Medicines & Healthcare products
Regulatory Agency

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[redacted]

19th March 2023

FOI 24/191

Dear [redacted]

Thank you for your email dated 26th February 2024 where you asked for information on the following:

- *For adverse reactions. AstraZenaca Batch Numbers PV46663 and PV46678 Pfizer Batch Number FK9413.*

It is important to note that 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 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.

Following a search of our database up to and including the 23rd February 2024, the total number of UK spontaneous suspected Adverse Drug Reaction (ADR) reports associated with each of the batch numbers requested is presented in Table 1 below.

Table 1: All UK spontaneous suspected ADR reports associated with COVID-19 Vaccine AstraZeneca batch numbers PV46663 and PV46678, and COVID-19 Vaccine Pfizer/BioNTech monovalent batch number FK9413.

Brand Name	Batch number	Total number of ADR reports
COVID-19 Vaccine AstraZeneca	PV46663	3787
COVID-19 Vaccine AstraZeneca	PV46678	2175
COVID-19 Vaccine Pfizer/BioNTech monovalent	FK9413	952

On a Yellow Card report, batch number is an optional field and is also in free text format. Therefore, this information may not always be provided or when this information is provided, entries will vary between reports depending on how the reporter has entered this information. Providing batch information requires manual review. We have now implemented a more robust way of providing this information, one of which is including four variations of batch number:

- A space between letters and numbers
- A dash between letters and numbers
- Variations between the number 0 and the letter O
- Variations between the number 2 and the letter Z

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Please find attached a Vaccine Analysis Print (VAP) for each of the COVID-19 vaccine batches requested. This lists all suspected adverse drug reactions reported to the MHRA for the COVID-19 vaccine AstraZeneca batch numbers PV46663 and PV46678 and for COVID-19 Vaccine Pfizer/BioNTech monovalent for batch number FK9413.

Please note that 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.

I hope the information provided is helpful. 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 Group