Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

Mr [redacted]
[redacted]

MHRA

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www.gov.uk/mhra

8th February 2024

Dear [redacted]

FOI 24/057

Thank you for your FOI request dated 16th January 2024, where you requested the following information:

1. *The odds of Chronic Tinnitus, Exploding Head Syndrome and Vitreous Eye Floaters occurring naturally.*
2. *How can Tinnitus not be listed as a potential undesirable effect of Covid-19 vaccination.*
3. *What is the correlation between the actual number of people reporting tinnitus as a side effect during the Moderna Vaccination and those of the years before it? Is it more or less?*
4. *How do you explain the relationship between 13% of adults experiencing prolonged tinnitus (assumingly at any point in their adult life) against those that have reported after receiving their vaccination. i.e. all at roughly the same time/time period? Is this just co-incidence too?*
5. *I would be grateful if you would forward me an actual/up to date list of **ALL** of the side effects currently listed for the Moderna Monovalent vaccination.*

We will address each of your questions in turn.

1. We can confirm that the MHRA does not hold information on the odds of the chronic tinnitus, exploding head syndrome and vitreous eye floaters occurring naturally.

2 and 4. As advised in previous correspondence, the MHRA has continually monitored the safety of COVID-19 vaccines. Part of our monitoring role includes reviewing reports of suspected side effects. Any member of the public or health professional can submit suspected side effects through the Yellow Card scheme. The nature of Yellow Card reporting means that reported events are not always proven side effects. Some events may have happened anyway, regardless of vaccination. This is particularly the case when millions of people are vaccinated as in the COVID-19 vaccination campaign with over 151 million doses of COVID-19 vaccines administered in the UK since December 2020 to date.

3. Please see the table below which shows the number of Yellow Card reports for the suspected adverse drug reaction (ADR) of tinnitus reported to the MHRA per year over the last 10 years in the UK.

Table 1. Number of suspected ADR reports of Tinnitus reported to the MHRA via direct spontaneous reports over the last 10 years per year in the UK (2014-2023)

Year	Number of suspected ADR reports of tinnitus	Total number of Yellow Card reports received
2014	144	31445
2015	161	38683
2016	229	42211
2017	202	43774
2018	186	42338
2019	204	43956
2020	198	40502
2021	7141	482450
2022	1256	113366
2023	581	88647
2024 (up to and including 06/02/2024)	51	9941

It is important to note that the number of reports received via the Yellow Card scheme does not directly equate to the number of people who suffer adverse reactions and therefore cannot be used to determine the incidence of a reaction or compare the safety profile of different medicines. It is also important to note that a report of a suspected side effect is not proof that the vaccine caused it but a suspicion of this by the reporter ADR reporting rates are influenced by the seriousness of ADRs, their ease of recognition, the extent of use of a particular medicine, and may be stimulated by promotion and publicity about a drug. Reporting tends to be highest for newly introduced medicines during the first one to two years on the market and then falls over time. Lastly, during the COVID -19 national immunisation campaign which started in December 2020, the Yellow Card scheme benefited from an increased spotlight and, as such, observed an increase in the total numbers of reports received across for both medicines and vaccines. The numbers of Yellow Cards received for the Covid-19 vaccines reflects the millions of doses administered and is not unusual for new vaccines for which members of the public and healthcare professionals were actively encouraged to report any suspected adverse reaction.

5. Information about the known side effects of medicines and vaccines is included in the Summary of Product Characteristics (SPC) for healthcare professionals and the Patient Information Leaflet, PIL) for patients. The SPC and PIL for the original monovalent COVID-19 vaccine Moderna are available at the following link: https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-moderna.

We hope the information provided is helpful, but 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 of this response; and can be addressed to this email address.

Yours sincerely,

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FOI Team,
Safety and Surveillance

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The Information Commissioner's Office
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