Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

[redacted]

MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

www.gov.uk/mhra

20th March 2023

Dear [redacted]

FOI 23/143

Thank you of your email dated 18 February 2023, where you requested:

a) the number of Yellow Card reports associated with AstraZeneca, batch AB0002.

b) Of these reports, i) how many were in relation to a suspected fatal adverse reaction and ii) how many were in relation to heart failure.

Following a search of our database up to and including 03 February 2023, I can confirm that the MHRA have received 3182 spontaneous suspected Adverse Drug Reaction (ADR) reports associated with batch number AB0002 for the COVID-19 Astra Zeneca vaccine reported in the UK. Of these suspected ADR reports, 42 reported a fatal outcome. Unfortunately, we are unable to disclose the number of reports which specifically report heart failure for this vaccine batch as the number of reports is less than 5. We are unable to provide data where the number of reports is less than 5 due to patient and reporter confidentiality.

Please note that batch number is not a required field when submitting a Yellow Card report and as such is not always provided. Please also note that the batch field is a free-text field, meaning any batches provided where it is unclear if it is AB0002 specifically, have not been included.

Conclusions on the safety and risks of the vaccines cannot be made on the data provided alone. 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. Please be assured that the MHRA reviews Yellow Card 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.

Lastly when reviewing ADR data, you should remember that:

- Reporters are asked to submit Yellow Card reports even if they only have a suspicion that the medicine or vaccine may have caused the adverse drug reaction. The existence of an adverse drug reaction report does not necessarily mean that the medicine or vaccine has caused the reaction.
- Many factors have to be considered when assessing whether a medicine or vaccine has caused a reported adverse drug reaction. When monitoring the safety of medicines, MHRA staff carry out careful analysis of these factors.

For a vaccine to be considered safe, the expected benefits will be greater than the risk of having harmful reactions. It is important to note that most people receive vaccinations without having any serious side effects. The MHRA continuously monitors the safety of vaccines through a variety of pharmacovigilance approaches 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. Our analysis of the Yellow Card reports takes into account product batch number.

I 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 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, 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:

The Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow

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