Medicines & Healthcare products Regulatory Agency

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MHRA Website

[redacted]

Our Ref: **FOI2024/00637**

14th November 2024

Dear [redacted]

Thank you for your Freedom of Information (FoI) request received on 17 October. You wrote:

> *Can you clarify the total amount of adverse reactions so far submitted and what are the 10 most common reactions reported?*

MHRA Response

We confirm that we hold the information you have requested.

Following a search of our database up to and including the 7th November 2024 I confirm the MHRA have received 490,397 UK spontaneous Adverse Drug Reaction (ADR) reports for COVID-19 vaccines. Within these reports 1,048,573 suspected ADRs were reported. Please note one report can contain multiple suspected reactions.

Please find the breakdown of the 10 most frequently reported reactions in table 1.

Table 1: Most frequently reported reactions included in UK spontaneous ADR reports received up to the 7th November 2024 for all COVID-19 Vaccines.

Reported ADR	Number of Yellow Card Reports
Headache	125,181
Fatigue	89,415
Pyrexia	82,747
Chills	59,841
Nausea	56,274
Myalgia	44,253
Pain in extremity	43,896
Dizziness	39,655
Arthralgia	39,182
Pain	32,401

When considering the above spontaneous data, it is important to be aware of the following points:

- Reporters are asked to submit Yellow Card reports even if they only have a suspicion that the vaccine may have caused the adverse reaction. The existence of an adverse reaction report does not necessarily mean that the medicine or vaccine has caused the reaction.

- It may be difficult to tell the difference between something that has occurred naturally and an adverse reaction. Sometimes reactions can be part of the condition being treated rather than being caused by the medicine or vaccine.
- Many factors have to be considered when assessing whether a vaccine has caused a reported adverse reaction. When monitoring the safety of medicines and vaccines, MHRA staff carry out careful analysis of these factors.
- It is not possible to compare the safety of different medicines or vaccines using Yellow Card data. Reporting rates can be influenced by many factors including the seriousness of the adverse reactions, their ease of recognition and the extent of use of a particular vaccine. Reporting can also be stimulated by promotion and publicity about a product.

The MHRA continuously monitors the safety of vaccines through a variety of pharmacovigilance processes, including the Yellow Card scheme. As part of our signal detection processes, all adverse reaction reports received by the Yellow Card scheme are assessed, and cumulative information is reviewed at regular intervals. If appropriate, regulatory action would be taken if any serious risks were confirmed.

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.

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