Medicines & Healthcare products
Regulatory Agency

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[redacted]

28th March 2024

FOI 24/208

[redacted]

Thank you for your Freedom of Information (FOI) request dated 29 February 2024:

> *Please could you clarify for the batch number 4120Z001 Maria Caulfield responded to Fleur Andersons request for information on this batch (copy attached) and stated that up to and including 17th January 2024 that 7112 adverse events were recorded against 4120Z001, then only two weeks later according to your chart up to and including 31st January 2024 6844 were recorded , 268 less?*
>
> *Please can you also clarify for the batch number 4120Z002 on the top 50 list for 2022 Foi 22762 (copy attached) there are a total of 5914 adverse events adding lines 8 and 35 now the figure given up to and including 31st January 2024 is 5220*
>
> *Please could you correct both of the above and also include deaths per batch in table?*

In your previous FOI 24/105, you asked for the data published on our website in FOI 22/611 to be recalculated and updated; for this we provided the most up to date information we hold and explained the process for extracting data relating to batch number.

Further to this, in your new request FOI 24/208, you have asked for further clarification around the data we provided to you, specifically in relation to batch numbers 4120Z001 and 4120Z002, with reference to other published information in the form of parliamentary questions and previous FOI responses.

As stated in FOI 24/105 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. The information provided to you in FOI 24/105 is the most up to date information we hold in relation to your request.

Additionally, we explained that 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. Since the time of the responses, you reference in your request and which remain published on our website, we have 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

We cannot account for all variations of batch number reported due to this field being free text. By implementing this to take into account the most common standard variations of batch number, we hope that this allows for consistency in the information we can now provide in responses such as this.

It does mean however that the information is likely to differ from that which has been provided previously. Additionally, due to the time taken to review the batch numbers, this new process allows us to provide information within the appropriate time and cost limit under FOIA.

Further to your request we can provide the number of reports with a fatal outcome alongside the total number of reports that was provided in 24/105, please see table 1 below.

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	Number of ADR reports with a fatal outcome
4120Z003	7511	18
4120Z001	6844	23
PV46664	6977	17
PV46671	5545	16
4120Z002	5220	13
AB0012	4990	13
PV46672	4961	7

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PW40009	4481	14
PV46669	4147	11
AB0011	3932	19

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.

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