# Freedom of Information Act 2000 (FOIA)

# Decision notice

**Date:** 11 August 2015

**Public Authority:** Medicines and Healthcare Products Regulatory Agency

**Address:** 151 Buckingham Palace Road
London
SW1W 9SZ

## Decision (including any steps ordered)

1. The complainant has requested copies of all correspondence dating from 24 August 2014 involving the chief executive of the Medicines and Healthcare Products Regulatory Agency (MHRA). The request was refused under sections 35, government policy, and 43, commercial information. During the course of the Commissioner's investigation the MHRA also sought to rely on sections 27, international relations,40, personal information, 41 information provided in confidence and section 42, legal professional privilege.

2. The Commissioner's decision is that MHRA is entitled to withhold the requested information under section 35(1)((a). Having found that all the information can be withheld under section 35 he has not gone onto to consider the application of the other exemptions cited.

3. The Commissioner does not require the public authority to take any further action in this matter.

## Request and response

4. On 15 October 2014, the complainant wrote to the MHRA and requested information in the following terms:

"Please provide copies of all correspondence and communications from August 24 to today's date involving Ian Hudson which relate to Ebola.

By "involving" I mean sent or received by Mr Hudson (including 'copied in' communications)."

5. The MHRA responded on 4 November 2014. It confirmed it held the requested information but stated that all the information was exempt under section 35 – formulation and development of government policy and that section 43 – prejudice to commercial interests applied, to some of the information. In respect of both these exemptions the MHRA explained that it had carried out a public interest test and concluded that the public interest favoured maintaining the exemptions.

6. The complainant sought an internal review of that decision the same day, 4 November. The MHRA did not provide an internal review. However during the course of the Commissioner's investigation it did clarify that it was applying section 35(1)(a) information relating to the formulation and development of government policy to all the requested information and that it believed both subsections of section 43 applied, i.e. 43(1)(a) – trade secrets, and (1)(b) prejudice to commercial interests, also applied to some of that information. It also applied additional exemptions to some of the requested information. These were sections 27(1)(a)(b)(c)(d) – prejudice to international relations, section 40(2) - third party personal data which was applied in respect of the names and contact details of people who were not senior civil servants, section 41 – information provided in confidence, and section 42 - information subject to legal professional privilege. MHRA also said that to the extent that the Commissioner found that any of the information was not covered by section 35 it would wish to apply section 36 – prejudice to the conduct of public affairs.

7. MHRA informed the complainant of these developments on 24 April 2015.

## Scope of the case

8. The complainant contacted the Commissioner on 12 December 2014 to complain about the way his request for information had been handled. At this time the complainant was concerned over the MHRA's failure to provide him with the outcome of its internal review. The Commissioner contacted the MHRA about the delay in providing a review and after no outcome had been provided by 25 February 2015 he commenced an investigation into its grounds for refusing the request.

9. The Commissioner considers that the matter to be decided is whether the MHRA is entitled to refuse the request under the exemptions cited above. As the MHRA has applied section 35 – information relating to the

formulation and development of government policy, to all the information he will consider its application first.

## Background

10. Dr Ian Hudson is the chief executive of the MHRA. The MHRA is an executive agency of the Department of Health (DH) and has responsibility for insuring medicines and healthcare products are safe. As such it had an important role to play in the search for a vaccine against the spread of Ebola and in particular, the approval of clinical trials for such a vaccine.

## Reasons for decision

### Section 35(1)(a) – formulation or development of government policy

11. So far as is relevant to this request, section 35(1)(a) of FOIA provides that information held by a government department is exempt if it relates to the formulation or development of government policy.

12. There are four important points to note. Firstly the exemption can only be applied by a government department. The MHRA is an executive agency of the Department of Health (DH). As such it is part of the DH and therefore eligible to claim the exemption, so long as the other conditions are satisfied.

13. Those other conditions concern the information itself. The information must relate to the formulation or development of government policy. The term 'relates to' is interpreted broadly and any significant link to production of government policy will be sufficient to bring that information within the scope of the exemption. However the information must relate to 'formulation' or 'development' of such policy. That is it must relate to the process of creating or producing of policy including the refinement or an existing policy. If it relates purely to the implementation of a policy the information will not be covered by the exemption.

14. Finally the policy to which the information relates must be 'government' policy. The defining ingredient of government policy is that ultimately it will be signed off either by the Cabinet or the relevant minister. This is because only ministers have the mandate to make policy on behalf of the government.

15. There are many ways of formulating policy. The most easily recognised is a formal process involving the production of a government white paper setting out policy options, followed by a consultation period after which legislation is drafted and put before Parliament. However, in an emergency policy has to be produced at a far swifter pace and the process has to be able to react to ever changing circumstances. The policy process in such emergencies is far less formal. This was the character of the process followed during the Ebola crisis as the UK government formulated its response to the emergency and worked with the rest of international community in combatting the spread of the disease.

16. The Commissioner has examined a great many emails, including extensive email chains, which the MHRA has identified as falling within the scope of the request.

17. It is abundantly clear from the information provided that one of the central planks of the UK government's response to the Ebola epidemic was to assist in the search for an effective and safe vaccine against Ebola. Furthermore it is clear that MHRA were taking the lead in advising the government on the safety of the drugs which might provide an effective vaccine. At a very practical level MHRA was involved in prioritising its resources so that the approval process of potential vaccines could be accelerated. It was then advising the relevant ministers directly, or through officials at the DH on how that process was progressing and in turn was receiving direction from ministers as to the level of progress expected.

18. In emergency situations reassurance of the public both at home and abroad can form an integral part of the government's response. Therefore policy development can extend to such matters as the issuing of press releases whether by the government itself, its international partners, or the drug companies involved in the production of a vaccine. During the course of the Commissioner's investigations the complainant was provided with links to such press releases, but MHRA has continued to withhold the emails to which those articles were attached.

19. The Commissioner is satisfied that the information, including that about press releases, relates to the formulation of the government's response to the global healthcare emergency. Although normally executive agencies operate with a degree of autonomy it is clear that because of its role and expertise in the approval of medicines MHRA played an important part in both informing the government's policy direction as well as pursuing those policy objectives. MHRA has informed the Commissioner that one of its directors was seconded to the main DH during the crisis which is further evidence of the close working

relationship between the Agency and its department which was required during the crisis.

20. The Commissioner is therefore satisfied that the requested information relates to the government's policy making process in respect of the Ebola crisis and that it therefore engages the exemption provided by section 35.

**Public interest test**

21. Section 35(1)(a) is subject to the public interest test as set out in section 2 of FOIA. The public interest test provides that even if an exemption is engaged the information can only be withheld if in all the circumstances of the case the public interest in maintaining the exemption outweighs the public interest in disclosing the information.

22. The MHRA has acknowledged that there is a general public interest in openness and in understanding how government develops its policies.

23. The complainant has submitted that at the time of his request the MHRA was involved in fast tracking the approval of a vaccine for Ebola. He has described this as a matter of national and international importance.

24. The Commissioner accepts both the MHRA's acknowledgment of the general arguments in favour of disclosure and the complainant's more specific arguments. The Commissioner is aware that UK trials of one drug had commenced by the time the request was made and MHRA's chief executive was quoted on one website as saying that the review of the clinical trial application was assessed and authorised in just four days. There is clearly a public interest in knowing more about how that acceleration was achieved and how robust that process was.

25. However despite these significant public interest arguments account must also be had for the public interest in maintaining the exemption and preventing any harm which section 35 is designed to protect against that would be caused by the disclosure of the correspondence.

26. Of prime importance in this case is the timing of the request. The trial of one potential vaccine had only just started and its efficacy and safety was still not known. Policy development in respect of the assessment of potential vaccines was therefore very much ongoing with ministers needing rapid updates on live issues so that could direct the government's response appropriately. As already set out, MHRA was heavily involved in this process. The Ebola crisis was at its height and a simple internet search reminds one that this was a period when healthcare workers from developed countries such as the UK and the USA were returning from West Africa with the Ebola virus and there was

increasing concern over the ability of the international community to control the epidemic.

27. To release information at the time of the request would erode the safe space necessary for the officials involved in the policy making process. Those advising ministers and responding to directions from ministers, require privacy to candidly assess, comment on and make judgements about the complex information they were required to consider without the distraction of external interference. This is more so when account is taken of the pressurised environment in which officials were working due to the importance of finding an effective vaccine.

28. The Commissioner accepts that there would be harm to the policy making process if information was released at a time when a number of medicines were under consideration. If information had been disclosed at the time of the request it could have led to efforts being distracted from properly assessing potential vaccines to dealing with enquiries about the different policy options presented by those drugs.

29. Furthermore the Commissioner considers that part of any government's policy for managing such crises extends to reassuring the public and the wider international community about the measures being adopted. To disclose information which could be misinterpreted at such a time would undermine those efforts.

30. The MHRA has expressed concern that had the information been released at the time of the request it would have diverted the focus away from ministers, who are ultimately responsible for policy decisions, on to the officials providing advice to those ministers. This, MHRA argues, would curb the free flow of ideas between ministers and their advisers. Again, in the circumstances of this case, the Commissioner accepts this argument.

31. The Commissioner has also considered whether there would be any chilling effect on the officials concerned. The chilling effect refers to the potential that officials may shy away from being entirely candid when offering advice to others, including ministers. The Commissioner finds that the media spotlight was already on the government's response to the crisis and in particular on the search for a vaccine. Against this background the Commissioner considers any disclosure would attract significant media interest and this would raise a real risk of having an impact on the conduct of officials as they continued to work on the government's response.

32. The safe space and chilling effect arguments discussed above relate mainly to the actual policy process. The Commissioner has also considered the impact that disclosing the information would have on the

policy itself. In its broadest terms the policy to which the information relates was how best to support international efforts to control the Ebola epidemic and provide healthcare treatments for those who have already contracted the disease. It must be recognised that the UK government was not acting in isolation. It was working with a wide range of international bodies and drugs regulators. The work required the cooperation of all these bodies as well as private sector pharmaceutical companies whose development of potential cures and vaccines represented a significant commercial investment for those companies. The request captures information relating to these stakeholders.

33. The public interest factors in maintaining section 35 are limited to those issues which the exemption is designed to protect i.e. the policy making process and the policy itself. It is not designed to protect international relations or commercial interests. However, if disclosing the requested information would result in such stakeholders no longer being prepared to share information with the MHRA this would make it impossible for MHRA to fulfil its role in assessing potential vaccines, approving the clinical trial of such vaccines and advising ministers on the policy options available. The Commissioner notes that the vast majority of the information captured by these international and private sector bodies are covered by well understood confidentiality protocols. Considering the urgency to find a vaccine any disclosure that meant others were reluctant to cooperate with MHRA for fear that their information would be disclosed would undermine the government's policy objectives.

34. To determine whether the information can be withheld under section 35 it is necessary to weigh the factors identified in favour of disclosure against those identified in favour of withholding the information.

35. The factors in favour of disclosure are weighty. There is a clear value in disclosing information which would reveal more detail about how the MHRA handled the fast tracking of the process for the approval of an Ebola vaccine and more generally how government departments and their agencies respond to such emergencies.

36. The actual subject of the request i.e. a global healthcare crisis increases the public interest in accessing this information. However this is a double edged sword. At the time of the request there was an urgent need to assess drugs for clinical trials and consider policy options so that the UK government could contribute to international efforts to contain the epidemic. Disclosing information which would undermine or disrupt efforts to find an effective vaccine would be against the public interest.

37. The Commissioner finds that the erosion of the safe space required for good policy making, the chilling effect on the contribution of officials that disclosing the requested information and, importantly, the impact

on international and private sector cooperation that are likely to result from disclosure would have a very serious impact on the search for an Ebola vaccine. He is satisfied that this outweighs the public interest in disclosing the information.

38. The Commissioner concludes that section 35(1)(a) is engaged and can be maintained in the public interest. He does not require the MHRA to take any further action in this matter.

## Right of appeal

39. 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: 0870 739 5836
    Email: GRC@hmcts.gsi.gov.uk
    Website: www.justice.gov.uk/tribunals/general-regulatory-chamber

40. 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.

41. 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 .....**

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