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Canary Wharf
London
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United Kingdom
gov.uk/mhra

[redacted]
By email at: [redacted]

22 April 2024

MHRA reference: FOI 24/296

Dear [redacted]

Thank you for your information request, which we received on 23 March 2024, which followed the advice and assistance provided in response to your previous requests FOI 24/182 and FOI 24/183. In refusing these requests under section 12(4), advice and assistance was provided that:

> *"While conducting our estimate of time needed to respond to these requests, we have identified several documents that if you wish to proceed with a narrowed request could be retrieved and considered for disclosure. These are the distributed CPRD bulletins related to the data quality issue and a copy of the CPRD internal Wiki Page about the subject up to 25th May 2023."*

In your request of 23 March 2024, you asked for:

> *"Thank you for your reply of 22 March to FOIs 24/182 and 24/183.*
>
> *You aggregated them and applied a Section 12 Exemption by claiming that answering would require time-consuming searches "to identify all and any (my emphasis) documents" relevant to the requests. However :*
>
> *a) both my requests only asked for "any" information, not "all"*
>
> *b) the information requested in each was distinct, not related*
>
> *c) in relation to 24/182, you identified relevant information : "distributed CPRD bulletins related to the data quality issue and a copy of the CPRD internal Wiki Page about the subject up to 25th May 2023." These should have been provided instead of inviting me to submit a further FOI to request them*

d) you actually answered 24/183 satisfactorily by confirming that the relevant MHRA staff could not recall any such meetings or relevant documentation.

So, rather than request an Internal Review of both FOIs (based on a) above), I would simply request that you provide the information in c) above in reply to 24/182."

Your request of 23 March 2024 therefore seeks the two documents indicated in the previous advice and assistance:

- *The distributed CPRD bulletins related to the data quality issue*
- *A copy of the CPRD internal Wiki Page about the subject up to 25th May 2023*

We have dealt with your request under the Freedom of Information Act 2000 (FOIA) and confirm we hold the requested information.

In response to your request, we are providing the two requested documents, and we consider that the majority of this information should be disclosed.

However, we consider that some information is exempt from disclosure. Under section 17(1) of the FOIA, when we refuse any part of the requested information, we must specify the relevant exemption and explain why the exemption applies.

We consider that certain information is exempt under section 40(2) and section 43(2), and we are withholding this information.

We are withholding the names of less senior staff and third-party individuals under section 40(2) of the FOIA; this applies when the requested information is the personal data of a living and identifiable individual and disclosure would breach one or more of the data protection principles. We do not consider that disclosing this personal data is necessary or justified. The individuals would have a reasonable expectation that their personal data would not be disclosed and there is no strong legitimate interest that would override the prejudice to the privacy rights of the individuals. Disclosing this information would therefore be unlawful and engage the exemption at section 40(2) of the FOIA.

For section 43(2), the ICO's guidance explains that this is a prejudice-based exemption, which means that information is exempt if its disclosure under FOIA if disclosure would, or would be likely to, prejudice the commercial interests of any legal person (including the public authority holding it).[1] A 'commercial interest' relates to a legal person's ability to participate competitively in a commercial activity.

[1] https://ico.org.uk/for-organisations/foi/freedom-of-information-and-environmental-information-regulations/section-43-commercial-interests/

In this case, disclosure of the requested information would be likely to prejudice the commercial interests of any third party supplier or suppliers who provide services to us, because the information is commercially sensitive and could prejudice the confidentiality between the agency and the supplier(s). Making the information available to competitors could likely compromise the supplier(s) position in the market and risk the supply of services essential to CPRD putting at risk further public health research.

S43(2) of the FOIA is a qualified exemptions and so requires consideration of the public interest in disclosure and in maintaining the exemption. We consider that there is a public benefit where releasing the information demonstrates openness and transparency, and where this could inform the public and contribute to public scrutiny and debate.

However, this must be balanced against the public interest in ensuring that such release does not cause the prejudice identified in the exemption. There is a public interest in ensuring that CPRD can operate as a business with its commercial interests, meaning that commercial organisations can supply CPRD with an expectation of sensitive information not being disclosed, as this could disincentivise further supplier relationships, consequentially putting at risk further public health research.

In this case, we consider that the factors in favour of maintaining the exemption have the greatest weight, and that section 43(2) therefore applies.

This concludes our response to your request.

If you have a query about this response, please contact us at info@mhra.gov.uk

Please remember to quote the reference number at the top of this letter in any future communications. Details of your appeal rights are below.

Yours sincerely,

Safety and Surveillance
Medicines and Healthcare products Regulatory Agency

Appeal rights

If you are dissatisfied with the handling of your request, you can ask us to conduct an internal review. Internal review requests should be submitted within two months of the date you receive this response and addressed to: info@mhra.gov.uk

If you remain 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 our handling of a request unless the requester has first asked us to conduct an internal review.

The Information Commissioner can be contacted through their online webform at: https://ico.org.uk/make-a-complaint/foi-and-eir-complaints/foi-and-eir-complaints/

Or in writing to: Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire, SK9 5AF

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