Medicines & Healthcare products
Regulatory Agency

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

[redacted]

26th February 2024

FOI 24/105

Dear [redacted]

Thank you for your Freedom of Information (FOI) request dated 04 January 2024 where you asked for the data published on our website in FOI 22/611 to be recalculated and updated. This includes details of the 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 COVID-19 vaccines. In your request, you specifically ask for the data relating to COVID-19 AstraZeneca vaccine.

As you may know, all FOI responses are a record of MHRA's position at that point in time and are not retrospectively updated in line with current policies and procedures. This response will also be published on our website in due course.

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

To be helpful however, we have provided you with the latest information we hold regarding the ten most frequently reported batch numbers of COVID-19 vaccine AstraZeneca; please see table 1 below.

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Table 1: Total number of UK spontaneous ADR reports for the 10 most reported batch numbers for the COVID-19 AstraZeneca vaccine up to and including 31st January 2024.

Batch number	Number of ADR reports
4120Z003	7511
4120Z001	6844
PV46664	6977
PV46671	5545
4120Z002	5220
AB0012	4990
PV46672	4961
PW40009	4481
PV46669	4147
PV46673	4079

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.

Lastly, 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.

I hope the information provided is helpful.

Yours sincerely,

FOI Team,
Safety and Surveillance Group

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The Information Commissioner's Office Wycliffe House
Water Lane Wilmslow Cheshire SK9 5AF

It may be helpful for you to consider that the batch number entry is a free text field on a Yellow Card form and as such includes vast amounts of variation where reporters have mistyped, added spaces/hyphens, or included expiry dates.