



Medicines & Healthcare products
Regulatory Agency

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[REDACTED]

FOI 23/795

7 December 2023

Dear [REDACTED]

Thank you for your email of 20 October 2023, we have responded to your request under the Freedom of Information Act 2000.

Your request

I would be grateful if you could provide a copy of **agenda and minutes of the most recent MHRA board meeting held in private**. I hope this simplifies my request and enables you to locate the documents.

Our Response

I can confirm that the Agency holds the information that you have requested. In this case, the information consists of an agenda and board papers for the August 2023 meeting.

After careful consideration we have decided that the information is exempt from disclosure under section 35(1)(a) of the FOIA. This provides that information can be withheld if the information relates to the formulation or development of government policy, and if the public interest is in favour of withholding the information.

Section 35(1)(a)¹ is a class-based exemption which means that the exemption will apply if the requested information meets the description in the exemption, in this case, the formulation or development of government policy; there is no requirement to consider the consequences of disclosure for the exemption to apply. The ICO considers that the term

¹ <https://ico.org.uk/for-organisations/foi-eir-and-access-to-information/freedom-of-information-and-environmental-information-regulations/section-35-government-policy/>

'relates to'² within the wording of section 35 should be interpreted broadly to include any information concerned with the formulation or development of policy including information used to inform the policy position. The guidance advises that the formulation of government policy relates to the early stages of the policy process when "*options are collated, risks are identified, and consultation occurs...*" and that development of government policy "*goes beyond this stage to improving or altering existing policy such as monitoring, reviewing or analysing the effects of the policy.*" We therefore consider that the requested information in this case engages section 35(1)(a) of the FOIA.

Public interest test in relation to section 35(1)(a) – formation of government policy

Some of the exemptions in the FOIA, referred to as 'qualified' exemptions, are subject to a public interest test (PIT). This test is used to balance the public interest in disclosure against the public interest in maintaining the exemption. We must carry out a PIT where we are considering using any of the qualified exemptions in response to a request for information. The 'public interest' is not necessarily the same as what interests the public. In carrying out a PIT we consider the greater good or benefit to the community as a whole if the information is released or not. Transparency and the 'right to know' must be balanced against the need to enable effective government and to serve the best interests of the public.

In this case, there is a general public interest in transparency and openness in government. Such openness can increase public understanding, inform public debate, and maintain public trust. In the context of this request, it is recognised that there would be a legitimate interest in disclosing the requested information, as this may inform the public in how government policy is developed and formulated and enable public scrutiny of the decision-making process. However, we recognise here that we hold public Board meetings for this very purpose – to provide greater transparency and insight into how we operate and to meet the wider public interest.

The strongest public interest factor in this case favours maintaining the exemption; this is that the disclosure of the information prejudice the future formulation of government policy. Officials need to preserve a safe space to freely discuss and consider policy formulation, policy implications and to enable full discussions of policy matters, and this is at the heart of policymaking processes. Officials need to be able to discuss difficult policy issues with openness and candour, and the release of this type of information would inhibit this, resulting in poorer decision making.

The publication of policy while being developed will also have a chilling effect: the ability to consider and explore potential options with key stakeholders to formulate recommendations could be reduced, undermining the effectiveness of the review process to inform and develop policy. Frank and open debate is an important component of high-quality policy formulation, and there is a public interest in maintaining a private space for discussion in order to formulate and develop decisions of private board meetings.

² [In UCAS v Information Commissioner and Lord Lucas \[2015\] AACR 25 at paragraph 46 the Upper Tribunal approved the approach of the FTT in the APPGER case where it said that "relates to" means that there must be "some connection" with the information or that the information "touches or stands in relation to" the object of the statutory provision.](#)

The recommendations in the agenda and minutes of private meetings will be considered in the current context to inform future policy development and, as this is the case, the release of this information would impact negatively on future discussions and the relationship between the Agency and stakeholders. This would inhibit the Agency's ability to formulate policy in a safe space³ and could ultimately result in weaker policy formulation. These factors favour the public interest in maintaining the exemption.

Conclusion

For the information being withheld under section 35(1)(a), the Agency concludes that the public interest in maintaining the exemption outweighs the public interest in disclosure on this occasion.

We hope that this explains why we are applying the exemption for this request.

Kind regards

MHRA Customer Experience Centre

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Appeal rights

If you disagree with how we have interpreted the Freedom of Information Act 2000 in answering your request, you can ask for an internal review. Please reply to this email, within two months of this reply, specifying that you would like an Internal Review to be carried out.

If you are dissatisfied with the outcome of the internal review, you have the right to apply directly to the Information Commissioner for a decision. Please bear in mind that the Information Commissioner will not normally review the handling of a request unless the public authority has first been asked to conduct an internal review.

The Information Commissioner can be contacted online via an electronic form:
<https://ico.org.uk/make-a-complaint/foi-and-eir-complaints/foi-and-eir-complaints/>

Or by writing to:

The Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF

³ <https://www.casemine.com/judgement/uk/5b2897fd2c94e06b9e19eb2d>