Freedom of Information Act 2000 (FOIA)

Decision notice

Date: **7 February 2013**

Public Authority: **Department of Health**
Address: **Room 317**
Richmond House
79 Whitehall
London
SW1A 2NS

Decision (including any steps ordered)

1. The complainant has requested copies of correspondence between the Chief Medical Officer, or officials acting on her behalf, and other persons on the subject of PIP (Poly Implant Prothese) breast implants. The Department of Health (DoH) agreed to the provision of some of the requested information but refused to disclose the remainder on the basis of section 35(1)(a) (formulation or development of government policy) of FOIA. The Commissioner's decision is that the exemption is engaged and that, in all the circumstances, the public interest in disclosure is outweighed by the public interest in maintaining the exemption. He does not therefore require any steps to be taken as a result of this notice.

Request and response

2. On 30 March 2012 the complainant wrote to the DoH and requested information in the following terms:

    - Please provide copies of all correspondence, including letters and emails, between the Chief Medical Officer [Professor Dame Sally Davies] or officials acting on her behalf and Sir David Nicholson [NHS Chief Executive] in relation to PIP implants between December 18 and December 23 and between January 4 and January 6.

    - Please provide copies of all correspondence, including letters and emails, between the Chief Medical Officer or officials acting on her

behalf and Dr Susan Ludgate at the MHRA [Medicines and Healthcare products Regulatory Agency] in relation to PIP implants between December 18 and December 23 and between January 4 and January 6.

3. The DoH responded on 1 May 2012 and confirmed that it held a number of emails relating to the requests. Some of these were disclosed subject to the redaction of the names of certain officials included in the information on the basis that section 40(2) (personal data) of FOIA applied. The DoH, however, refused to provide the remainder of the correspondence, citing section 35 of FOIA as its basis for doing so.

4. The complainant subsequently wrote to the DoH (date unspecified) challenging its reliance on section 35 of FOIA. In particular, he doubted whether the exemption could be engaged and, even if it was, considered the public interest firmly favoured disclosure.

5. The DoH subsequently carried out an internal review, the findings of which were provided to the complainant on 31 May 2012. This upheld the original position that the requested information was exempt from disclosure under section 35 of FOIA.

Scope of the case

6. The complainant contacted the Commissioner to complain about the way his request for information had been handled. Specifically, he has asked the Commissioner to consider the DoH's reliance on section 35 of FOIA as grounds for withholding information. The Commissioner has therefore proceeded on this basis.

7. During the course of the investigation the DoH decided to disclose some further information covered by the scope of the request, albeit subject to the redaction of the names of officials below Senior Civil Service level in accordance with section 40(2) of FOIA. The complainant has subsequently confirmed that he does not require the disclosure of any names of officials below that grade and so this information did not need to feature as part of his complaint. Accordingly, the Commissioner has not considered this information further and instead focused solely on the remaining material withheld under section 35 of FOIA.

Reasons for decision

Section 35 – formulation of government policy

8. The DoH is seeking to rely on section 35(1)(a) of FOIA. This states that information held by a government department, or by the National Assembly for Wales, is exempt information if it relates to –

   (a) the formulation or development of government policy

9. Section 35 is a class based exemption. This means that if the requested information relates to the activities that section 35(1)(a) describe then the exemption is necessarily engaged; there is no requirement for disclosure to have a prejudicial effect on these activities. As it is also a qualified exemption, however, section 35 is subject to the public interest test.

10. What is meant by "the formulation or development of government policy" is not made clear in the legislation. Indeed, it is common ground that providing a definition of "policy" is in itself problematic in that it can be produced in many ways. This was ably demonstrated in the UCL's report "Understanding the Formulation and Development of Government Policy in the Context of FOI"[1]. In many cases policy making will follow more structured processes, which will include the publication of white papers and the drafting of bills. However, the Commissioner is also alive to the possibility that policy making can be made as an impromptu reaction to events, rather than planned in advance, and may even be a form of crisis management.

11. In his decision on FS50083726[2], which involved the Foreign and Commonwealth Office (FCO), the Commissioner suggested that the formulation and development of government policy could be described thus –

    "60. The Commissioner takes the view that the 'formulation' of policy comprises the early stages of the policy process – where options are generated and sorted, risks are identified, consultation occurs, and recommendations/submissions are put to a Minister. 'Development' may

[1] http://www.ico.gov.uk/upload/documents/library/freedom_of_information/research_and_reports/ucl_report_government_policy_in_the_context_of_foi.pdf

[2] http://www.ico.gov.uk/~/media/documents/decisionnotices/2009/FS_50083726.ashx

go beyond this stage to the processes involved in improving or altering existing policy such as piloting, monitoring, reviewing, analysing or recording the effects of existing policy. At the very least 'formulation or development' suggests something dynamic, i.e. something that is actually happening to policy […]"

12. The context for the information request in this case relates to the UK government's response to fears regarding the safety of PIP silicone gel breast implants. For clarity's sake, the circumstances in which the requested information was produced are briefly recounted.

13. Reports in the media indicated that the French government would issue a statement on 23 December 2011 recommending that all women with PIP breast implants should have them removed as a preventative measure. An announcement by the French Ministry of Health was duly made on that date. This made reference to the findings of the French cancer institute, INCa, one of which was that they had not identified any increased risk of cancer in women who had PIP implants compared to other implants.

14. The same day Professor Dame Sally Davies, Chief Medical Officer, addressed an open letter to General Practitioners, NHS Medical Directors and Cancer and Plastic Surgeons on this issue[3]. Extracts of this letter are reproduced below –

"You may already be aware of today's recommendation by the French Government that all women in France who have PIP breast implants should have them removed as a pre-cautionary, but non-urgent measure because of their concerns about high rates of implant rupture.

"In the UK, the Medicines and Healthcare products Regulatory Agency (MHRA) is not however recommending routine removal because they have no evidence of any disproportionate rate of implant rupture. Moreover, there is no evidence of any increase in incidence of cancer associated with these implants. The MHRA expert advisers do not therefore believe that the risks associated with surgery from breast implant removal can be justified in the absence of further evidence."

[3] http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_132011.pdf

15. Shortly after the announcement, an expert group, chaired by Sir Bruce Keogh, was set up to review the data produced on PIP implants and provide a report to the DoH, on what would turn out to be an interim basis[4]. This agreed with the MHRA advice that there was no specific safety concern identified which required a recommendation of routine removal of PIP implants. It did, however, recommend the collection of additional information which would enable the group to reach a more informed view.

16. Corresponding with the production of the expert group's report, Professor Dame Sally Davies[5] and the Chief Executive of the NHS, Sir David Nicholson[6], wrote to health professionals on 6 January 2012 with updates on PIP implants following the publication of the report of the expert advisory group. Each of the updates also included a description of the model of care that should be offered to patients who received a PIP implant from the NHS.

17. In accordance with its recommendation, the expert group continued its work into PIP implants. This resulted in the production of a report published some time after the date of the information request, in June 2012[7].

18. The DoH considers that the policy formulation and development on PIP implants is ever-evolving, being dependent upon the availability of on-going research and evidence. Significantly, at the time of the request, the expert group had yet to publish its final report. Furthermore, the DoH has informed the Commissioner that Sir Bruce Keogh, chair of the expert group, will continue to look at any new emerging evidence on PIP implants as part of his overall work on the wider system of regulation for cosmetic interventions.

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[4] http://www.dh.gov.uk/health/2012/01/pip-implants-interim-report/

[5] http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_132102.pdf

[6] http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_132103.pdf

[7] http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_134624

19. When considering whether the requested information is covered by section 35(1)(a) of FOIA, it is necessary to refer to the wording of the exemption itself which speaks of information 'relating to' the formulation or development of government policy. The Commissioner considers that the term 'relates to' can be interpreted broadly, even though it follows that the exemption will capture a wide range of information as a consequence.

20. This follows the decision of the Information Tribunal in *Department for Education and Skills* [DfES] *v the Information Commissioner & the Evening Standard* [EA/2006/0006][8]. In that case the Tribunal considered that 'relates to' could safely be given a broad interpretation because, even where the exemption was found to be engaged, any non-harmful information should be disclosed as a result of the consideration of the public interest test.

21. The withheld information comprises an email dated 22 December 2011 and two emails from January 2012, all of which concern the preparing of text for press releases. The DoH has argued that at that time the debate about the formulation of the policy was in fact being conducted in relation to its development and the presentation of it by way of the precise wording of the press releases.

22. Having had sight of the withheld information, the Commissioner agrees with the view of the DoH. In particular, he accepts that the decision making process evidenced in the information is one which is covered by the activities described by the exemption. In forming this view, the Commissioner has reminded himself of the FCO case, referred to above at paragraph 11. In that instance the Commissioner considered a request made to the FCO for its analysis of an article which appeared in the Lancet medical journal about the level of civilian casualties in Iraq following the invasion in May 2003. Although the circumstances of the cases differ, both concern information created in the context of preparing a press statement.

23. The Commissioner accepted in the FCO case that some of the requested information was subject to section 35(1)(a) of FOIA. However, he found otherwise for information relating to the Foreign Secretary's comments to the media and the Prime Minister's statements in Parliament given as immediate responses to the Lancet article –

[8] http://www.informationtribunal.gov.uk/DBFiles/Decision/i70/DFES.pdf

"62. […] *the Commissioner does not accept that this decision making process is one which constitutes policy formulation or development. Rather this process is simply the Government's consideration of, and reaction to, a particular press article. Simply because this information reflects decision making within government departments, this does not mean that it must relate to government policy making. If the Commissioner were to accept that such information fell within the scope of section 35(1)(a) then a consequence of this approach would be that every time the government prepared and reacted to some negative (or indeed positive) comment in the media then such a process would constitute the formulation or development of government policy* […]"

24. Unlike the FCO case, the Commissioner has determined here that the press statements being prepared were not merely reiterating an established policy position but, crucially, were drafted at a time when the relevant policy was in the course of being reassessed and therefore potentially subject to change. Reflecting on these circumstances, the Commissioner is satisfied that the exemption is engaged. The reasons for this are two-fold.

25. Firstly, the Commissioner has no doubt that, because of the impetus generated by events in December 2011, steps were taken to review the government's position on PIP implants. As the statements were being drafted, a number of issues had to be considered, including the UK government's position on the removal of the PIP implants. Consequently, the UK government's response would be indicative of something dynamic happening to policy – weighing up what, if any, policy commitments should be made against the backdrop of events which precipitated the release of statements on the UK government's position.

26. Secondly, the Commissioner is prepared to accept that information about a press statement, which relays something about the formulation or development of government policy, is exempt under section 35(1)(a) simply by virtue of the fact that it 'relates' to that policy formulation or development. Here, this would apply even if the statement was reiterating something about an established position because it is evident that the situation was evolving and the policy issues were not settled.

27. In other words, the Commissioner is well aware that a response to any external event can trigger a change in approach to an issue, either by identifying a concern that needs to be responded to or requiring a re-examination of an existing policy. This could have the effect that the thinking process involved in responding will constitute the formulation and development of government policy; a situation that the Commissioner considers was happening here.

28. The Commissioner has therefore found that section 35(1)(a) of FOIA is engaged and has gone on to assess the public interest test attendant to the exemption.

Public interest arguments in favour of disclosure

29. There is clearly a strong public interest in favour of disclosure. This reflects the significant number of individuals directly affected by the PIP implant scare and the inevitable concerns that this would have raised.

30. The Commissioner agrees with the complainant's argument that considerable weight must be placed on the public's right to know more about the government's reaction to the PIP implant issue, not least its thinking behind its initial announcements on the subject. This weight is present because the nature of the issue, and the effect it could have on the tens of thousands of women who have had implants, is particularly concerning.

31. In essence, the release of the withheld information is likely to result in one of two effects, both of which strongly support the case for disclosure. Either it could assuage concerns the public had about the effectiveness of the government's response or it could help stimulate further debate about what could or should have been done to serve better the interests of those affected.

32. The complainant also considers that the weight of the public interest in disclosure is augmented by the realisation that before December 2011 many women were not aware that PIP implants had been banned in 2010 or that tests had been carried out that same year on the contents of the implants. The background to these events is described on the MHRA's website[9] –

"On 29 March 2010, the French medical device regulatory authority (AFSSAPS) informed the MHRA that it had suspended the marketing, distribution, export and the use of silicone gel filled breast implants manufactured by PIP (a French breast implant manufacturer). They also recalled all of these devices in France. Following an inspection of the PIP manufacturing plant, AFFSAPS established that breast implants

[9] http://www.mhra.gov.uk/Safetyinformation/Generalsafetyinformationandadvice/Product-specificinformationandadvice/Product-specificinformationandadvice-A-F/Breastimplants/Typesofbreastimplants/index.htm

manufactured since 2001 had been filled with a silicone gel with a composition different from that approved.

The MHRA issued a Medical Device Alert (MDA/2010/025) on 31 March 2010 advising UK clinicians not to implant these devices. […]"

33. Further testing of the implants was carried out by various agencies. Initial findings were that there was no significant health risk to women.

34. The Commissioner has no way of knowing how aware the public were of the banning of the PIP implants. Nevertheless, he acknowledges the validity and force of the overall arguments of the complainant which can fairly be interpreted as saying that, in matters directly relating to the health of individuals, a public authority should be, and also seen to be, entirely transparent in respect of its actions and decisions. This is the best way of securing the public's trust and confidence in that authority.

Public interest arguments in favour of maintain the exemption

35. The DoH has advanced a number of arguments in support of its view that the public interest favours the maintaining of the exemption. These can be summarised as follows –

    a. Disclosure of the withheld information is unlikely to result in the public, particularly women who may be affected, being better informed about the issues at hand.

    b. The issues relating to PIP implants arose during the Christmas holiday period which meant the advice of clinicians would not have been easily accessible.

    c. The first drafts of the press statements were written by press officers on the understanding that the statements would be commented upon and clarified by policy and clinical colleagues. As a consequence, not all of the phrases used to describe the situation were accurate and the sight of which could result in public confusion about what was meant.

    d. Removal of a PIP implant is classed as major surgery and carries with it the usual risk that other major surgery entails. If the messages and advice provided had been misinterpreted, there was a risk that unnecessary surgery might be carried out.

    e. Ministers and government officials need time to properly reflect on key research when making decisions. They must be able to make decisions in an environment which is as free as possible from public controversy.

f. Exposure of internal deliberative processes could deter officials from participating fully and candidly in discussions about policy formulation and development.

g. Ministers and government officials need to be able to engage in free and frank discussion of all the policy options, including the merits and demerits as appropriate.

36. The Commissioner has not felt it necessary to address each of these arguments in turn as part of this notice but notes that all have been taken account of when reaching a decision.

Balance of the public interest

37. The Commissioner recognises that the public interest arguments in this case are finely balanced. On the one hand it is accepted that the public has a legitimate expectation that information about the government's response to a health scare should be made available. On the other hand, the DoH has reasonably argued that there is a pressing need to protect and sustain the space in which officials can feel confident that issues, particularly controversial or sensitive ones, can be fully explored and discussed.

38. The Commissioner has felt that, as with most cases, the balance of the public interest must ultimately rest on two factors – the timing of the request and the content of the withheld information itself.

39. Where it is found that information is captured by section 35(1)(a), and thus relates to policy formulation or development, the Commissioner will normally adopt the view that any harm though disclosure is likely to decrease once the process of formulation and development has been completed. In the DfES case, referred to at paragraph 20 above, the Information Tribunal considered if and when the process of policy formulation and development could be considered as ended, particularly in the context of how timing would affect the public interest test. It disagreed with the DfES that development of policy would often be a continuous process described as a "seamless web". Instead, it found that it was possible to identify a definite conclusion of the policy making process, which may take the form of a series of discrete stages each with a beginning and an end.

40. Reflecting this position, the first question the Commissioner has asked himself is whether the policy formulation and development had effectively been completed at the time of the request.

41. It is noticeable that by the time of the request a number of weeks had passed since the press statements had been released. Furthermore, the interim report of Sir Bruce Keogh had been produced and placed in the

public domain. The Commissioner has therefore considered whether the announcements by the government and the publication of the expert's interim report meant that this stage of the policy formulation development had been concluded. In his view, it did not.

42. This is because at the date of the request it was clear that further work was being carried out in relation to the safety of the PIP implants, with the expert group due to issue a final report at a later date. The Commissioner's view is that policy formulation and development would be directly shaped by the findings of the expert group. Thus, in the circumstances, he considers it would be inappropriate to isolate the one from the other and conclude that a particular stage of the policy development and formulation had been concluded in January 2012.

43. Building on this analysis, the Commissioner finds merit in the DoH's argument that it was entitled to space in which it could refine its policy on PIP implants away from public attention. As stated, at the time of the request the picture regarding PIP implants was still not in clear focus – with the work preparing the press statements only the first part in the wider review of the issue.

44. It is in this context that the Commissioner considers that significant weight must be placed on the need to protect the deliberative process as it relates to policy making. As indicated by the DoH, the application of the exemption in this case is intended to ensure that the possibility of public exposure does not deter from full, candid and proper deliberation of policy formulation. Similarly, this weight extends to the need for ministers and government officials to be able to engage in the free and frank discussion of all the policy options, taking account of circumstances as they developed after the release of the press statements. Ultimately, the Commissioner considers that it was critical for officials to have the space to settle on a well-thought out policy position, especially bearing in mind the number of people directly affected by this policy.

45. The next question the Commissioner has therefore had to consider is whether the importance of the withheld information for the purposes of the public interest test is sufficient to trump the strong arguments in favour of maintaining the exemption. In his view, it is not.

46. In arriving at this conclusion, the Commissioner has taken into account the DoH's explanation that the statements were initially prepared by press officers and not officers who had clinical expertise. Consequently any changes to, or discussions on, the initial drafts were in part simply clarifying this input from a clinical perspective. Furthermore, as the issues with PIP implants arose during the Christmas period, the withheld information was not based on complete and final information. Leading

on from this, the Commissioner shares the DoH's view that premature disclosure of incomplete information could unnecessarily distress those women who relied upon the advice of the DoH.

47. In all the circumstances of this case, the Commissioner has decided that the public interest in the disclosure of the withheld information, which has relatively limited usefulness for the purposes of transparency and accountability, is outweighed by that in avoiding harm to the wider policy making process.

Right of appeal

48. Either party has the right to appeal against this decision notice to the First-tier Tribunal (Information Rights). Information about the appeals process may be obtained from:

    First-tier Tribunal (Information Rights)
    GRC & GRP Tribunals,
    PO Box 9300,
    LEICESTER,
    LE1 8DJ

    Tel: 0300 1234504
    Fax: 0116 249 4253
    Email: informationtribunal@hmcts.gsi.gov.uk
    Website: www.justice.gov.uk/guidance/courts-and-tribunals/tribunals/information-rights/index.htm

49. If you wish to appeal against a decision notice, you can obtain information on how to appeal along with the relevant forms from the Information Tribunal website.

50. Any Notice of Appeal should be served on the Tribunal within 28 (calendar) days of the date on which this decision notice is sent.

Signed .....

Graham Smith
Deputy Commissioner
Information Commissioner's Office
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SK9 5AF