Freedom of Information Act 2000 (FOIA)

Decision notice

Date:	**9 January 2012**
Public Authority:	**Medicines and Healthcare Products Regulatory Agency**
Address:	**151 Buckingham Palace Road Victoria London SW1W 9SZ**

Decision (including any steps ordered)

1. The complainant requested the following:

   "There was a meeting held on Fri 13th May at the MHRA offices, 151 Buckingham Palace Road, concerning brand prescribing. It was chaired by Prof. Stuart Ralston representing the Commission on Human Medicines. The invitation to attend the meeting came from the MHRA.

   Could I have the following information about the meeting?
   A list of who attended and who they were representing.
   The agenda for the meeting.
   The minutes of the meeting."

2. The Information Commissioner's decision is that the Medicines and Healthcare products Regulatory Agency (MHRA) correctly applied section 35(1)(a) of the FOIA (formulation or development of government policy). He considers that the public interest in maintaining the exemption outweighs the public interest in disclosing the requested information. Therefore, the MHRA is not required to disclose the information in full or in a redacted form and it is not necessary for the Information Commissioner (the Commissioner) to go on to consider the MHRA's application of section 43(2) of the FOIA (commercial interests).

Request and response

3. On 28 June 2011, the complainant wrote to the MHRA and requested the information outlined in paragraph one.

4. The MHRA responded on 26 July 2011. It provided the complainant with a list of attendees and the agenda for the meeting. The MHRA refused to provide the meeting minutes under section 43(2) of the FOIA.

5. Following an internal review the MHRA wrote to the complainant upholding its original decision.

6. The Commissioner contacted the MHRA to explain that the complainant's case had been accepted for investigation. In its reply the MHRA stated that, in addition to section 43(2) of the FOIA, it was relying on section 35(1)(a) of the FOIA to withhold the meeting minutes.

Scope of the case

7. The complainant contacted the Commissioner to complain about the way his request for information had been handled. He specifically asked the Commissioner to consider whether the MHRA should have disclosed the meeting minutes (the disputed information) in full, or alternatively, in a redacted form.

8. The Commissioner notes that under the FOIA the MHRA is not a public authority itself but it is an executive agency of the Department of Health (DOH). Therefore, the public authority in this case is the DOH rather than the MHRA. However, for the sake of clarity, this decision notice refers to the MHRA as if it were the public authority.

9. In the course of his investigation the Commissioner has considered all of the arguments made by the complainant and the MHRA including those not specifically referenced within this decision notice.

Reasons for decision

Section 35(1)(a) of the FOIA

10. Section 35(1)(a) of the FOIA states that information is exempt if it is held by a government department and relates to the formulation and development of government policy. Section 35(1)(a) of the FOIA is a class based exemption. Where a class based exemption is claimed it is not necessary to demonstrate prejudice or harm to any particular interest in order to engage the exemption. Instead, it is only necessary to show that the information falls within a particular class of information.

11. The Commissioner considers that the term 'relates to' can safely be given a broad interpretation. This is because the exemption is qualified and a public authority would be obliged to disclose information where it

was in the public interest to do so. The Commissioner takes the view that the 'formulation' of government policy comprises the early stages of the policy process – where options are generated and sorted, risks are identified, consultation occurs and recommendations or submissions are put to a Minister.

12. The MHRA's functions are defined in a framework document drawn up by the DOH in consultation with the MHRA.[1] The framework document states the following:

"In the United Kingdom, control of medicines is governed by the Medicines Act 1968, relevant subordinate legislation under the Act and a body of European Union legislation[1]. The legislation provides a regulatory framework in respect of the safety, quality and efficacy of medicinal products to be sold, supplied or administered to patients. The MHRA discharges, on behalf of Ministers, functions that they exercise, singly or collectively, as the "Licensing Authority"[2], "Health Ministers"[3] or the "competent authority"[4]."

13. The framework document also outlines the aims and key activities of the MHRA. One of the MHRA's aims is:

"Protecting public health through regulation, with acceptable risk:benefit profiles for medicines, devices and blood and blood components."

14. One of the MHRA's key activities is to:

"Provide[s] advice and support on policy issues to Ministers in the Department of Health and the devolved administrations."

15. The disputed information is contained within the meeting minutes for the first meeting of an ad hoc working group which has been established to provide advice on the broad policy area concerning whether, and in what circumstances, brand medicines may be replaced with generic medicines. The ad hoc working group is an advisory committee to the Commission on Human Medicines (CHM). The remit of the CHM is outlined in the Medicines Act 1968 (MA 1968) as follows:

[1] MHRA Framework Document, http://www.mhra.gov.uk/Publications/Corporate/FrameworkDocument/index.htm, February 2010.

"3.— Functions of the Commission

(1) The Commission shall give to either or both of the Ministers 2 advice on matters–
(a) relating to the execution of this Act,
(b) relating to the exercise of any power conferred by this Act,
(c) relating to the execution of the Marketing Authorization Regulations, the Homoeopathic Regulations, the Herbal Regulations or the Clinical Trials Regulations,
(d) relating to the exercise of any power conferred by those regulations, or
(e) otherwise relating to medicinal products,

where either the Commission consider it expedient, or they are requested by the Minister or Ministers in question, to do so."

16. In practice the CHM provides advice to the MHRA which discharges functions under the MA 1968 on behalf of Ministers and provides advice to Ministers as outlined in its Framework Agreement with the DOH.

17. The Commissioner considers that the MHRA's remit specifically includes responsibility for advising Ministers on policy formulation and development in medicines matters as one of its key activities. The advice provided to the MHRA by the CHM supports it in carrying out this function.

18. Having concluded that the MHRA carries out functions relating to the formulation or development of government policy, the Commissioner will now go on to consider whether the disputed information in this case relates to those functions. In forming a conclusion as to whether the exemption under section 35(1)(a) of the FOIA is engaged, the central factor is the content of the information in question.

19. The Commissioner recognises that the term 'policy' is not a precise one and to some extent what is regarded as policy depends upon context. However, there would appear to be a general consensus that policy is about the development of options and priorities for ministers, who determine which options should be translated into political action and when. The white paper 'Modernising Government' refers to it as:

"*the process by which governments translate their political vision into programmes and actions to deliver 'outcomes' - desired changes in the real world*."[2]

20. The Department of Health (DOH) conducted a consultation in 2010 on proposals to implement 'generic substitution' in primary care that would enable pharmacists and other dispensers of medicines to fulfil a prescription for a branded medicine by dispensing an equivalent generic medicine.[3] The DOH's proposals included a provision for the prescriber to opt out of substitution where, in their clinical judgement, a branded medicine should be prescribed to a patient. The DOH's preferred option for generic substitution was to:

"Introduce dispensing flexibility but limiting the scheme in such a way that the arrangements only apply to a selected group of products on a select list."

21. The DOH published its response to the consultation in October 2010.[4] It was accompanied by a press release which stated that the government had decided not to continue with the implementation of plans to allow for the generic substitution of branded medicines in primary care.[5] It went on to state that:

"The further use of generic medicines may still provide valuable savings and the Department of Health is instead building on existing initiatives as well as looking at other ways of supporting the use of generic medicines where it is appropriate and safe and does not add extra burdens for healthcare professionals."

22. The Commissioner considers that the DOH's response to the consultation determined the high-level policy that the government would adopt in

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[2] Cabinet Office, *'Modernising Government'* White Paper, http://www.archive.official-documents.co.uk/document/cm43/4310/4310.htm, March 1999.
[3] Department of Health, *'The proposals to implement 'Generic Substitution' in primary care, further to the Pharmaceutical Price Regulation Scheme (PPRS) 2009'* Consultation, http://webarchive.nationalarchives.gov.uk/+/www.dh.gov.uk/en/consultations/liveconsultations/DH_110517, January 2010.
[4] Department of Health, *'The proposals to implement 'Generic Substitution' in primary care, further to the Pharmaceutical Price Regulation Scheme (PPRS) 2009'* Response to the Consultation, http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_120433.pdf
[5] Department of Health, *'No Plans to Implement Generic Substitution of Medicines'*, http://www.dh.gov.uk/en/MediaCentre/Pressreleases/DH_120502, October 2010.

this area. In short, it has decided that plans to enforce generic substitution in primary care were too prescriptive, they may not have provided an overall benefit to the NHS and other more appropriate methods of supporting the use of generic medicines would be considered. In the Commissioner's view the DOH's press statement makes clear that following the consultation there were ongoing policy issues to be addressed. Of particular relevance in this case is the government's acknowledgement that there should be further consideration of the circumstances in which replacing branded medicines with generic medicines is *"appropriate and safe"*.

23. The MHRA is responsible for advising ministers on policy formulation and development in relation to medicines matters. The function of the ad hoc group is to consider what, if any, advice should be provided to aid in the possible formulation and development of policy in this area. The ad hoc panel's membership was chosen on the basis of the standing of the participants in their particular fields of expertise and their knowledge of the issues under consideration. The MHRA has explained that this was the first meeting of the group and any discussions could not be taken to be the final word on any of the issues being discussed.

24. The disputed information in this case consists of the meeting minutes for the first meeting of the ad hoc working group. The meeting agenda included a list of 'potential problem areas' which have been identified where replacing branded medicines with generic medicines may be problematic. In the meeting the 'potential problem areas' were discussed by the ad hoc group and opinions were expressed about the potential risks and possible approaches to prescribing medicines in each of these areas.

25. The Commissioner draws a distinction between the stages of formulation and development, taking 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 or decision makers. The disputed information indicates that the ad hoc group had noted its remit and has started to discuss the 'potential problem areas' in order to identify risks and formulate any advice that it deemed necessary on the possible policy approaches to address those risks. The Commissioner considers that the disputed information relates to the early stages of policy formulation and that, as the MHRA has argued, the ad hoc group's discussions represent an ongoing policy process.

26. The Commissioner is satisfied that the ad hoc group's remit includes responsibility for considering whether 'potential problem areas' may require a policy response and, if so, providing advice to the MHRA in relation to the formulation of policy to address any risks that are

identified. In turn the MHRA discharges the functions of Ministers and advises Ministers as it deems appropriate.

27. For the reasons outlined above the Commissioner considers that the withheld information relates to the formulation of government policy and that section 35(1)(a) of the FOIA is engaged.

The public interest test

28. Having found that section 35(1)(a) of the FOIA is engaged, the Commissioner will go on to consider whether, in all the circumstances of the case, the public interest in maintaining the exemption outweighs the public interest in disclosure.

Public interest arguments in favour of disclosing the requested information

29. The MHRA has recognised the general public interest in openness and transparency in government decision making, including transparency with respect to the advice provided to Ministers which impacts on policy decisions. It has also recognised that there is specific public interest in transparency of information relating to debates about the substitutability of medicines.

30. The MHRA has argued that in this specific instance the disputed information does not shed any particularly relevant light on general accountability, transparency or the policy making process. Having considered the disputed information the Commissioner disagrees with the MHRA's assessment. He considers that the disputed information shows how ad hoc committees of the CHM conduct their business and how issues are discussed at the initial stages of policy formulation.

31. The Commissioner notes that the members of the ad hoc panel are senior professionals. In the Commissioner's view senior professionals should expect to be exposed to public scrutiny and be willing to stand by the opinions they express and decisions they make.

32. The Commissioner also considers that there is strong public interest in providing information to the public that would allow them to contribute more constructively to the ongoing public debate about the substitutability of medicines. The concern among patients and practitioners is evidenced in the government's response to the 'generic substitution' consultation which stated:

"The DH's greatest concern in considering the analysis of the consultation responses was the 'general and wide-ranging'… perception that generic substitution posed a threat to patient safety."

33. The disputed information relates to the potential risks associated with replacing branded medicines with generic medicines. In the Commissioner's view members of the public, particularly those patients that are prescribed with medicines falling within the 'potential problem areas', will have strong opinions about whether generic substitution is appropriate. The disputed information would aid public understanding of the potential risks involved in replacing branded medicines with generic medicines. In turn the Commissioner considers that the disclosure of the disputed information may enhance the quality of debate and has the potential to lead to better policy outcomes.

Public interest arguments in favour of maintaining the exemption

34. The MHRA has referred the Commissioner to the Information Tribunal's decision in HM Treasury v Information Commissioner (EA/2007/0001) which stated that the interest that section 35(1)(a) of the FOIA is designed to protect is the "efficient, effective and high-quality formulation and development of government policy." It also referred to the Information Tribunal decision in the case of Department for Education and Skills v Information Commissioner (EA/2006/0006) (DFES case) which was quoted in the High Court case of Office of Government Commerce v Information Commissioner [2008] EWHC 737 as follows:

"Ministers and officials are entitled to time and space, in some instances to considerable time and space, to hammer out policy by exploring safe and radical options alike, without the threat of lurid headlines depicting that which has been merely broached as agreed policy."

35. The Commissioner recognises that there is a strong public interest in maintaining a 'safe space' for the formulation of government policy and the debate of 'live' issues without hindrance from external comment, lobbying or media involvement. The Commissioner considers that the policy process the disputed information relates to is ongoing and releasing the disputed information would erode the 'safe space' in which discussions are taking place. He does not consider that the public interest in maintaining the 'safe space' has been diminished due to the government's overall high-level policy decision having been made. This is because the government's statement recognised the importance of further evaluating the potential risks of generic substitution when considering other ways of supporting the use of generic medicines. The Commissioner considers that there is a particularly strong public interest

in maintaining 'safe space' in this case due to the "contentious nature of the generic substitution policy proposal."[6]

36. The MHRA has also argued that there is a real risk that disclosure of the disputed information would have a deterrent effect on expert members of the CHM and its ad hoc groups providing advice due to the fact it may be disclosed. In this particular instance the MHRA has stated:

"The Ad Hoc Group is considering whether there is an issue that may merit advice regarding a policy response by the very free and frank exchange of views. Disclosure of information at such an early stage of the process could stifle such exchanges and thus affect the quality of the policy formulation process."

37. The Commissioner accepts that the disclosure of the disputed information could have a 'chilling effect' by reducing the candour and frankness of future contributions of the members of the ad hoc panel on this particular issue. Having reviewed the disputed information the Commissioner considers that the debate and the individual contributions that are recorded in the minutes are open and candid. The disclosure of the disputed information could therefore lead to a less well informed debate, poorer quality advice to Ministers and less well formulated policy in this area.

Balance of the public interest arguments

38. In considering the balance of the public interest arguments outlined above, the Commissioner has taken into account the comments of Information Tribunal in the DFES case which involved the application of the section 35(1)(a) of the FOIA. In that case the Information Tribunal found that in relation to the balance of the public interest the central question is the content of the requested information and that the timing of the request is also of paramount importance.

39. The MHRA has argued that the recent nature of the disputed information and the fact that it relates to a very early stage in the policy process means that the public interest in maintaining the exemption outweighs the public interest factors in favour of disclosure.

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[6] Department of Health, *'The proposals to implement 'Generic Substitution' in primary care, further to the Pharmaceutical Price Regulation Scheme (PPRS) 2009'* Response to the Consultation, http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_120433.pdf, p 10.

40. The Commissioner notes that the disputed information relates to the early stages of policy formulation as it records the discussions at the first meeting of the ad hoc group that has been established to consider the substitutability of medicines. He has afforded particular weight to the 'safe space' arguments made by the MHRA due to the 'live' nature of the issue. He also considers that if the disputed information is disclosed there is a real risk of a 'chilling effect' on the frankness and candour of participants in future discussions on this particular issue, especially due to the contentious nature of the issue being addressed.

41. Whilst the Commissioner expects senior professionals to have an expectation that they be exposed to public scrutiny, and a willingness to stand by their opinions, he does not attribute any significant weight to this factor in the circumstances of this case. This is because of the candid nature of discussions, the contentious nature of the issue being addressed and the likely 'chilling effect' if the members of the ad hoc panel expected the information to be made public. He considers that the members may be less willing to provide opinions based on their experience where in the forum of the meeting they may not have the empirical evidence available to hand to substantiate those opinions.

42. The Commissioner recognises that there is considerable public interest in providing the public with information concerning the substitutability of medicines due to the public concern that was evidenced in the DOH's response to the consultation. He considers that this would improve the ability of the public to contribute to the ongoing debate and that this could lead to better quality policy outcomes. In addition to this there is the general public interest in improving the transparency and openness of the MHRA, the CHM, its ad hoc groups and the policy making process.

43. However, he also considers that the level of public concern about the substitutability of medicines reinforces the need for an effective policy process with sufficient 'safe space' to identify risks and formulate any necessary policy solutions to address 'potential problem areas'.

44. Taking into account all of the factors outlined above, on balance, the Commissioner considers that the public interest in maintaining the exemption outweighs the public interest in disclosing the information. The MHRA is not, therefore, required to disclose the disputed information in this case either in full or in a redacted form.

Right of appeal

45. 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

46. 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.

47. 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 ……

Faye Spencer
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