Freedom of Information Act 2000 (FOIA)

Decision notice

Date: 13 March 2020

Public Authority: Medicines and Healthcare Products Regulatory Agency

Address: 10 South Colonnade
Canary Wharf
London
E14 4PU

Decision (including any steps ordered)

1. The complainant has requested information associated with a Commission on Human Medicines' Expert Working Group report on Hormone Pregnancy Tests. The Medicines and Healthcare Products Regulatory Agency (MHRA) released some information and withheld the remainder under sections 36(2)(b) and 36(2)(c) of the FOIA (prejudice to effective conduct of public affairs) and section 40(2) (personal data). Its position is that the public interest favours maintaining the section 36 exemptions. The complainant disputes MHRA's reliance on section 36 to withhold some of the information she has requested.

2. The Commissioner's decision is as follows:

    - The disputed information engages the exemptions under section 36(2)(b) but not that under section 36(2)(c).

    - The public interest favours disclosing the withheld information.

3. The Commissioner requires MHRA to take the following steps to ensure compliance with the legislation.

    - Release the information being withheld under section 36(2)(b), having first redacted all the personal data from it.

4. The public authority must take these steps within 35 calendar days of the date of this decision notice. Failure to comply may result in the Commissioner making written certification of this fact to the High Court pursuant to section 54 of the Act and may be dealt with as a contempt of court.

Request and response

5. On 2 September 2019 the complainant, a journalist for Sky News, wrote to MHRA and requested information in the following terms:

> "[1] *Please can I refine the first part of the request by requesting:*
>
> *All correspondence (electronic or otherwise) received or sent between 1st October 2017 and 30th November 2017 by the MHRA/CHM or its staff members, relating to the drafting, redrafting and final publication of the Report of the Commission on Human Medicines' Expert Working Group on Hormone Pregnancy Tests, published 15th November 2017.*
>
> [2] *The second part of the request remains:*
>
> *The names of every individual who attended the following two meetings, including MHRA staff members and legal advisors:*
>
> *1. The meeting of the Commission on Human Medicines board on 6th October 2017 where it discussed the draft report of the Expert Working Group on Hormone Pregnancy Tests.*
>
> *2. CHM 17/10th MEETING on 2-3 November 2017 where Hormonal Pregnancy Tests Working Group Feedback – Final Report was dicscussed* [sic]*."*

6. MHRA responded on 29 October 2019. It withheld the information it holds relating to part 1 of the request under section 36(2)(b) and 36(2)(c) of the FOIA and said the public interest favoured maintaining these exemptions. Regarding part 2 of the request, MHRA released some information and withheld the remainder under section 40(2) of the FOIA.

7. The complainant was dissatisfied with MHRA's application of section 36(2) to some of the information she has requested. Following an internal review, MHRA wrote to the complainant on 27 November 2019. It maintained its reliance on section 36(2)(b) and section 36(2)(c).

Scope of the case

8. The complainant first contacted the Commissioner on 1 August 2019 to complain about the way a separate but related request for information had been handled. Regarding the current request, she subsequently confirmed that she is dissatisfied with MHRA's application of section 36 to part 1 of her request.

9. The Commissioner's investigation has therefore focussed on whether MHRA can rely on section 36(2)(b) and/or section 36(2)(c) to withhold information falling within the scope of part 1 of the complainant's request, and the balance of the public interest.

Reasons for decision

10. Section 36(2)(b) of the FOIA says that information is exempt information if, in the reasonable opinion of a qualified person, disclosure would, or would be likely to inhibit, under subsection (i) the free and frank provision of advice or under subsection (ii) the free and frank exchange of views for the purposes of deliberation.

11. The Commissioner considers that section 36(2)(b) concerns processes that may be inhibited at the time of the request and in the future, rather than harm arising from the content or subject matter of the requested information itself. The key issue in this case is whether disclosure would or would be likely to inhibit the process of providing free and frank advice and exchange of views for the purposes of deliberation, in this case deliberation associated with a draft report.

12. Section 36(2)(c) of the FOIA says that information is exempt information if, in the reasonable opinion of a qualified person, disclosure would otherwise prejudice, or would be likely otherwise to prejudice, the effective conduct of public affairs.

13. This means that section 36(2)(c) can only apply in instances when the envisioned inhibition or prejudice to the effective conduct of public affairs does not concern the giving/receiving of advice or the exchange of views. A public authority may apply both section 36(2)(b) and section 36(2)(c) to information but the envisioned prejudice under section 36(2)(c) must concern something other than the inhibition to advice or the exchange of views, which are covered by 36(2)(b).

14. Section 36(2)(c) is concerned with the effects of making the disputed information public. Prejudice to the effective conduct of public affairs could refer to an adverse effect on the public authority's ability to offer

an effective public service or to meet its wider objectives or purpose, but the effect does not have to be on the authority in question; it could be an effect on other bodies or the wider public sector. It may refer to the disruptive effects of disclosure, for example the diversion of resources in managing the effect of disclosure.

15. Section 36 differs from all other prejudice exemptions in that the judgement about prejudice must be made by the legally authorised, qualified person for that public authority. The qualified person's opinion must also be a "reasonable" opinion, and the Commissioner may decide that the section 36 exemption has not been properly applied if she finds that the opinion given is not reasonable.

16. MHRA has provided the Commissioner with a copy of the submission it sent to the qualified person about the request for information and proposed reliance on section 36. It has also provided associated email correspondence. To determine, first, whether MHRA correctly applied the section 36(2) exemptions, the Commissioner must consider the qualified person's opinion as well as the reasoning that informed the opinion. To establish that the exemptions have been applied correctly the Commissioner must:

    i) ascertain who the qualified person (QP) was

    ii) establish that the QP gave an opinion

    iii) ascertain when the opinion was given; and

    iv) consider whether the opinion was reasonable.

17. MHRA says it sought the views of a Department of Health and Social Care minister as its QP in considering this request. The Commissioner is satisfied that, in line with section 36(5)(a) of the FOIA, it is appropriate for such an individual to act as QP.

18. Regarding the second of the above criteria, an email from the Private Secretary to the Secretary of State for Health and Social Care confirms that "ministers" have reviewed [the submission] and agreed to the use of section 36. The Commissioner is therefore satisfied that the QP gave an opinion.

19. Turning to the third criterion, the submission to the QP and covering email are dated 22 October 2019. The above email from the Private Secretary is dated 29 October 2019. Given that the request was submitted on 2 September 2019 and MHRA responded to it on 29 October 2019, the Commissioner is satisfied that the QP gave an opinion by the time the request was refused under section 36.

20. Finally, the Commissioner has considered the fourth of the criteria – whether the QP's opinion is reasonable. It is important to note that this is not determined by whether the Commissioner agrees with the opinion provided but whether the opinion is in accordance with reason. In other words, is it an opinion that a reasonable person could hold? This only requires that it is a reasonable opinion, and not necessarily the most reasonable opinion. The test of reasonableness is not meant to be a high hurdle and if the Commissioner accepts that the opinion is one that a reasonable person could hold, she must find that the exemption is engaged.

21. The opinion given on 29 October 2019 is that the prejudice envisioned under both section 36(2)(b)(i) and (ii) and section 36(2)(c) would be likely to occur if the disputed information was disclosed. 'Would be likely' imposes a less strong evidential burden than the higher threshold of 'would'.

22. The QP's opinion, given in the submission, was that section 36(2)(b) would be engaged because disclosing the information would be likely to inhibit the free and frank provision of advice or exchange of views in relation to the independent experts who provide advice to the Licencing Authority on the authorisation of new medicines and important public health issues. This would in turn otherwise prejudice the effective conduct of public affairs (section 36(2)(c)) as it could inhibit experts from exchanging free and frank views in the future, and result in ill-informed advice.

23. The Commissioner does not consider that the reasoning behind the QP's opinion regarding section 36(2)(b) and (c) to be particularly clear or strong. The reasoning appears to be that disclosure would be likely to inhibit experts (generally, rather than the individuals in the Expert Working Group in this case) from providing advice and exchanging views. This would result in experts (generally) being inhibited from exchanging free and frank views in the future, which would lead to ill informed advice.

24. Sections 36(2)(b) and 36(2)(c) concern two different matters and the Commissioner would expect the related opinions to be distinct. The Commissioner does not consider the above two opinions are sufficiently distinct; they are somewhat tautological. And while the submission to the QP provides a background and context to the request for information, it is not clear that the QP actually viewed the withheld information in question. That diminishes the strength of the QP's opinion somewhat.

25. Since the Commissioner considers that the two opinions are more or less the same, she cannot find them both to be reasonable. Of the two, the

arguments that have been presented about the harm that would be caused by disclosure are only relevant to section 36(2)(b). This is because of MHRA's discussion of the 'chilling effect' elsewhere in the QP submission. The 'chilling effect' is associated with section 36(2)(b). With reference to her explanation of the two exemptions at paragraphs 11-14, the Commissioner also considers that the public interest arguments MHRA has discussed more closely align with the prejudice under section 36(2)(b) than the prejudice under section 36(2)(c). As the opinion/submission to the QP does not identify any grounds for finding there is some other, additional, harm, there does not appear to any significant basis for applying 36(2)(c). Therefore, the Commissioner cannot find that the opinion that section 36(2)(c) is engaged is a reasonable one.

26. Whilst noting her concern that the QP appears not to have viewed the withheld material, the Commissioner is satisfied that the QP had sufficient appropriate information about the request to enable them to form an opinion on the matter of whether section 36(2)(b) was engaged. As such she finds that the opinion associated with section 36(2)(b) is reasonable but that associated with section 36(2)(c) is not.

27. Regarding section 36(2)(b), the Commissioner finds that all the points at paragraph 16 have been satisfactorily addressed. As a result, she must find that the QP's opinion on section 36(2)(b)(i) and (ii) is one a reasonable person might hold and that, therefore, the information in question engages that exemption. The Commissioner has found that not all the points at paragraph 16 have been satisfactorily addressed regarding section 36(2)(c). She therefore finds that that opinion is not one a reasonable person might hold and that the requested information does not therefore engage section 36(2)(c). The Commission has gone on to consider the public interest arguments associated with section 36(2)(b).

Public interest test

Public interest in disclosing the information

28. This request concerns a report the Commission on Human Medicines' Expert Working Group (EWG) produced on hormone pregnancy tests (HPT). The most widely used HPT in the UK was 'Primodos', which was available from the 1950s to the late 1970s. The EWG's final report was published on 15 November 2017. The report's overall finding was that the available scientific evidence does not support a causal association between the use of HPTs during early pregnancy and adverse pregnancy outcomes. The complainant is seeking information on changes that were made to the report including, she says, the overall conclusion, while it was in draft and before it was finalised.

29. The complainant says that the chair of the EWG has said publicly that the conclusion of the final report was "strengthened" on the recommendations of the Commission on Human Medicine (CHM). She considers that there is a strong public interest for transparency around the reasons the CHM gave for this recommendation, and any discussions that took place about redrafting the report.

30. MHRA has acknowledged the general public interest in promoting transparency, accountability and public understanding. It notes in its submission to the QP that hormone pregnancy tests are a contentious issue.

Public interest in maintaining the exemption

31. In its submission to the QP, MHRA notes the following arguments for withholding the disputed information:

- It would have a 'chilling effect' on open and frank discussions for members of expert groups if they believe that all their emails on difficult deliberations could be released.
- The experts on its independent advisory bodies operate on a voluntary basis. This sort of disclosure might make it more difficult for MHRA to find volunteers. In the current case, several members have been subjected to public criticism.
- MHRA's experts are often called upon to make judgements on complex scientific issues. It believes that there is stronger public interest in having fully informed expert reviews and the public seeing final conclusions, rather than internal deliberations which do not reflect those collective conclusions.
- MHRA considers that, on balance, the public interest test falls in favour of withholding the information as there is a stronger public interest in having fully informed expert reviews and the public seeing final conclusions, rather than internal deliberations which do not reflect the ultimate conclusions of the expert committee.

32. In a submission to the Commissioner on 3 March 2020, MHRA confirmed that it considers that its Expert Working Groups generally may be inhibited from providing advice and exchanging views in the future if the information was to be released in this case.

33. MHRA has explained that the CHM advises Department of Health and Social Care ministers and the Northern Ireland Health ministers. These are the Licensing Authority (referred to in the QP submission) on the authorisation of new medicines and also important drug safety issues.

CHM functions as a body corporate, not as a collection of individuals representing their own specialisms.

34. It says that for many specialist or particularly complex issues, the CHM convenes ad hoc Expert Working Groups, such as the EWG on Hormone Pregnancy Tests. These EWGs are made up of leading subject matter experts.

35. The CHM and its EWGs operate on a voluntary basis with a remuneration. In order to carry out its statutory public health role, the CHM depends on being able to attract leading experts for its EWGs. EWGs report to the CHM and it is also necessary for discussions within EWGs and between EWGs and the CHM to be open and frank. This structure ensures high quality advice to ministers and ultimately public health protection.

36. Therefore, while the EWG on HPTs no longer exists, the CHM and its expert advice structure continues to operate, and MHRA believe that releasing the disputed material would have a prejudicial impact on that. In addition to the arguments above, MHRA advised the Commissioner that the EWG on HPTs reviewed all available evidence on this issue and concluded the evidence did not support a causal association between the use of HPTs and birth defects or miscarriage. It says that HPTs were widely used to diagnose pregnancy in the 1960s and 1970s and they have not been available in the UK since the 1970s.

37. Finally, MHRA indicates that the public interest in the issue has been met through the report of the EWG on HPTs, all of the evidence it considered, and all its meeting minutes having been available online since November 2017.

38. Given all of above, MHRA considers that the public interest test falls in favour of withholding the information. It argues that there is a stronger public interest in having a robust structure for conducting informed expert reviews and the public seeing final conclusions. There is less public interest in the public seeing internal deliberations which do not reflect the ultimate conclusions of an expert group and may be used to 'target' individual members.

Balance of the public interest

39. As discussed, arguments under section 36(2)(b)(i) and (ii) are usually based on the concept of a 'chilling effect' and MHRA's QP submission refers to this concept. Civil servants and other public officials are expected to be impartial and robust when giving advice, and not easily deterred from expressing their views by the possibility of future disclosure. It is also possible that the threat of future disclosure could

actually lead to better quality advice. However, the chilling effect argument is that disclosing discussions would inhibit free and frank discussions at the time of the request or in the future, and that the loss of frankness and candour would damage the quality of advice and deliberation and lead to poorer decision making.

40. Chilling effect arguments operate at various levels. If the issue in question is still live, arguments about a chilling effect on those ongoing discussions are likely to be most convincing. Arguments about the effect on closely related live issues may also be relevant. However, once the decision in question is finalised, chilling effect arguments become more and more speculative as time passes. It will be more difficult to make reasonable arguments about a generalised chilling effect on all future discussions.

41. Whether it is reasonable to think that a chilling effect would occur will depend on the circumstances of each case, including the timing of the request, whether the issue is still live, and the actual content and sensitivity of the information in question.

42. Considering the timing of the request first, the complainant submitted her request for communications about the report on 2 September 2019. This was approximately two years after the EWG's report on HPTs had been published. It is therefore true that the discussions about the report's contents, recorded in the requested email exchanges, had been completed at the time of the requested. The decisions in the report had been finalised.

43. As to whether the issues were still live at the time of the request, as discussed above, the EWG's report had been published in 2017 and the report's decisions had been finalised and so the report was not itself still a live issue.

44. However, the Commissioner notes that Sky News had investigated Primodos in 2017 and was continuing to publish articles about the matter, and the EWG's report, through 2018 and 2019. It had published an article about the report in April 2019 and another in August 2019 ie shortly before the time of the request. The August 2019 article reports that parents who consider their babies were damaged by Primodos were preparing to take legal action.

45. Although the report on HPTs had been finalised and published, the substantive matter of the safety or otherwise of Primodos was therefore still live at 2 September 2019.

46. Third, the sensitivity of the disputed information. The substantive matter of the safety or otherwise of HPTs is very sensitive, with some people

considering that HPTs caused congenital anomalies in their children or in themselves. Regarding the withheld information, MHRA has provided copies of this material to the Commissioner. It comprises copies of iterations of the draft report, and parts of the draft report, into which individuals' comments and suggested text and other 'track changes' have been inserted; associated email correspondence; and a small amount of material relating to an associated presentation. Some of the comments and track changes concern routine 'proof reading' matters, and other comments and email correspondence contain suggestions about the content of the draft report and, as such, are more substantial. They are, however, the type of comments and views that the Commissioner would expect the process of finalising such a draft report to generate. The broad subject of HPTs is sensitive, and the associated report is therefore sensitive. But the report's final contents had been published and, in the Commissioner's view, the correspondence about the report does not have the same degree of sensitivity in and of itself.

47. The Commissioner has considered all the circumstances of this case in order to come to a decision on where the balance of the public interest lies. She appreciates that there is sensitivity around the issue of HPTs and that this broad issue was still live at the time of the request.

48. The report on HPTs, however, had been finalised and published two years previously. The final content and conclusion of the report is therefore known. It is also known that the draft report went through different iterations before it was published – the complainant wants to know *why* certain changes to the report were made, hence this request for correspondence about the report. The complainant considers that the EWG's final recommendations in the report were influenced by the CHM.

49. The focus of MHRA's public interest argument for non-disclosure is that EWGs generally may be inhibited in the future in their discussions, if it was thought that records of their discussions would be released. The quality of the Groups' advice and decision-making would therefore be compromised. In the Commissioner's opinion, members of such a Group, convened by the CHM, will understand that the FOIA exists and that recorded information the Group generates may be disclosed in response to a request for it, if it is legal to do so. Disclosure will all depend on the nature of each request. The Commissioner would expect and hope that future EWG's would not therefore feel inhibited in their deliberations.

50. Regarding MHRA's argument that it may be more difficult to recruit volunteers to EWGs, the Commissioner acknowledges this concern and that some members of the HPT EWG had been publicly criticised. However, she refers to her point above, and notes that she would

expect all personal data to be redacted from any disclosed material, in this case.

51. MHRA has argued that the report's final decision is what is key and that there is little value in the deliberations behind that decision. However, the Commissioner considers that the requested information has a public interest that extends not only to those specific individuals who consider they were affected by HPTs, but to the wider general public. In the Commissioner's view there is strong general public interest in knowing whether the conclusion of the EWG's report about HPTs was or was not influenced by another body – particularly as the issue of HPTs was still 'live' at the time of the request. This would demonstrate that MHRA's processes are open and transparent and help to maintain public confidence in it.

52. That is not to say that MHRA's concerns do not carry weight. There is a strong public interest in MHRA's Expert Working Groups being able to attract suitably qualified members and having the confidence to provide appropriately and robustly advise on and discuss important and sensitive matters. However, the Commissioner has not been persuaded that disclosing the requested information in this case would be likely to prevent that from happening. In addition, it should generally be possible for a public authority to put the disclosure into context. It should usually be possible to provide an explanation if, for example, draft documents differ significantly from a final version.

53. The arguments are finely balanced in this case but, having considered all the circumstances, the Commissioner is satisfied that, at the time of the request, the public interest favoured releasing the information withheld under section 36(2)(b).

Right of appeal

54. 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@justice.gov.uk
    Website: www.justice.gov.uk/tribunals/general-regulatory-chamber

55. 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.

56. 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

Pamela Clements
Group Manager
Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF