Medicines & Healthcare products Regulatory Agency

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

[redacted]

22nd February 2024

Dear [redacted]

FOI 24/108

Thank you for your Freedom of Information (FOI) request dated 1 February 2024 in which you requested *'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, COVID-19 Vaccine Moderna and GSK/Sanofi VidPrevtyn Beta vaccine up to the date of this email which is 31/1/2024. I would also like to know the ages and sex of those reporting for each.'*

I can confirm that we do hold the requested information on batch numbers, patient age and patient sex where these are provided by the reporter of the Yellow Card. In order to be able to respond to your request however, we require further clarification surrounding the information you are seeking. Within your request you ask for the *batch numbers that appear most often in the Adverse Drug Reaction (ADR) reports* – we would be grateful if you could confirm how many batch numbers per vaccine you would like this information for.

In accordance with Section 16 of the FOI, concerning the provision of advice and assistance to those requesting information under FOI, we have provided some examples of what we are able to provide for you based on your request, within the appropriate limit under Section 12 of the FOIA:

- The most frequently reported batch number for each of the four vaccines listed on your original request, including separate aggregated tables for patient age and patient sex, for each of the four batches.
- The three most frequently reported batch numbers for each of the four vaccines listed on your original request. Including separate aggregated tables for patient age and patient sex, for all the three batches combined, for each of the four COVID-19 vaccines requested.
- The ten most frequently reported batch numbers for each of the four vaccines listed on your original request.

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
Medicines and Healthcare products Regulatory Agency

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
Cheshire
SK9 5AF