Information Tribunal Appeal Number: EA/2006/0067

Information Commissioner's Ref: FS 50075607

Heard in Chambers

On 22 October 2007

Decision Promulgated

2nd November 2007

Freedom of Information Act 2000 (FOIA)

Decision Reached on Consideration of the Papers Only

BEFORE

INFORMATION TRIBUNAL

DEPUTY CHAIRMAN

David Marks

And

LAY MEMBERS

David Wilkinson

Henry Fitzhugh

Between

JOHN JENKINS

Appellant

And

INFORMATION COMMISSIONER

Respondent

And

DEPARTMENT FOR ENVIRONMENT, FOOD AND RURAL AFFAIRS

Additional Party

Decision

Reasons for Decisions

Introduction

1. This case concerns various requests made by the Appellant to the Veterinary Medicines Directorate (VMD), an executive agency of the Department for Environment, Food and Rural Affairs (DEFRA) which is the Additional Party, for detailed information regarding a product called Rimadyl and its ingredients. The Appeal raises various issues being principally first the applicability and scope of section 12 of the Freedom of Information Act 2000 (FOIA) and the reliance by DEFRA on two allegedly applicable exemptions. The first exemption is the absolute exemption contained in section 41 of FOIA which exempts information provided to a public authority in confidence, and the second exemption is a qualified exemption contained in section 43 which provides that information is exempt if its disclosure under the Act would or would be likely to prejudice the commercial interests of the person or public authority holding it. As will be seen below, the Tribunal has been persuaded that this Appeal represents an opportunity to deal with a particular sub-issue which relates to section 12. Finally, a related matter, though minor, in scope arises about the applicability of section 16 of FOIA which obliges a public authority to provide advice and assistance to a person making a request where appropriate. This Appeal is being dealt with following a consideration of the papers alone.

The Facts

2. By letter dated 1 November 2004, the Appellant sent his first written request to VMD. The letter was headed "RIMADYL: ADVERSE REACTION". The Appellant asked for:

"... full and frank disclosure of ALL data in your possession detailing clinical trials and results and adverse reaction reports supplied to you as REGULAR from the License HOLDER Pfizer in the case of RIMADYL [carprophen]"

Some of the background to the request can be seen from the terms of the request itself. The Appellant had a dog called Ben. Rimadyl had been prescribed and administered to Ben which in the Appellant's opinion caused the dog's death. The Tribunal has seen a veterinary expert's draft report dealing with the circumstances surrounding Ben's death. It appears that after experiencing vomiting and similar problems, the dog was diagnosed with gastritis and then prescribed a number of drugs, including Rimadyl, used it seems specifically to address inflammation suffered by the dog.

The Appellant was particularly concerned that Rimadyl was being administered in the United Kingdom without proper testing. He stated that the drug was the subject of an ongoing litigation in the United States.

3. VMD replied by letter dated 23 November 2004. VMD pointed out that FOIA did not come into force until 1 January 2005. The letter went on to say that no point would be taken against the Appellant on that account and nothing further turns on this. The Appellant was told he would get a substantive reply only after 1 January 2005. In the meantime however, he was supplied with a copy of what was called an SPC, namely a Summary of Product Characteristics for Rimadyl. Information about data supplied to

a European data base regarding serious adverse reactions would not however be supplied.

4. The Appellant then made a second request dated 1 January 2005. In effect, the Appellant amplified his first request by stating that he was “keen” to have:

“... a full appraisal of the precise DATES, TIMES and SPECIFICS of the Marketing Authorizations applicable to RIMADYL for use in the UK. To this end could you outline the different kinds of information held by the VMD which might meet the terms of this request. In addition are you able to provide a reference, catalogue or index which gives a comprehensive listing of information on Marketing Authorizations held by you as the UK Licensing Authority.”

5. Under cover of its reply of 23 November 2004, the VMD had also supplied a so-called Traffic Light Document (TLD) which was a document entitled “Memorandum of Understanding between the Association of the British Pharmaceutical Industry, Medicines and Health Care Products Regulatory Agency, National Office of Animal Health & the Veterinary Medicines Directorate”. It reflected a general description of what information could be disclosed or withheld after discussion with the relevant affected bodies. It was dated September 2004 and represented an outline guide to the foreseen operation of FOIA. The reason the document was called a TLD was to reflect the fact that certain information could or could not be released under the TLD depending on its importance. If the information could not be released under FOIA, then it was red; if it could be released it was green and if it was to be considered for release it was amber.
6. The disclosure of this TLD prompted the Appellant to ask in his second request for the following items, namely:

- “1 Veterinary Medicines Advisory Board Minutes where RIMADYL was discussed and any background papers.
- 2 History of Licensing of RIMADYL with VMD [TLD too].
- 3 Pre-clinical safety data – All published literature and any non-published data.
- 4 Evidence of Animal Testing Certificate Applications
 - disclosure of Adverse drug reactions exhibited in clinical trials
 - disclosure of clinical trial results after the grant of Marketing Authorization.
- 5 Pfizer expert Report &/or common technical document indicating overall safety and ethicacy.
 - Any assessment reports produced by the VMD on safety and ethicacy.
 - Any correspondence/e mails between VMD, Advisory Body and Pfizer.
 - copy of package leaflet on RIMADYL applicable at 19/7/2000.
- 6 Please supply a number of suspected adverse reaction reports SAR's with reference to RIMADYL.
 - any Periodic Safety Update reports with regard to RIMADYL.
 - Information on Adverse reaction reports listed by drugs' substance [carprophen] ascribed to any other particular products.”
7. In this second request, and prior to the passage quoted above, the Appellant in effect asked for information in the form of correspondence

files, etc pertinent to the preparation of the TLD and similar material between VMD and the Royal College of Veterinary Surgeons (RCVS) with regard to adverse reactions to Rimadyl. On any view, this second request went well beyond the scope of the Appellant's first request.

8. VMD acknowledged this second request by letter dated 7 January 2005. The letter was signed by John O'Brien as Director of Licensing in the VMD. A detailed provision of what was called "some of the information you requested" was provided under cover of a VMD letter dated 28 January 2005, again signed by Mr O'Brien. The Tribunal accepts that the VMD provided the Appellant with a significant amount of information, but prefaced its reply by stating that it wished to extend the time limit while it considered "the public interest test" and asking the Appellant: "to narrow down your request to focus more clearly on the precise information you are seeking". The remaining contents of the letter in effect provided information as to the following items, namely:

- (1) the fact that there was no available correspondence with Pfizer;
- (2) the presence of all marketing authorisations on the VMD's own website;
- (3) the date of authorisation as to Rimadyl's Small Animal Injection;
- (4) the fact that the RCVS was not a public authority;
- (5) the dates and nature of meetings concerning the TLD;
- (6) the number of SARs in relation to Rimadyl expressed as a percentage of sales and the nature of adverse reactions to a predecessor drug to Rimadyl, namely Zenecarp.

Reference to SARs was a reference to suspected adverse reaction reports.

9. The Tribunal feels it is important to note that prior to its response to the second request, Mr O'Brien had quite sensibly been taking steps to see how much the copying charges of any matters which might be disclosed would cost. By an email of 12 January 2005, i.e. shortly before his lengthy reply mentioned above, he was informed, no doubt by a colleague, that to retrieve and print off approximately 500 pages from a microfiche would cost £750 plus VAT. As will be explained more fully below the appropriate costs' limit prescribed by FOIA and the appropriate Regulations puts the figure of £600 in play as the limit, beyond which a public authority can in general terms refuse to supply the information on the grounds of excessive costs. The Tribunal finds that it was quite clear that by mid-January, Mr O'Brien knew what the size of the task faced by the VMD was likely to amount to in the light of the second request.

10. In any event, the Appellant did thereafter attempt to "narrow down" his previous request or requests, leading to what could be viewed as his third request. Whether he did in reality effect any form of narrowing down is debateable since he asked for the following under cover of an email dated 1 February 2005, namely:
 - (1) so-called SPC information, not only on Zenecarp, but also on two other drugs entitled "Norocarp" and "Carprodyl", the same to be provided by 28 February 2005;
 - (2) the "precise date" when Zenecarp was authorised for use on dogs;
 - (3) the "ACTUAL" numbers of Adverse Events reported to the VMD up to and including what he called "it's [sic] withdrawal from the market ...";
 - (4) a response to his six points as set out in the second request; and
 - (5) "access" to any appropriate catalogues and indexes held by the VMD.

11. On 4 February 2005, Mr O'Brien wrote to Pfizer asking for permission to disclose principally safety data and safety update reports regarding SARs as well as Animal Test Certificate (ATC) applications, clinical trial results and sales data. This request was refused by Pfizer, reflecting the terms and effect of the Memorandum of Understanding already referred to. In particular, as to the sales information sought, Pfizer relied on the need to protect its commercial sensitivity.

12. However, by letter dated 11 February 2005, VMD did provide the Appellant with some of the information he had requested in the second request, namely:

(1) a history of the licensing of Rimadyl Small Animal Injection with reference being given, namely Vm0057/4193 as well as the history of the licensing regarding Rimadyl tablets in two sizes, i.e. 20mg and 50mg and also with regard to Zenecarp injections and Zenecarp tablets;

(2) copies of the leaflet and the SPC that had applied in July 2000.

13. However, reflecting a further separate request to Pfizer to supply any further details, especially in relation to PSURs, i.e. Periodic Safety Update Reports and ATCs (Animal Testing Certificates), the VMD was compelled to send the Appellant a letter dated 28 February 2005 declining to disclose principally pre-clinical safety data and expert reports, PSURs, ATC applications, the results of clinical trials after the grant of a Marketing Authorisation and sales data. The letter, again sent by Mr O'Brien went on to add:

“Over and above all the reasons I have given which prevent us from disclosing the information you have requested, Section 12 of the Act allows us to refuse to answer requests for information if the cost of complying would exceed the “appropriate limit” prescribed in the

Regulations. The cost of retrieving the information you have requested from our archives greatly exceeds the appropriate limit of £600. For example, the cost of printing some of this information from our microfiche would amount to approximately £750. This does not take account of staff time in accessing both the information held on microfiche and printed copies of the data which to date on this enquiry amounts to about 60 hours equivalent to £1500 at £25 per hour.”

14. Naturally, at this stage there was no breakdown of these costs. In particular, it was not made clear to the Appellant whether the estimated cost related to information then claimed to be exempt or to non-exempt information or indeed to both. The Tribunal will revert to this question below in relation to the sub-issue raised in connection with section 12.
15. By letter dated 5 March 2005, the Appellant sought an internal review, in effect a further request. This further request was with regard to a substance which has not been previously mentioned and which for the present purposes can be called simply “Cox 2”.
16. By letter dated 25 April 2005, the VMD sent back a lengthy response reporting on the result of the internal review. The letter stressed, perhaps not unnaturally, that the information requested by the Appellant on Rimadyl was “extensive”. The letter again in the Tribunal’s view, quite properly summarised the actions taken by the VMD adding that the VMD in the person of the author of the letter, a Mr Chris Bean, a Director of Corporate Business was “satisfied” that the VMD had “acted in accordance with the requirements of” FOIA. The letter referred again to the fact that the £600 limit had been reached with regard to the cost of “providing the information requested from our archives”. Indeed he went on to say that the appropriate limit of £600 had been “greatly” exceeded. Nevertheless, the VMD did provide information with regard to Cox 2 and the Appellant was invited to clarify that request and another issue

regarding which the Appellant had provided a description, namely, “the EU law dimension”.

17. On about 12 May 2005, the Appellant complained to the Commissioner. By letter dated 28 April 2006, the VMD informed the Commissioner’s office that the information withheld from the Appellant was “extremely voluminous” adding:

“For example, part of the information requested by Mr Jenkins was that supplied by the company on clinical efficacy and target species tolerance in support of their original application for the authorisation and runs to seven volumes, one of which totals in excess of 400 pages.”

Pausing here, it was still not clear whether this referred to material which was the subject of exemptions which had by then been claimed under sections 41 and 43. In Mr O’Brien’s letter of 28 February 2005, there had been specific reference to the fact that it was withholding such materials as the pre-clinical safety data and PSURs, etc under section 43 of FOIA. The letter went on to claim reliance on both sections 43 and 41 of FOIA with detailed reasons being given for their applicability. The letter ended with further facts about the expense incurred. In the present case, the request had been given a unique code which was AT1001. Staff kept a record of the time spent. The total time spent in “identifying and putting together the information covered by this request” had been recorded as 89.91 hours. In addition, the VMD had received the quotation for printing which has been referred to and it was estimated that it would take a member of staff approximately a further 7.5 hours to print these volumes from the microfiche. Overall, the VMD took the view, quite properly in the Tribunal’s view, that the “cost had already been greatly exceeded in processing this request”. It was therefore decided that it was “not appropriate to proceed with this”.

18. It should perhaps be pointed out and added that on 23 May 2006 a member of the Commissioner's staff visited VMD and according to the Decision Notice which will be dealt with below, noted "the volume of material and VMD's reference catalogue for Rimadyl – one of numerous such indexes" and that "the VMD confirmed that the information stored on microfiche could only be extracted in paper form" (see Decision Notice, paragraph 4.3).

The Decision Notice

19. The Commissioner's Decision Notice is dated 31 July 2006. Overall, the Commissioner found that DEFRA had dealt with the Appellant's request in accordance with Part I of FOIA but had failed to comply in a manner it called "fully" with its obligations under section 16. The Tribunal pauses here to note that the action required with regard to this non-compliance was to require VMD to take no action save in respect of its then existing offer to the Appellant to provide him with a copy of VMD's relevant catalogues and indexes. This was done, and therefore for present purposes it can be taken, and the Tribunal so finds that there has been in effect compliance with section 16 subject to the findings made below.
20. At paragraph 4.4, the Commissioner noted that the VMD had provided a substantial amount of documentary information but went on to point out that the VMD was refusing to disclose the following, namely:

"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 reaction cases which, if combined with the % reaction incidents data already given could enable commercially sensitive sales data to be calculated."

The above materials recited in the quotation were subject to reliance by VMD on sections 41 and 43 of FOIA as well as the costs limitation prescribed by section 12.

21. As to sections 41 and 43, the Commissioner duly found that the public interest in maintaining both exemptions justified the retention of the material. With regard to the cost limit, the Commissioner recited what has been set out above in this judgment and decided: “that the appropriate limit has been reached in this case and the VMD are therefore justified in refusing to do more, although 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).”

The Grounds of Appeal

22. The Appellant’s grounds are set out in this letter to the Tribunal dated 25 August 2006. The matters set out in the letter can be summarised as follows, namely:
 - (1) the Appellant maintained that the Commissioner appeared to have found the Appellant’s complaint justified and on that basis should have ordered the VMD to disclose more information to him;
 - (2) the Appellant further maintained that there was an overriding public health & safety issue raised by virtue of his request such as to justify the release of commercially sensitive information: to that end, he attached the report of a veterinary doctor, a James Van Buren, with regard to the test conducted on his dog prepared or dated 24 April 2002 and already referred to above.
23. The Tribunal respectfully adopts the observations made by the Commissioner to his Reply with regard to the above two contentions. As has been made clear from this judgment already, the only part of the

Appellant's complaint that the Commissioner found to be justified was in relation to the failure to provide catalogues and indexes.

24. The second contention raised by the Appellant is in effect a contention that though the section 43 exemption was engaged, the Commissioner applied the public interest test required by the terms of section 43 incorrectly. This ground will be considered in more detail below. It is sufficient to state that in his Reply, the Commissioner rejected the argument that he had applied the section 43 exemption incorrectly adding that nothing in Mr Van Buren's report persuaded him to exercise the public interest balancing test differently. In particular, the Commissioner observed that in the inclusion data report, Mr Van Buren stated that Rimadyl was administered to the Appellant's dog "in an extra-label fashion", i.e. that it was administered notwithstanding that the information on the label would have indicated that it was not appropriate that it be administered to the Appellant's dog in the light of the symptoms which the dog exhibited. Indeed the Commissioner stressed that Mr Van Buren's written report stated that Rimadyl should not have been given to the Appellant's dog at least without a prior diagnostic test, such as a blood sample. The Commissioner also noted that Mr Van Buren had referred in two footnotes to his report, to two papers on adverse reactions to Rimadyl otherwise publicly available, thus adding greater weight to the Commissioner's conclusion that in this case the public interest in maintaining the section 43 exemption outweighed the public interest of disclosure. The Commissioner concluded in his Reply by noting that the Appellant apparently did not contest the applicability of the exemptions in section 42, however the Tribunal is minded as indicated above, to deal with a number of particular sub-issues that arise from the applicability of section 12 in this case.

Subsequent events

25. It is fair to add that following the Commissioner's Reply, the Appellant formally objected to the fact that he might otherwise have been taken to have conceded that section 41 and section 12 did apply adducing what he called new evidence consisting principally of a then recent newspaper investigative article about transactions involving multi-national drug companies, including Pfizer and the relationship with the UK Government as well as details of a United States Legal Class Action dealing with Rimadyl. The Commissioner has not contended that these additional items were irrelevant to the issues in the Appeal, and the Tribunal respectfully agrees.
26. By letter dated 2 October 2006 and in response to the Commissioner's Decision Notice, the VMD disclosed the relevant indexes redacting the names of any individuals whose names appeared in those indexes and related materials.

The evidence

27. The Commissioner provided written evidence predominantly as to the steps which the Commissioner had taken to verify the VMD's claim that the applicable fees limit has been exceeded. This evidence is in the form of a written statement provided by Dr Roy Wernham, one of the Commissioner's Complaints Resolution Officers. The Tribunal will not spend too much time dealing with the contents of Dr Wernham's statement which is dated 8 February 2007 since its contents are in effect revisited in greater detail by evidence provided by DEFRA.
28. In essence, Dr Wernham took the view that after he visited the VMD offices on 23 May 2006, it was confirmed to him that the VMD staff had spent "at least 24hrs of relevant staff time" at £25 per hour. He added at paragraph 22 that in relation to the time spent which he considered at or during the meeting, some of the information was held on microfiche and would need a further 7.5 hours of staff time to print it. Alternatively it

would cost £750 to commission a service to print it and he accepted at the time that that was not required. He also confirmed that VMD had in turn confirmed to him that VMD was unable to retrieve the microfiche information electronically and that this would include company summaries of the product safety data.

29. DEFRA and the VMD have provided written statements from Mr O'Brien. He has provided two open witness statements and a closed witness statement. His first witness statement is dated 26 February 2007. At paragraph 14 and particularly at 14(5), after having confirmed that he had earlier indicated reliance on section 43 to the Appellant, and in the course of reciting the history of the VMD's exchanges with the Appellant, Mr O'Brien confirmed that at the time he wrote to the Appellant by letter dated 28 February 2005, he explained to the Appellant that the £600 limit was being applied as "spending on these enquiries had already totalled £1500". This represented 60 hours of staff time. He provided a table, found at page 181 of the bundle before the Tribunal which showed there were 38 volumes stored in microfiche form giving a total of 4,121 pages. Significantly however, he provided a separate schedule found at page 184 of the bundle being as he described it:

"... a table of additional documents in paper form containing information which fell within the scope of the request by Mr Jenkins"

These were documents not held on microfiche and all of them were contended by VMD to be subject to the section 43 exemption.

30. It is therefore apparent that at this stage, or at least by 28 February 2005, the VMD acting by Mr O'Brien took the view that as a result of the acts of determining whether it held the information requested and/or locating the information and/or retrieving it and/or extracting the information from documents which contained the information, all of which are distinct

activities addressed by the costs regulations, the £600 estimate was thought to have been greatly exceeded.

31. Mr O'Brien supplied a far more detailed picture in his second open witness statement of 27 July 2007. The second statement was produced in effect in response to open directions made at an oral hearing on 22 June 2007, the terms of which need not be set out here, save to note that the Tribunal by those directions in effect ordered that all relevant issues were to be considered on the final determination of the Appeal.
32. At paragraph 11, although Mr O'Brien quite properly recognises that for the purposes of the appropriate fees Regulations, a public authority can only take into account time spent determining whether it holds the information requested, locating it, retrieving it or extracting it, and although the VMD recorded how much time had been spent working on a particular topic or project, it did not break such time down into the different types of work done. Nonetheless, to his credit Mr O'Brien did make an attempt to estimate, based on his memory of what occurred at the time, how much time was spent on each of the itemised activities set out above and apportion the time accordingly.

Retrieval of adverse reaction data	8.33 hours
Locating and retrieving data provided by the applicant company in support of his applications	3.00 hours
Retrieval of licensing information	11.25 hours
Reviewing data held to assess whether it fell within the scope of the request	<u>21.00</u> hours
Total:	43.58 hours

- At a charge of £25 per hour, this amounted to a £1,089.50.
33. Mr O'Brien then confirmed that the present appeal was primarily concerned with four categories of information, namely:
- (1) data provided when seeking a marketing authorisation from VMD dealing with the quality, safety and efficacy of the product;
 - (2) VMD database materials containing details of SARs, i.e. suspected adverse reactions to Rimadyl and Carprofen products;
 - (3) Serious Adverse Reaction Reports, i.e. SARRs; and
 - (4) PSURs.
34. He then revisited the printing costs attributable to printing off records held on microfiche as to category (1). On revisiting the issue, he stated that far from what was initially thought to be 900 to 1000 pages in microfiche, there were in fact 3,004 that would need to be printed which alone would cost £625. In addition there were 1,117 pages of information not held on microfiche which would have cost £200 to print.
35. As to category (2), Mr O'Brien estimated that it would take two hours to interrogate the VMD database at a total of cost of £50, whilst category (3) SARs information was stored in paper form comprising in this case 22 files which would cost £550 to copy. As to category (4), the estimate in time as to extraction and copying was six hours but in terms of cost was subsumed in category (3).
36. The next operation which Mr O'Brien describes is the redaction required which he describes as "significant". The redaction in question involved principally the redaction of individuals' names and addresses which he said would inevitably arise had VMD continued to deal with the Appellant's request. He therefore considered that "on a very conservative estimate" it

would take one person, one minute per page to view each of the 4,121 microfiche pages, yielding a total of 69 hours, just short of two working weeks at a cost of £1,717. The same exercise he added would need to be repeated for the database, as well as SARs and PSURs as they too might also contain information on particular identities, company contact details, etc. This led to him estimating that it would take a further 28.5 hours, i.e. £712.50 to redact the information provided with regard to the documents and categories (2), (3) and (4), giving a total cost of £2,429.50. On that basis the cost of redacting alone, would have exceeded four times over the section 12 limit of £600.

37. At paragraph 27 of second witness statement, the total was set out as follows:

(a) work actually done in locating and retrieving data:	
£1,089.50	
(b) work required to print information from microfiche:	
£625.00	
(c) work required to copy comb-bound information:	£200.00
(d) work required to sort and print database:	£50.00
(e) work required to copy SARs and PSURs:	£550.00
(f) work required to redact all information:	<u>£2,429.00</u>
Total:	£4,918.50

38. Mr O'Brien then went on to deal again, quite properly in the Tribunal's view with an issue that had arisen at the oral directions hearing mentioned above. At this hearing, the Commissioner had contended that if at the

point of applying the section 12 exemption, the VMD had information that was “ready to be sent” or, as it was put at the hearing, ready to be put in a brown envelope but for the application of the other exemptions relied on in this case, the VMD could not rely on section 12 alone as a reason for refusing to disclose the information. This came to be called the brown envelope point and will be dealt with in further detail below.

39. For the moment, however, it is sufficient to note that Mr O’Brien has refuted the suggestion, that on the facts of this case the VMD did have information that could have been put in the brown envelope. This is because as he described it, although a good deal of information had been identified and located, the information held on microfiche and hard copy had not been extracted or copied at the point of which the exemption was applied. He went on to add the following, namely:

“Similarly, the information on the database had not been sorted, printed and redacted, although it could quite easily have been and it may be that, had s.41 and 43 not applied to it as outlined above, VMD would have exercised its discretion to send it notwithstanding that the s.12 limit had already been exceeded. Nevertheless, this would have been an exercise of discretion as further costs would have needed to be incurred to interrogate the database to bring up the correct range of reports, print and redact the records before sending them.” (see paragraph 25 of his second witness statement).

40. Mr O’Brien then dealt with the claimed applications of the exemptions in section 41 and 43. He explained that apart from European Community Authorization a Marketing Authorization, i.e. a MA is required from the VMD before a veterinary medicinal product can be sold or supplied in the United Kingdom. Information is required on three principal issues, namely: quality, safety and efficacy. In addition, expert reports as to each of these issues has to be provided with suitable labels and literature

- including a summary of product characteristics, i.e. a SPC as mentioned above. Quite apart from the above, the VMD collects and analyses SAR data which emanate from any source, primary sources being veterinary surgeons. The relevant company itself provides PSURs.
41. Mr O'Brien places particular reliance on the penal provisions of section 118 of the Medicines Act 1968. The section make it an offence to disclose information provided for the purpose of that Act (save in respect of disclosure under FOIA; see SI 2004 No. 3363, article 4) from which it follows the VMD would itself be guilty of a criminal offence were it to disclose the type of data referred to above without the applicant company's consent. This in turn justified VMD's position in treating such information supplied by such applicant as confidential.
 42. He also confirmed that in effect the traffic light document referred to above reflected this abiding need to treat all such information provided to the VMD as both confidential and also as commercially sensitive. The "red" designation in practical terms meant that information relating to quality would not be disclosed, whilst information as to safety and efficacy would be disclosed generally only if parts of those subjects were published in scientific journals.
 43. Finally, he pointed to the exchanges between Pfizer and the VMD which reflected the company's understanding that it regarded the information requested as constituting information which fell in the "red" category. He ended with the observation that when it considered the public interest in maintaining the exemption against the public interest in disclosure, the VMD considered that the "understanding" between it and the industry that commercially sensitive information would not be disclosed had in fact helped to maintain an open dialogue with companies that would be damaged were disclosure to occur in this type of case. The anticipated result was, according to him, that Pfizer and companies in general "would

- not be as open in their dealings with VMD or indeed might not provide the necessary information for fear of public disclosure.”
44. The Tribunal should add that its two lay members in this case did conduct a visit to VMD’s premises so that those members could see for themselves the extent of the documentation in issue. The Tribunal feels that in the circumstances it can legitimately confirm the fact that the scale of the operation conducted by Mr O’Brien and his team is more than adequately reflected in his witness statement and his evidence generally. The Tribunal feels that it should stress that at every stage, he and his team were never less than extremely cooperative with any questions put to them by the Tribunal.
45. As for Mr O’Brien’s closed witness statement and in the light of the evidence which forms the basis and content of his second open witness statement and for quite understandable reasons, Mr O’Brien gave unredacted details of the time spent in dealing with the Appellant’s requests by particular named individual members of staff. Of necessity he exhibited on a confidential basis and for the Tribunal’s own consideration a sample of database material as well as sample SARs and PSURs which show the type of material which has contributed to the overall costs estimate which was described by him in his second open witness statement.

The rival contentions: section 12

46. Section 12 of FOIA provides as follows:
- “(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.

- (2) Subsection (1) does not exempt the public authority from its obligation to comply with paragraph (a) of section 1(1) unless the estimated cost of complying with that paragraph alone would exceed the appropriate limit.
- (3) In subsections (1) and (2) “the appropriate limit” means such amount as may be prescribed, and different amounts may be prescribed in relation to different cases”.

Subsection (5) provides that the Secretary of State may by regulation 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 relevant regulations are the Freedom of Information and Data Protection (Appropriate Limit and Fees) Regulations 2004 (SI 2004 No 3244) (the “Regulations”). The relevant regulations are the following, namely:

“3(2) In the case of a public authority which is listed in Part I of Schedule 1 to the 2000 Act, the appropriate limit is £600.

Estimating the cost of complying with a request – general

4 (1) This regulation has effect in any case in which a public authority proposes to estimate whether the cost of complying with the relevant request would exceed the appropriate limit.

(2) A relevant request is any request to the extent that is a request
–

(b) information to which sections 1(1) of the 2000 Act would, apart from the appropriate limit to any extent apply.

- (3) In a case in which this regulation has effect, a public authority may, for the purpose of its estimate, take account only of the costs it reasonably expects to incur in relation to the request in –
- (a) determining whether it holds the information,
 - (b) locating the information, or a document which may contain the information,
 - (c) retrieving the information, or a document which may contain the information, and
 - (d) extracting the information from a document containing it.
- (4) To the extent to which any of the costs which a public authority takes into account are attributable to the time which persons undertaking any of the activities mentioned in paragraph (3) on behalf of the authority are expected to spend on those activities, those costs are to be estimated at a rate of £25 per person per hour.”

Estimating the cost of complying with the request – aggregation of related requests

- 5 (1) In the circumstances in which this regulation applies, where two or more requests for information to which section 1(1) of the 2000 Act would, apart from the appropriate limit, to any extent apply, are made to a public authority –
- (a) by one person or

the estimated cost of complying with any of the requests is to be taken to be the total costs which may be taken into account by the authority, under regulation 4, of complying with all of them.

- (2) This regulation applies in circumstances in which –
 - (a) the two or more requests referred to in paragraph (1) relate, to any extent, to the same or similar information, and
 - (b) those requests are received by the public authority within any period of sixty consecutive working days.

Maximum fee for complying with section 1(1) of the 2000 Act

- 6 (1) Any fee to be charged under section 9 of the 2000 Act by a public authority to whom a request for information is made is not to exceed the maximum determined by the public authority in accordance with this regulation.
- (2) Subject to paragraph (4), the maximum fee is a sum equivalent to the total costs the public authority reasonably expects to incur in relation to the request in –
 - (a) informing the person making the request whether it holds the information and
 - (b) communicating the information to the person making the request.”

47. The principal issue between the Commissioner and DEFRA is whether the words “extracting the information from a document containing it” include

the redaction of exempt information containing it. The Commissioner claims that:

- (1) the actions set out in Regulation 4(3) are sequential;
- (2) extracting information is in effect the task of extracting information to be disclosed from a document where either the whole document or a large part of the information contained within it has been requested: this follows from the language of Regulation 4(3)(d) itself which talks of extracting the information “from a document containing it”;
- (3) in any event, redaction can be viewed as part of the time spent considering whether information is exempt and as such may be charged as a part of a fee under Regulation 6 of the Regulations: the Tribunal pauses here to note that this was not disputed by DEFRA;
- (4) the reading suggested by the Commissioner is faithful to the scheme of Regulation 4 as a whole, namely that on a proper reading of Regulation 4(3)(a)-(d) on a sequential basis, the extraction will be from a document which has been located or retrieved and therefore for a document to “contain” information requested, there must be other information not requested within it;
- (5) when the Regulations speak of a “relevant request” in Regulation 4(2), account should be taken of the words “to any extent”; the Commissioner claims that these words are plainly intended to indicate not only that Regulation 4 applies whenever a “request for information” falling within the meaning of section 1(1) of the Act is received, but also whenever such a request is made, section 1(1) always applies to some extent even if, in the event, e.g. by claiming the exemption or having the same endorsed or determined by the Commissioner or by the Tribunal, the public authority is relieved of its duty under section 1(1)(b) to communicate that information to the

applicant; in other words, section 1(1) will always apply “to some extent”.

48. Against that, DEFRA claims that:

- (1) Regulation 4(3)(d) is about what it calls getting information “out” of whatever document is in question; in particular DEFRA claims that it seems “unlikely” that the purpose of Regulation 4(3)(d) is only to cover the removal of the relevant material as opposed to the redaction or extraction of exempt material as well;
- (2) reliance can be placed on Regulation 6 as well as, incidentally, Regulation 7 which deals with a maximum fee which applies to the fees under Regulation 6: DEFRA claims that it is clear that Regulations 6 and 7 show that public authorities are permitted to charge for Regulation 4 costs plus Regulation 6 costs, and therefore it is clear that the cost of redaction would be included under one or the other as the overall purpose of the Regulations, particularly of Regulation 6 and 7 to permit costs’ recovery;
- (3) the Ministry of Justice’s own guidelines in paraphrasing Regulation 4(3) add the following parenthesis after Regulation 4(3)(d), namely: “(including editing or redacting information)” within an accompanying footnote which reads as follows:

“This can include the first time an individual working in the authority reads information to establish what is contained within a file or document, although any subsequent readings, (e.g. to consider exemptions), or if the information is passed to others to read, should not be included.”;
- (4) as also indicated above, the wording of Regulation 4(2) with its reference to “information to which section 1(1) of the 2000 Act would,

apart from the appropriate limit to any extent apply” necessarily means that if information is exempt, then it is information to which section 1(1) does not apply and therefore if time is needed to “extract” disclosable material from material which does not fall to be disclosed, then that time can be counted.

49. The Tribunal finds the Commissioner’s contentions more persuasive, although the point is not entirely free from doubt. This is partly because of the drafting in Regulation 4 itself, and indeed in the Regulations as a whole which the Tribunal finds could perhaps more clearly have expressed its intentions with regard to the issue under consideration. However, it is perhaps understandable that in the early days of this regime, specific attention was perhaps not afforded to the addressing of this issue, namely whether an allowable cost can be counted in respect of extracting exempt material.

50. The Tribunal finds, as does the Commissioner, that proper force and effect should be given to the language of Regulation 4(3)(d) which speaks in an unqualified manner of extracting the information, i.e. the information which has been requested out of a document which, of necessity, contains other information that has not been requested. If, as the Tribunal finds, the remaining material represents unrequested information, the act of extraction addresses itself to requested information in the sense that extraction refers to and forms part of the process of disclosure. On the other hand, extracting or as it is somewhat curiously put in the Ministry of Justice’s guidelines, “redacting” exempt information is in effect an actual deletion as the Commissioner also contends. The Tribunal agrees with the Commissioner that such an act of deletion, i.e. removal of what may be thought to be exempt material, even at the stage at which the exercise is carried out, cannot sensibly be viewed as coming within the provisions of Regulation 4(3)(d) as it is presently drafted.

51. The exercise which a public authority may embark on in order to consider whether an exemption applies and the extent to which material otherwise disclosable may be subject to an exemption, is a separate exercise. The Commissioner and DEFRA agree that Regulation 6 is wide enough to encompass the charge of a fee in that respect. The Tribunal does not find that the Ministry of Justice guidelines add anything to what is ultimately a question of statutory interpretation: those guidelines are no more than guidelines.
52. The above determination is not, both the above two parties accept, directly relevant to the facts of this case. The Tribunal confirms that given the evidence in this case which shows that the costs incurred by DEFRA in dealing with the request have been so large, the issue of whether the costs of redacting the exempt information for the purpose of section 12 is, as it was put, largely if not wholly, “academic”.
53. The next issue concerns the so-called brown envelope point. On this issue which has been sketched out above, the Tribunal is unwilling to do anything other than address the facts which are, for the moment, unchallenged. The Commissioner and DEFRA have, together, debated whether or not, as a point of principle, there is an obligation on a public authority in general terms to provide information requested from an applicant, and not be able to rely on section 12 if the material has already been identified, located, retrieved or extracted. As to the facts in this case, both parties are agreed that in the light of the evidence provided by Mr O’Brien in his second witness statement (see in particular paragraphs 28 and 29) to the extent that the complete contents of a microfiche tape or of a ring-bound book failed to be the subject of disclosure, if there were no need for any further process of extraction or separation, then the information could have been ready for sending to the Appellant. However, the Tribunal is not prepared to go behind, what it regards as the plain meaning of Mr O’Brien’s evidence, particularly at paragraph 29. Without

the benefit of cross-examination, it finds that what Mr O'Brien was saying was that in relation to the information held on microfiche, such information still had to be extracted by means of a print-out or similar method. The same applied, arguably, to the inspection of any ring-bound files. It follows that the Tribunal is not prepared to find that, quite apart from the operation of sections 41 and 43, Mr O'Brien necessarily stated that the information in question had already been identified, located, retrieved and/or extracted within the meaning of Regulation 4(3)(a)-(d) of the Regulations and was therefore ready to be communicated to the Appellant without additional time being spent on the exercise, no doubt in the process of further extraction in the sense of printing the relevant material.

Sections 41 and 43

54. Section 41 is an absolute exemption since it provides as follows, namely:

“(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.

(2) The duty to confirm or deny does not arise if, or to the extent that, the confirmation or denial that would have to be given to comply with section 1(1)(a) would (apart from this Act) constitute an actionable breach of confident.”.

Section 41 is an absolute exemption to which the public interest test under FOIA does not apply. However, the public interest does fall to be considered when determining whether or not the exemption applies.

55. The Tribunal agrees that the four categories of information described by Mr O'Brien at paragraph 12 of his second witness statement and as set out above, all have the necessary hallmark of confidence. Overall, the information in question comprised information that Pfizer considered to be either constituting a trade secret or as information which had it been disclosed to a third party might have caused significant harm to Pfizer. There is no doubt that the information in question was imparted in circumstances which imported an obligation of confidence.
56. The Tribunal therefore respectfully agrees with both the Commissioner and DEFRA that there is in fact little, if any, public interest in the disclosure of all these categories of information. Nor has Mr Jenkins himself sought to advance any arguments in relation to the application of the exemption. The only arguable element advanced by the Appellant is the one highlighted above, namely that the Appellant suggested that incidents such as the regrettable one involving his dog entailed some "overriding public health & safety concern". No reliance can be placed on the report of Mr Van Buren for the reasons advanced earlier. The Tribunal therefore upholds the Commissioner's finding that there is no overriding public interest in this case that would provide the Defence to inaction for a breach of confidence were any of the categories of information to be disclosed.
57. With regard to section 41, a small difference or emphasis has surfaced as between the Commissioner and DEFRA. In its written submissions, DEFRA argues that reference to "all the circumstances of the case" otherwise found in section 2(2) of FOIA and which is necessarily required in relation to the public interest to be considered, means that public interest should be considered "in the round". This Tribunal agrees with the findings on this issue made by the Tribunal in *Hogan and Oxford City Council v Information Commissioner* (EA/2005/0026), especially at paragraphs 59 and 60, to the effect that the focus should be upon the

public interest expressed explicitly or implicitly in the particular exemption in question. However, in the circumstances of this case, the Tribunal respectfully agrees with DEFRA that any distinction between the two positions is academic.

58. With regard to section 43, the same provides an exemption that protects commercial interests as follows, namely:

“(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).”

59. The Tribunal has no hesitation in finding that the information withheld in the present case is plainly information to which section 43 applies, subject to the application of the public interest test. Again, the Appellant has not sought to suggest that the information is not information which, were it disclosed, would be likely to prejudice Pfizer’s commercial interests. On the contrary, the Appellant simply claims that the issue is one of public safety. The Tribunal upholds the Commissioner’s decision that the VMD was entitled to rely on the exemption in section 43.

Section 16

60. Section 16 of FOIA provides that:

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

(2) Any public authority which, in relation to the provision of advice or assistance in any case, conforms with the code of practice and that

section 45 is to be taken to comply with the duty imposed by subsection (1) in relation to that case.”

61. The Appellant did not refer to section 16 in his grounds of appeal, but has done so in a short witness statement since that time. One complaint is that the VMD failed to provide him with a copy of the index and that constituted a failure under section 16. The Tribunal agrees with the Commissioner that this complaint is misconceived. In addition, the Appellant complained about the content of the information communicated to him, in particular the so-called “reaction, current figures”. The Commissioner, quite properly in the Tribunal’s view, contends that this complaint goes to the form or format in which the information was communicated to him, whereas section 16 is a section directed as it clearly states to the information the public authority may need to consider to clarify a request that has been made to it. The Tribunal has no hesitation in upholding the Commissioner’s decision that VMD fulfilled its obligations under section 16.

62. The observations of the Appellant have prompted the Commissioner to remind the Tribunal that there is a typographical error in the Decision Notice. At paragraph 4.10, it is stated:

“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 relating to Rimadyl.”

This is clearly a mistaken reference to section 16. The Tribunal does not feel in the circumstances of this case that there is any practical point in amending the Decision Notice for the sake of a simple typographical error when any sensible reading of the paragraph in question would show what the sense really was.

Conclusion

63. For all the above reasons, the Tribunal dismisses this Appeal.

Signed

Date: 2nd November 2007

David Marks
Deputy Chairman