Medicines & Healthcare products Regulatory Agency

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[redacted]

31 May 2023

FOI 23/219
FOI 23/244
FOI 23/352

Dear [redacted]

Thank you for your emails dated 24 March 2023, 3rd April 2023 and 17 May 2023 in which you requested information concerning Yellow Card reports for specific batch numbers of COVID-19 Vaccine AstraZeneca. Please accept our apologies for the delay in responding to your first two requests.

As you will know, conclusions on the safety and risks of the COVID-19 vaccines cannot be made on the Yellow Card data alone. As outlined in Dr Cave's letter to you of 26 May 2023, we have in place a proactive strategy to do this for COVID-19 vaccines. Through this strategy we supplement our routine safety monitoring with other epidemiology studies, including data analysis on national vaccine usage, anonymised GP-based electronic healthcare records, and other healthcare data to proactively monitor safety. These combined safety data enable the MHRA to detect side effects or safety issues associated with COVID-19 vaccines. We also consider the international position based on data from other countries using the same vaccines. Through this we can then take any necessary action to best protect public health.

Specifically in relation to batch use, we would not expect the number of Adverse Drug Reaction (ADR) reports for all batches to be the same as they have been administered to different numbers of patients and vary in size.

Furthermore, different batches would have been used at different stages of the vaccination campaign, and in different patient groups, which also impacts 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 communicate any concerns raised with the public and healthcare professionals.

Please see the below responses to each of your three Freedom of Information (FOI) requests. When considering the data below, 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 the batch you requested have not been included.

You should also consider the below when reviewing the data within this response:

- 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.

FOI 23/219

Following a search of our database up to and including 30 April 2023, I can confirm that the MHRA have received 5341 spontaneous suspected Adverse Drug Reaction (ADR) reports associated with batch number PV46671 for the COVID-19 AstraZeneca vaccine reported in the UK. Of these suspected ADR reports, 15 reported a fatal outcome.

Regarding your request in relation to how many people made those reports, I can confirm that all Yellow Card reports will have a least one reporter. In some instances, we may have received a Yellow Card report from the patient themselves and another from their healthcare professional regarding the same experience. In this instance, where we identify the reports are duplicates, we can merge them, ensuring all information from both reports are captured in one place. Additionally, to note some reports are submitted indirectly to us from patients of healthcare professionals via pharmaceutical companies.

As explained above, the MHRA holds the information that you have requested. However, we have also determined that the information is exempt under Section 12 of the FOI Act and we cannot process your request any further. Section 12 of the Act allows public authorities to refuse requests where the cost of dealing with them would exceed the appropriate limit, which for central government is set at £600. This represents the estimated cost of one person spending 24 working hours in determining whether the department holds the information, locating, retrieving and extracting the information.

Although we hold information on how many individuals made these reports, this information is not easily extractable. As stated above, the MHRA has received 5341 spontaneous suspected ADR reports associated with batch number PV46671 for the COVID-19 AstraZeneca vaccine reported in the UK. An individual would need to manually open each Yellow Card report to check the number of reporters within an ADR report. Checking a single Yellow Card report for evidence of follow up would take a minimum of 45 seconds and in some instances longer. This would equate to an individual spending over 65 hours for this aspect of your request alone, not including further review to determine if your request for information had been answered and drafting the response.

If refined to fall under the appropriate time limit for FOI requests, the MHRA cannot provide more granular information and would have to apply the Section 41 exemption. The Agency considers this criteria is met as outlined for FOI 23/244 below, in relation to information provided as part of, or in response to, a Yellow Card report.

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FOI 23/244

Following a search of our database up to and including 29 March 2023, the MHRA have received 1523 UK spontaneous suspected ADR reports associated with batch number AB0002 for the COVID-19 Vaccine AstraZeneca that have been reported by a healthcare professional.

The remainder of the information requested under FOI 23/244, including how many of the COVID-19 Vaccine AstraZeneca reports that report batch AB0002 alongside a fatal outcome had a post-mortem or a coroner's verdict associating the death with the vaccine, as well as how many of the reports had a pre-existing life limiting condition, is exempt from disclosure under Section 41 the FOI act.

The MHRA consider the use of Section 41 to be appropriate for this request for the reasons detailed below:

S41(a) the information must be provided by a third party

Members of the public and healthcare professionals voluntarily submit reports of suspected side effects to the MHRA through the Yellow Card scheme.

S41 (b) - to be met, disclosure of the withheld information must constitute an actionable breach of confidence. In the ICO's view a breach will be actionable if:

a) The information has the necessary quality of confidence

Information will possess the necessary quality of confidence if;

- ***it is more than trivial;***

The figures requested in relation to post-mortems, coroners' verdicts and past medical history are part of clearly sensitive health data submitted through or as follow up on Yellow Card reports.

The information requested under this FOI could be cross-referenced with the analysis prints (which provides a list of adverse reactions reported for each COVID-19 vaccine including whether the report was one with a fatal outcome) published and other information found in the summary of Yellow Card reporting.

We consider that the data requested relating to post-mortems, coroners' verdicts and past medical history, is special category data when linked to other elements within a report and, cumulatively, would be potentially identifiable. We therefore consider that the information requested is more than trivial.

- ***not otherwise accessible***

The information is held on the Yellow Card database and is not otherwise accessible.

b) The information has the necessary quality of confidence and was communicated in circumstances importing an obligation of confidence.

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As part of our proactive vigilance surrounding the COVID-19 vaccines, the MHRA collects reports of suspected side effects via the Yellow Card scheme. The Yellow Card scheme underpins medicines and vaccines safety monitoring in the UK. Through this scheme, members of the public and healthcare professionals voluntarily submit reports of suspected side effects to the MHRA. The key strength of the Yellow Card scheme is that it allows any member of the public or health professional across the UK to immediately alert us to any concerns they have without a formal diagnosis. As such, Yellow Card reports are constantly reviewed and may contribute to the identification of a potential safety signal. As outlined above, the information requested, where held, is received as part of , or as a follow up to, a Yellow Card report and are contained within the same database with the same Privacy and legal requirements.

The Agency Yellow Card Privacy Policy[1] states that:

"We do not share your identity with any person outside the MHRA without your explicit consent unless we are required or permitted to do so by law. Examples include if we receive a court order to do so or if you are a healthcare professional reporting an adverse incident relating to a medical device, further details of which can be found below. Exceptionally, we may share this where we have established a lawful basis for sharing personal data and can demonstrate that it is both necessary and proportionate to do so.

We may receive requests for Yellow Card report data under the Freedom of Information Act. While we are legally obliged to provide some of the requested information, we only provide high-level summary information with all person-identifiable data excluded." (my emphasis).

Our lawful basis for processing personal data is General Data Protection Regulation (GDPR) Article 6(1)(e), which allows us to process personal data when this is necessary to perform our public tasks as a regulator.

The lawful bases we rely on to process special category personal data are Article 9(2)(i) of the GDPR and Schedule 1 part 1(3) of the DPA, both of which enable us to process such information when it is necessary for reasons of the public interest in the area of public health.

Where we share Yellow Card data for scientific or public health research purposes, we rely on GDPR Article 9(2)(j) as our lawful basis for processing special category personal data and Schedule 1 part 1(4) of the DPA. These bases permit us to process personal data for these purposes where it is in the public interest, subject to appropriate safeguards to protect the reporter/patient's rights and freedoms. We consider that the information requested, taken as a whole, meets that threshold for special category personal data and are considered to be submitted to the MHRA in confidence. The above information is outlined in our Privacy Policy[1].

Whether or not all or any of this data is special category data, we cannot rely on legal obligation to disclose it, other than on the basis of consent or legitimate public health interests. The ICO guidance[2] relied upon here states that:

[1] https://coronavirus-yellowcard.mhra.gov.uk/privacy-policy
[2] https://ico.org.uk/media/for-organisations/documents/1213/personal-information-section-40-regulation-13.pdf

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Although you have a legal obligation to respond to an FOI or EIR request, the test for the exemption is whether disclosure 'otherwise than under' these laws would contravene the data protection principles. Therefore, you cannot argue that the legal obligation basis at 6(1)(c) justifies disclosure under FOIA or the EIR.

1. ***Unauthorised disclosure would cause a specific detriment to either the party which provided it or any other party; and***
2. ***Although Section 41 is an absolute exemption, the law of confidence contains its own built in public interest test with one defence to an action being that disclosure is in the public interest.***

Detriment may be assumed where the information concerns the individual's personal or private life, which we consider this information does. Notwithstanding, we consider that disclosure of this information would not be in the public interest for the following reasons.

The MHRA has been working proactively to encourage members of the public or health professionals across the UK to immediately alert us to any concerns they have without a formal diagnosis using the Yellow Card scheme. The information and data provided to us by these third parties are shared in confidence and, as above, are personal data. Sharing the information and data received with the enquirer would not reflect the commitments in MHRA's confidentiality agreements which would be of detriment both to the application of the Agency's regulatory function and public health more widely. As this is personal data in relation to an individuals' medical information, this would be of detriment to them and may damage the engagement with the scheme.

We have carefully considered whether the law of confidence would be breached, and whether, notwithstanding this, there is sufficient public interest in disclosure. We consider that disclosure of this information is not in the public interest and, therefore, do not consider any such breach defensible. Yellow Card reports are constantly reviewed and may contribute to the identification of the individual submitting the report or to whom the report is about.

FOI 23/352

I can confirm that as of the 24 May 2023 the MHRA have received 42 UK spontaneous suspected Adverse Drug Reaction (ADR) reports for COVID-19 Vaccine AstraZeneca that report the AB0002 batch alongside a fatal outcome.

The remainder of the information requested under FOI 23/352 is exempt from disclosure under the FOI act. As outlined above, the information requested under FOI 23/219 exceeds the appropriate time limit as defined by the FOI act. The information you have requested under FOI 23/352, in addition to that requested above, continues to exceed the time limit defined by the FOI act and is therefore exempt under Section 12 of the Act. Furthermore, if refined to fall under the appropriate time limit, the MHRA is unable to disclose the information requested under 23/352 and would apply the Section 41 exemption. The Agency considers this criteria is met as outlined for FOI 23/244 above, in relation to information provided as part of, or in response to, a Yellow Card report.

As you will know, 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

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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
Medicines and Healthcare products Regulatory Agency

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