Medicines & Healthcare products Regulatory Agency

10 South Colonnade
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United Kingdom

[redacted]

24 January 2024

Dear [redacted]

FOI 23/1005

Thank you for your Freedom of Information request dated 30 November 2023, and your subsequent clarification, which requested the below information for each of the COVID-19 vaccines used in the UK vaccination programme:

1) *The number of doses administered in the UK which the MHRA uses to calculate UK adverse event rates.*
2) *The numbers of serious adverse events in the UK so far reported to the MHRA from all sources.*
3) *The estimated rate of UK serious adverse events reported to the MHRA - using whatever denominator the MHRA uses in estimations of such rates.*

I can confirm that we hold some of the information requested. Please find our response to each of your questions below:

1) Whilst the MHRA have access to information on the number of doses of COVID-19 vaccines administered in the UK for the purposes of safety surveillance activities, this information is held by the UK Health Security Agency (UKHSA), who can be contacted at enquiries@ukhsa.gov.uk. The MHRA no longer routinely calculate adverse event rates, although this information has been provided in past in the Summary of coronavirus Yellow Card reporting, which was updated on a regular basis.

2) The MHRA publishes a complete listing of all suspected adverse reactions that have been reported to the MHRA via the Yellow Card scheme for the following vaccines:

   - COVID-19 Vaccine Pfizer/BioNTech monovalent
   - COVID-19 Vaccine Pfizer/BioNTech bivalent
   - COVID-19 Vaccine AstraZeneca
   - COVID-19 Vaccine Moderna monovalent

- COVID-19 Vaccine Moderna bivalent
- COVID-19 Vaccine - brand unspecified or not in routine use in the UK
- COVID-19 Vaccine Novavax

These listings include all reports received from healthcare professionals, members of the public, and pharmaceutical companies. The listings are interactive and the filters on the left-hand side can be used to break the data down further, including to display numbers of reactions according to their seriousness. These reports can be accessed here: What is being reported | Making medicines and medical devices safer (mhra.gov.uk).

There are several vaccines used in the UK vaccination programme which aren't currently published on our website. For the vaccines that aren't available on our website, please see Table 1 below which details the numbers of UK spontaneous Adverse Drug Reactions (ADRs) within the serious[1] ADR reports received for each of these vaccines. Please note that listings for these vaccines will be published on our website using the same format as above in due course, and as such this information is exempt under Section 22 of the Freedom of Information Act (intended for future publication).

Table 1: Numbers of UK spontaneous suspected Adverse Drug Reactions (ADRs) within the serious ADR reports received by the MHRA for COVID-19 Vaccine VidPrevtyn Beta, Comirnaty Omicron XBB.1.5 and Spikevax Omicron XBB.1.5, up to and including 18/01/2024

COVID-19 Vaccine	Number of serious ADR reports	Number of ADRs within serious ADR reports
COVID-19 Vaccine VidPrevtyn Beta	665	2027
Comirnaty Omicron XBB.1.5	966	2606
Spikevax Omicron XBB.1.5	374	1061

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

- A reported reaction does not necessarily mean it has been caused by the vaccine, only that the reporter had a suspicion it may have. The fact that symptoms occur after use of a vaccine, and are reported via the Yellow Card Scheme, does not in itself mean that they are proven to have been caused by the vaccine. Underlying or concurrent illnesses may be responsible and such

[1] The seriousness criteria for ADR reporting were determined by a working group of the Council for International Organizations of Medical Sciences (CIOMS) and are defined as 6 possible categories which are documented on the Yellow Card. Reporters can select one or more of the following criteria by ticking the appropriate box on the Yellow Card. The criteria are: (1) patient died due to reaction (2) life threatening (3) resulted in hospitalisation or prolonged inpatient hospitalisation (4) congenital abnormality and (5) involved persistent or significant disability or incapacity or (6) if the reaction was deemed medically significant. ADR reports can also be classified as serious if the reactions within them are considered serious in our medical dictionary.

events can also be coincidental.

- It is also 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. ADR reporting rates are influenced by the seriousness of ADRs, their ease of recognition, the extent of use of a particular drug or vaccine and may be stimulated by promotion and publicity about a drug or vaccine.

3) The MHRA do not hold an estimated rate for UK serious ADRs reported to the MHRA therefore we are unable to provide this information.

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,

FOI Team
Safety and Surveillance
Medicines and Healthcare products Regulatory Agency

If you have a query about this email, please contact us. If you are unhappy with our decision, you may ask for it to be reviewed. That review will be undertaken by a senior member of the Agency who has not previously been involved in your request. If you wish to pursue that option please write to the Communications Directorate, 4-T, Medicines and Healthcare products Regulatory Agency, (via this email address). After that, if you remain dissatisfied, you may ask the Information Commissioner at:

The Information Commissioner's Office
Wycliffe House
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