Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

[redacted]

MHRA
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12th September 2023

Dear [redacted]

RE: FOI 23/626

Thank you for your email dated 13th August 2023, where you asked questions following the last FOI response you received as well additionally asking for:

You did not seem to respond to the request for the data for each CCG. This seems to suggest that you actually have the data that was requested but are refusing to disclose it due to a vague "confidentiality" concern. Your denial is not expressed in accordance with the FOI Act nor does it seem to be in accordance with the act as disclosure would not compromise any patient data as data from the patients is not requested, just the figures.

In line with monitoring faulty batches then such data is required in order that the MHRA could warn, track or intervene if a bad batch or series of batches was detected. Failure to disclose such data also prevents the public from being aware of any adverse reaction trends that may be below MHRA thresholds but be relevant or significant to certain clinical cohort groups that may be represented at certain CCG's due to the distribution clinical care specialities within the region.

In particular can you please disclose any historical adverse reaction data by reports per month and region that shows "gout" type reactions to Covid vaccines (existing gout being triggered to spread or get worse after covid vaccines) nationally and regionally.

As the request doesn't seem to be outside the FOI Act or compromise patient confidentiality please reconsider this reply and supply the information requested. If it is refused again please escalate it to an internal review.

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Firstly, please accept my apologies for the confusion and that you were unhappy with the response to your previous FOI. In response to the questions following your previous FOI, to clarify that while we hold some information on reporters addresses and the GP practices they work at, that this information is not available for the majority of reports (where they are reported by vaccinees or their families). Where we do hold information on reporter address this is not mapped to individual GP practice names, which would be recorded in a free text address field. Reporter names and addresses are protected as confidential information under the Yellow Card Privacy Policy; as outlined in the policy we can provide aggregated information. For addresses we aggregate to CCG, meaning that we can provide location-based information for both patient and healthcare professional reports, in the interests of being as helpful as possible while protecting reporters privacy. I hope that answers your concerns regarding the data we hold in relation to your previous FOI response.

Please note our analysis of Yellow Card reports alongside other data sources will always take into account various factors including the batch of the medicine or vaccine. Not all batches are the same size or area of distribution. 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.

Further to your request for data as above, up to and including 30th August 2023 I can confirm the MHRA has received 330 direct UK spontaneous Yellow Card reports for all COVID-19 vaccines where gout has been recorded as a suspected adverse reaction. It's important to note that this number may not represent those that had existing gout which got worse after the COVID-19 vaccination, as information on medical history is not a mandatory field and therefore not always provided by the reporter.

Please see the attached table which lists the number of reports of COVID-19 vaccines associated with gout by reporter CCG or Health Board. As you will be aware addresses and post codes are not mandatory fields, therefore, this information may not be a complete representation of all reports from within each area. Where we have less than 5 reports we have replaced this with ^ as this information is exempt from release under section under Section 40 (personal data) and Section 41 (information provided in confidence) of the Freedom of Information (FOI) Act 2000. Section 40 protects personal data, the disclosure of which would breach one or more of the data protection principles. Section 41 is an absolute exemption and no consideration of the public interest is required, except to state that we consider its disclosure to constitute an actionable breach of confidence. This is the same for data published in COVID-19 vaccine reports.

Please note we have not provided the number of reports per month for each CCG as this would result in all of the data provided being censored as per the above exemption. To try to be helpful and provide you with as much data as possible, we have provided you with the total number of reports for COVID-19 vaccines and gout by month, listing the CCGs connected to a least one report within the single month period.

When considering the spontaneous data provided in this response, it is important to keep in mind 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 drug or 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. Reporting tends to be highest for newly introduced medicines during the first one to two years on the market and then falls over time. For these reasons the above data should not be used as a basis for determining incidence of side effects. During assessment we take into account of the variable levels of reporting as part of our monitoring procedures.

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,
Vigilance and Risk Management of Medicines Division