Medicines & Healthcare products Regulatory Agency

MHRA Central Freedom of Information Team
10 South Colonnade
Canary Wharf
London
E14 4PU

foi.request@mhra.gov.uk.

MHRA Website

[redacted]

Our Ref: **FOI2025/00025**

3 February 2025

Dear [redacted],

Thank you for your Freedom of Information (FOI) request received on 8 January 2025. You wrote:

> *On Wed 5, Dec 2024 [redacted] received correspondence from the MHRA to inform us that the agency and the independent experts in CHM will be reviewing the decision to expand the [redacted] that was approved on [redacted], based on the evidence that was presented. We have been advised that this referral is necessary because it is not completely aligned with the previous decision made by the CHM some time ago. We request that all information which is held by the MHRA and CHM pertaining to this previous CHM decision is shared.*

MHRA Response
We are able to confirm that the information you seek is held by the Agency.

However, we are engaging an exemption from disclosure because it relates to the formulation or development of government policy – Section 35(1)(a) of the Freedom of Information Act. This exemption protects the private space within which policy makers can develop policies without the risk of disclosures that would undermine this process and result in less robust, well-considered or effective policies.

As required by the FOI Act the use of this qualified exemption requires the public interest for and against disclosure to be assessed.

Public interest test
Section 17(3) of the Act requires us to conduct a Public Interest Test (PIT) when considering this class-based exemption. In applying this exemption, we are required to consider whether, in all the circumstances of the case, the public interest in providing this information outweighs the public interest in withholding the information you have requested. In carrying out a PIT, we consider the greater good or benefit to the community as a whole in providing this information. The 'right to know' must be balanced against the need to enable effective procedural governance and to serve the best interests of the public.

Considerations in favour of providing information requested
We recognise that there is a public interest in the current referral process, which will be reviewing the decision to [redacted] and we understand that this will provide greater transparency of the agency's decision-making process.

Considerations in favour of withholding the information
The regulatory review is still ongoing and has not yet concluded. This means that Section 35(1)(a) is engaged and will remain engaged until our review has concluded.

To provide the information requested at this point could prejudice this review, by releasing information into the public domain that could be used for persons to try to reach their own conclusions before we have concluded our review or could be used to try to lobby MHRA/CHM to try to ensure that the referral reaches a conclusion they are happy with. These outcomes would not allow MHRA the private safe space to conduct the referral and the CHM to reach their independent conclusion.

After consideration of these circumstances, the public interest favours withholding this information while the review is ongoing. Please also be aware that even after our review has concluded, other exemptions may apply to some information relevant to your request, such as Section 41 (information provided in confidence), Section 43 (commercial interests), and Section 21 (information accessible by other means).

If you have any queries about this letter, please contact us quoting the reference number above.

Yours sincerely,

MHRA Central Freedom of Information Team
Medicines & Healthcare products Regulatory Agency

Your right to complain under the Freedom of Information Act

If you are not happy with this response you may request an internal review by e-mailing foi.request@mhra.gov.uk or by writing to: MHRA Central Freedom of Information Team, 10 South, Colonnade, Canary Wharf, London, E14 4PU

Any request for an internal review must be received by us within 40 working days of the date of this letter. Please note we are not obliged to provide a review if it is requested after more than 40 working days.

If you are not content with the outcome of the internal review you may apply directly to the Information Commissioner's Office for a decision. Generally, the Commissioner cannot make a decision unless you have exhausted our own complaints procedure. The Information Commissioner can be contacted at: The Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire SK9 5AF.
Website: ICO FOI and EIR complaints or telephone 0303 123 1113

Re-use of our information