Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

[redacted]

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30th June 2023

Dear [redacted]

RE: FOI 23/381

Please accept our apologies for the delay with this response. Thank you for your email dated 27th May 2023, where you asked for the following:

- Please could you resend the data for tables 3-7 as it was previously displayed.
- Where would I find 'deaths' in current display for adverse events? In the previous versions totals were also given and how many deaths totalled- please provide it in same format as last time with same info offered.

As stated in our previous response, up to and including 08th March 2023 the MHRA have received 1,052 direct UK spontaneous Yellow Card reports associated with a Covid-19 vaccine where the reporter provided a postcode registered within the Isle of Man (IM1 to IM9). As we mentioned before, addresses and post codes are not mandatory fields for completing an ADR report therefore, this information may not be a complete representation of all reports from this area.

Five tables are attached (tables 1 to 5 as per the previous response), which list the reactions received for all the Covid-19 vaccines. Further to your request you will see that we have included reaction counts at the PT level rather than HLT as provided previously. Unfortunately, we cannot disclose the number of reports where there is less than 5, as this information is exempt from release 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.

Further to your second query regarding information on fatal reports. I can confirm we have received a total of 5 reports across all COVID-19 vaccines reporting a fatal outcome. As detailed above, we cannot disclose any further information on these reports.

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