FOI 23/305 – adverse events relating to Covid-19 batches to April 2023

REQUEST
23 April 2023

Can you please update this FOI released in April 2022. It's a list of Covid-19 batch numbers with numbers of adverse events and deaths reported relating to each batch number. Can you update the information, providing figures up to April 2023.

https://www.gov.uk/government/publications/freedom-of-information-responses-from-the-mhra-week-commencing-6-june-2022/freedom-of-information-request-on-specific-batch-numbers-on-the-adverse-reactions-reported-following-the-covid-19-vaccinations-foi-22661

MHRA RESPONSE
23 May 2023

Thank you for submitting an FOI request dated 23rd April 2023, where you requested updated data as provided in FOI 22/611. 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 the COVID-19 Pfizer/BioNTech Vaccine, COVID-19 Vaccine AstraZeneca and COVID-19 Vaccine Moderna.

As mentioned in the response to FOI 22/611, the MHRA continuously monitors the safety of vaccines through a variety of pharmacovigilance processes including the Yellow Card scheme. As part of our signal detection processes all adverse reaction reports received by the Yellow Card scheme are assessed and cumulative information reviewed at regular intervals. The MHRA takes all reports of side effects with the utmost seriousness, including those that sadly report a fatal outcome.

Please note that our analysis of the reports, which takes into account product batch number, did not result in any safety concerns. Please be assured that the MHRA reviews this data regularly and we would communicate any concerns raised with the public and healthcare professionals. If you would like further information on batch usage, please contact the UK Health Security Agency (UKHSA) who hold this information.

As per your request, please find attached Annex 1, which shows the total number of UK spontaneous suspected Yellow Card reports, including fatal reports, for the 10 most reported batch numbers up to and including 30th April 2023 for COVID-19 Pfizer/BioNTech vaccine, COVID-19 AstraZeneca vaccine, and COVID-19 Moderna vaccine, respectively.

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 can confirm the total sum of the UK spontaneous suspected ADR reports received by the MHRA from the 10 most commonly reported batches is 33,994 reports for COVID-19 Pfizer/BioNTech vaccine, 49,132 reports for COVID-19 AstraZeneca vaccine, and 13,377 reports for COVID-19 Moderna vaccine.

Please note that reporters have the option to include batch number within a free text field, however this is not mandatory. As this information is collected in a free text field, entries within that field may vary between reports depending on how the reporter details the batch number. For the purpose of this FOI request, we have searched the batch number field for batch numbers as they are listed in Annex 1 and have also accounted for the following variations:

- 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

Considerations detailed in FOI 22/611 continue to apply in this request. In particular, it is important to note that as it is not mandatory to provide batch numbers when submitting an adverse reaction report for a medicine or vaccine, 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.
When considering the attached spontaneous ADR data, it is important to be additionally aware of the following points:

• 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 fact that symptoms occur after use of a vaccine, and are reported via the Yellow Card Scheme, does not in itself mean that they are proven to have been caused by the vaccine. 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. ADR reporting rates are influenced by the seriousness of ADRs, their ease of recognition, the extent of use of a particular drug or vaccine, and may be stimulated by promotion and publicity about a drug or vaccine.

I hope the information provided is helpful.
Yours sincerely,

FOI Team,
Safety and Surveillance Group

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, Medicines and Healthcare products Regulatory Agency, (via this email address).

After that, if you remain dissatisfied, you may ask the Information Commissioner at:

The Information Commissioner's Office
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