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: FOI2024/00560

16th October 2024

Dear [redacted],

Thank you for your FOI request dated 19 September 2024, where you requested the following information:

> "As per Freedom of Information Act, I request details of the three batch numbers that appear most often in the Adverse Drug Reaction (ADR) reports, including those with a fatal outcome, reported to the Yellow Card scheme in association with the COVID-19 Pfizer/BioNTech Vaccine, COVID-19 Vaccine AstraZeneca, COVID-19 Vaccine Moderna and GSK/Sanofi VidPrevtyn Beta vaccine, including separate aggregated tables for patient age and patient sex, for all the three batches combined, for each of the four COVID-19 vaccines requested, up to the date of this email which is 19/09/2024."

MHRA Response

We confirm that we hold the information you have requested and provide it below.

Please find below the three most frequently reported batch numbers up to and including 19/09/2024 for the requested Covid-19 vaccines:

Table 1: Three most frequently reported batch numbers within UK spontaneous suspected ADR reports for requested COVID-19 vaccines up to and including 19/09/2024.

Vaccine	Batch number
COVID-19 MRNA VACCINE BIONTECH*	ER1741, ER1749, EW4109
COVID-19 VACCINE MODERNA*	3002332, 3002621, 3001659
COVID-19 VACCINE ASTRAZENECA	4120Z003, 4120Z001, PV46664
VIDPREVTYN BETA	W2B042M, W2B061M, W2B051M

*excludes bivalent and booster Covid-19 vaccines

We would also like to provide an update in this letter to the previous response for FOI 24/301, On review of the data extracted, it has since become clear that the breakdown by age provided in table 2 and 4 of the response was incorrect. Please accept my sincerest apologies for this error. This error has been resolved in the data provided below.

Tables 2 and 3: Covid-19 Vaccine BioNTech aggregated patient age groups and sex for batch numbers stated in Table 1.

Patient age (years)	Number of Yellow Card reports
0 - 9	15
10 - 19	126
20 - 29	1215
30 - 39	3061
40 - 49	2365
50 - 59	2167
60 – 69	1357
70 - 79	1080
80 - 89	393
90 - 99	42
100 +	1
Unknown	1540

Patient Sex	Number of Yellow Card reports
Female	9702
Male	3064
Unknown	596

Tables 4 and 5: Covid-19 Vaccine Moderna aggregated patient age groups and sex for batch numbers stated in Table 1.

Patient age (years)	Number of Yellow Card reports
0 - 9	4
10 - 19	116
20 - 29	1305
30 - 39	2116
40 - 49	1661
50 - 59	135
60 – 69	12
70 - 79	3
80 - 89	2
Unknown	837

Patient Sex	Number of Yellow Card reports
Female	4322
Male	1554
Unknown	315

Tables 6 and 7: Covid-19 Vaccine AstraZeneca aggregated patient age groups and sex for batch numbers stated in Table 1.

Patient age (years)	Number of Yellow Card reports
0 - 9	5
10 - 19	154
20 - 29	1641
30 - 39	2462
40 - 49	3537

50 - 59	8545
60 – 69	4129
70 - 79	184
80 - 89	29
90 - 99	5
Unknown	2347

Patient Sex	Number of Yellow Card reports
Female	16044
Male	6115
Unknown	879

Tables 8 and 9: Covid-19 Vaccine Vidprevtyn Beta aggregated patient age groups and sex for batch numbers stated in Table 1.

Patient age (years)	Number of Yellow Card reports
0 - 9	1
10 - 29	2
30 - 59	1
60 – 69	2
70 - 79	122
80 - 89	101
90 - 99	14
100 +	1
Unknown	20

Patient Sex	Number of Yellow Card reports
Female	126
Male	108
Unknown	30

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

- A reported reaction does not necessarily mean it has been caused by the vaccine, medicine, or device only that the reporter had a suspicion it may have. The fact that symptoms occur after use of a vaccine, medicine, or device, and are reported via the Yellow Card scheme, does not in itself mean that they are proven to have been caused by it. Underlying or concurrent illnesses may be responsible and such 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 or compare the safety profile of different vaccines, medicines, or devices. ADR and Device incident reporting rates are influenced by the seriousness of adverse reactions, their ease of recognition, the extent of use of a particular medicine or device, and may be stimulated by promotion and publicity. Reporting tends to be highest for newly introduced medicines during the first one to two years on the market and then falls over time.

Yellow Card data cannot be used to compare the safety profile of different vaccine batches. It is not mandatory to provide batch numbers when submitting an adverse reaction report for a medicine or vaccine, and therefore the number of reports provided may not be a true reflection of the number of Yellow Card COVID-19 vaccine reports submitted for the respective batches.

Not all batches of the COVID-19 vaccines are the same size, and some batches may have had more wastage than other batches or be distributed more widely outside of the UK. Therefore, we would not expect the number of ADR reports for all batches to be the same as they have been administered to different numbers of patients.

Furthermore, different batches would have been used at different stages of the vaccination campaign, and in different patient groups, which could also impact reporting rates. For example, reporting rates were typically higher at the beginning of the vaccination campaign as individuals received their first dose and the likelihood of experiencing a reaction, as well as the propensity to report it, differs across patients of different ages.

Similarly, it is important to note that Yellow Card data cannot be used to derive side-effect rates or compare the safety profile of COVID-19 vaccines between sexes and in different age groups as many factors can influence ADR reporting. For example, the extent of the use of different COVID-19 vaccines and populations vaccinated at different stages of the vaccination campaign, and the preferred COVID-19 vaccines in different age groups. Data from the Yellow Card scheme and other reporting systems suggest that for medicines in general a higher proportion of reports relate to women rather than men. This has also been observed in relation to COVID-19 vaccines however our continued safety surveillance of these vaccines does not suggest that adverse reactions are more likely to occur in women compared to men.
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.

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