FOI 23/012 & FOI 23/014

26th January 2023

Dear

Thank you for your emails dated 7 and 9 January 2023 where you asked for clarification on the MHRA response to FOI 21/1267 as well as several questions surrounding the data included in our coronavirus vaccine - summary of Yellow Card reporting. Please see below for the response to each of your specific questions.

FOI 23/012

a) Does the MHRA collate and include ADR's for Vaxzevria (Oxford Astra zeneca vaccine) administered outwith the UK in their tally of ADR's for this brand or is the Yellow Card figure made up of UK based ADR reports only?

The information displayed in our summary of Yellow Card reporting concerns Adverse Drug Reaction (ADR) reports from the UK only. Whilst the data presented in the published summary concerns UK data only, it is important to note that the MHRA work with our international counterparts to gather information on the safety of vaccines in other countries. When conducting our analysis on the UK Yellow Card data and specific safety topics, we also take into account the international experience based on data from other countries using the same vaccines.

b) If the answer to (a) is no, can you please advise who would have the global figure for ADR's in respect of Vaxzevria to include reports from every country where it is used?

The Marketing Authorisation Holder (MAH) for Vaxzevria, AstraZeneca, will hold the global figure for ADR reports in which the suspect vaccination is listed as Vaxzevria.

c) Despite the fact that Covishield does not hold a UK PL does the MHRA collate and include Covishield ADR's in the overall tally of ADR's in respect of Vaxzevria?

The MHRA includes the UK spontaneous ADR reports we have received in association with Covishield within the total of reports for COVID-19 Vaccine AstraZeneca within the summary of Yellow Card reporting. Please note that as Covishield is not used in the UK, the number of UK spontaneous ADR reports for this product are very small as they will concern UK nationals who received the Covishield vaccine abroad.

d) If the answer to (c) is no, could you please explain why not.

Please see response to c).

FOI 23/014

Could you please explain how sections 35 and 43 of the FOIA permits the MHRA to withhold information re specific Covid vaccine batches to members of the public in the UK when they are sharing them with other agencies and they are appearing on the internet? Surely the exemptions in section 35/43 of FOIA allowing information to be withheld from members of the public re specific batches of covid vaccine are unsustainable with the placing of specific ADR reports (and specific batch codes), on the internet/in the public domain?

The MHRA issued a response to on 29th December 2021 explaining that the data requested, specifically all reported issues that patients have reported regarding batch 4120z003 COVID-19

vaccine, was exempt under Section 35 of the FOI act. Section 35 of the FOI Act protects the internal deliberative process as it relates to government policy making. At the period of time when the information in FOI 21/1267 was requested, the MHRA and Department of Health were undertaking discussions around the level of data and associated fields that should be placed in the public domain. Until this policy decision had been agreed we were unable to release additional data beyond what was included in the summary of Yellow Card reporting.

Following the conclusion of these discussions, the MHRA is now able to release limited information under the FOI act in relation to vaccine batch number, as long as it does not compromise patient or reporter confidentiality. The MHRA will not provide information under the FOI act which risks sharing the identity of anyone submitting a Yellow Card report with any person outside the MHRA without their explicit consent, unless we are required or permitted to do so by law. As a Yellow Card report is personal data in relation to an individuals' health, sharing this information with the general public would be of detriment to them and may damage the engagement with the Yellow Card scheme.

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