Medicines & Healthcare products Regulatory Agency

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

foi.request@mhra.gov.uk.

MHRA Website

[redacted]

Our Ref: **FOI2026/00759**

27 July 2026

Dear [redacted]

Thank you for your Freedom of Information (FOI) request received on 13 July 2026. You wrote:

> *"I am writing to make a request for information under the Freedom of Information Act 2000.*
>
> *Please provide copies of all Joint MHRA Health Canada pharmacovigilance inspection reports since January 2025.*
>
> *If the information is held electronically, I would prefer to receive it in electronic format by email.*
>
> *If clarification or refinement of this request would assist in processing it, please let me know as soon as possible.*
>
> *If any of the requested information is exempt from disclosure, I would be grateful if you could:*
>
> - *Provide the non-exempt information that can be disclosed, and*
> - *Clearly identify the exemption(s) relied upon for any information withheld."*

MHRA Response

We have dealt with your request under the Freedom of Information Act (FOIA) 2000.

We confirm that we hold some of the information you have requested. In response to your request, we are providing the following:

- Bayer - Insp GPvP 10/16303918-0005
- Pfizer Group of Companies - Insp GPvP 57-6709-0021
- Moderna - Insp GPvP 53720/36115546-0001

Please note that some redactions have been applied to the document under the following Sections of the FOIA:

- Section 40(2): Information is exempt information if it contains elements of personal data, the disclosure of which would be unfair in that it would breach the first principle of the Data Protection Act which says that information must be processed fairly and lawfully.
- Section 43(2): Information is exempt information if its disclosure under this Act would, or would be likely to, prejudice the commercial interests of any person (including the public authority holding it).

Section 40(2)
We are unable to provide you with some of the information requested as it constitutes personal data of someone other than yourself and as such, it is being withheld in accordance with section 40(2) of the Freedom of Information Act.

Section 40(2) exempts information in response to a request if it is personal data belonging to an individual other than the requester and it satisfies one of the conditions listed in the legislation. In this case the condition contained in section 40(3A)(a) applies - that disclosure would breach one of the data protection principles, specifically that “Personal data shall be processed lawfully, fairly and in a transparent manner...”.

We do not consider that disclosing this information is necessary or justified in order to satisfy your information request and the requirements of the FoI Act. In relation to this request, we consider that there is no strong legitimate interest that would override the prejudice to the rights and freedoms of the data subject.

Personal data are subject to UK General Data Protection Regulation (UK GDPR) and the Data Protection Act 2018

MHRA maintains the following policy on disclosure of personal information:
"All personal information held in MHRA records is regarded as confidential. Information will not normally be disclosed to third parties without the consent of the person concerned. Information may normally be disclosed without consent to meet statutory requirements; to comply with a court order; to prevent duplication of payments from public funds; or where there is a compelling public interest in making the disclosure."

All disclosures made by MHRA, in order to be considered authorised must be able to demonstrate that at least one of the above criteria apply.

Section 43(2)
Release of all, or part of, the information would be likely to cause harm to the third party’s commercial interests. We have considered the balance of the public interest when applying this exemption. The exemption is to safeguard the commercially sensitive information / industrial secrets of a third party / commercial enterprise (which can include a Government Department). This exemption is conditional on the public interest in releasing it not outweighing the company's/commercial enterprise's right to confidentiality and the probable damage that the company/commercial enterprise could suffer as a result of the information being released. In this case we have not identified any issues which would benefit the public as a whole by being brought to their attention (examples of issues would be a major public health risk or a major procedural failure or irregularity).

Section 43 is a qualified exemption and requires that we consider the public interest.

Public interest test
Section 17(3) of the Act requires us to conduct a Public Interest Test (PIT) when applying of a qualified exemption. In applying this exemption, we are required to consider whether, in all the circumstances of the case, the public interest in withholding the information outweighs the public interest in releasing the information held. The 'public interest' is not 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 in withholding. The 'right to know' must be balanced against the need to enable effective procedural governance and to serve the best interests of the public. The FOI Act is 'applicant blind'. This means that we cannot, and do not, ask about the motives of anyone who asks for information. In providing a response to one person, we are expressing a willingness to provide the same response to anyone.

Considerations in favour of releasing the information
To release all information available in these documents would be of benefit in general to show transparency in MHRA's day-to-day work for the public to see how MHRA has considered different aspects of pharmacovigilance system used by the marketing authorisation holders (MAH) to determine whether they comply with pharmacovigilance obligations established within the UK.

Considerations in favour of withholding the information
We recognise that there is a public interest in the disclosure of commercial information relating to the supply chain (sites involved in the manufacture and distribution) for medicines. However, when considering arguments against disclosure, there is a great interest to rival companies who are manufacturing, marketing or looking to market their own rival products. Knowledge of a supply chain and commercial arrangements with third parties can help rival companies in being able to source their active ingredient, excipients and services from these sources.

On balance we are satisfied that, in this instance, the public interest in applying the exemption outweighs the public interest in disclosure.

This concludes our response to your request.

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
The MHRA information supplied in response to your request is subject to Crown copyright. Information created by the MHRA which is disclosed under the Freedom of Information Act is made available for re-use under the Open Government Licence (OGL) v3.0, except where this is otherwise stated. There are some restrictions on re-use under the OGL and these can be viewed here:
https://www.nationalarchives.gov.uk/doc/open-government-licence/version/3/