Medicines & Healthcare products
Regulatory Agency

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom
gov.uk/mhra

[redacted]

23 April 2024

Dear Ms [redacted]

FOI 24/301

Thank you for your Freedom of Information (FOI) request dated 22 March where you requested:

"The three most frequently reported batch numbers for each of the four vaccines listed on my original request. 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."

I can confirm that the MHRA hold the information requested. Please find below the three most frequently reported batch numbers up to and including 31/01/2024 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 31/01/2024.

Vaccine	**Batch Numbers**
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

Tables 2 and 3: Covid-19 MRNA 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
20-29	176
30-39	1376
40-49	3124
50-59	2295
60-69	2141
70-79	1255
80-89	1051
90-99	331
>100	34
Unknown	1536

Patient Sex	Number of Yellow Card reports
Female	9692
Male	3047
Unknown	595

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
20-29	172
30-39	1494
40-49	1975
50-59	1560
60-69	93
70-79	11
80-89	2
90-99	2
Unknown	827

Patient Sex	Number of Yellow Card reports
Female	4293
Male	1537
Unknown	310

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	146
20-29	1503
30-39	2252
40-49	3265
50-59	7853
60-69	3730
70-79	162
80-89	26
90-99	5
Unknown	2140

Patient Sex	Number of Yellow Card reports
Female	14643
Male	5641
Unknown	1098

Tables 8 and 9: 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
30-39	2
60-69	1
70-79	2
80-89	148
90-99	107
>100	9
Unknown	23

Patient Sex	Number of Yellow Card reports
Female	143
Male	111
Unknown	39

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.

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:

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Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF