

**FOI 22-1232 – reports on disproportionality analysis and impact of Covid vaccine reports**

**MHRA RESPONSE**

**18 May 2023**

Thank you for your request under the Freedom of Information Act, we apologise for the delay in response.

You requested:

**In June 2022 MHRA gave the Commission on Human Medicines Pharmacovigilance Expert Advisory Group :**

- a) a presentation on how MHRA conducts disproportionality analysis as part of your signal detection process, and**
- b) the report of an investigation into the impact of the large proportion of Covid vaccine reports in the Yellow Card database on disproportionality analysis and signal detection.**

I would be grateful if you could send me a copy of a) and b) above.

We confirm that we hold the information you have requested. Please find attached the presentation and the report. Please note that redactions have been made to the report to remove staff names in accordance with Section 40 (Personal Information) of the Freedom of Information Act.

Furthermore, under Sections 40 and Section 41 (Information provided in confidence) we have also redacted any number ('n') of 5 or less in the tables within the report. We consider that providing this information could lead to an individual being identified, and therefore would be exempt under Section 40 and 41 as those about whom Yellow Card reports have been submitted have not consented to their personal data being supplied to third parties other than as outlined in the Privacy Policy. Additionally, it would contravene data protection principles.

If you are dissatisfied with the handling of your request, you have the right to ask for 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](mailto:info@mhra.gov.uk)  
Please remember to quote the reference number above in any future communications.

If you were to remain dissatisfied with the outcome of the internal review, you would 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 your request unless you have first contacted us to conduct an internal review. The Information Commissioner can be contacted at:

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

Yours sincerely

**MHRA Customer Experience Centre**

Communications and engagement team

Medicines and Healthcare products Regulatory Agency

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