Medicines & Healthcare products Regulatory Agency

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[redacted]

29 April 2024

Dear [redacted]

FOI 24/310 - An estimation of the degree of underreporting of drug adverse events

Thank you for your Freedom of Information (FOI) request dated 31 March 2024 in which you requested *"your estimate of the degree of underreporting to your 'Yellow Card' scheme, and subsequently your estimate of the actual number of deaths and adverse events, likely to be related to the covid 19 vaccine, at least in the view of the injured party".*

The MHRA do not hold an estimate of the degree of underreporting to the Yellow Card scheme, nor an estimate of the actual number of deaths and adverse events, likely to be related to the COVID-19 vaccines.

To be helpful however we have provided some background information below which may be of interest.

Overall ADR reporting rates are variable and are influenced by several factors such as the seriousness of ADRs, their ease of recognition, the extent of use of a particular drug, and may be stimulated by promotion and publicity about a drug. Reporting tends to be highest for newly introduced medicines during the first one to two years on the market and then falls over time. It is important to note that Yellow Card data cannot be used to derive ADR rates or compare the safety profile of drugs or vaccines. During assessment we take into account of the variable levels of reporting as part of our monitoring procedures.

We have in place a Yellow Card strategy that works to increase awareness, actively promote and make reporting to the scheme more accessible for everyone. More information about the Yellow Card scheme and the campaigns we have run can be found via the Yellow Card website.

All spontaneous ADR reporting systems worldwide, like the Yellow Card scheme, are known to be subject to under-reporting. Underreporting of ADRs is thought to occur less frequently

with serious and unlabelled reactions (those reactions which are not yet on the product information). The disproportionality statistical analyses which we use to routinely review the whole Yellow Card database are purposefully designed to minimise the impact of under-reporting by comparing between drugs or vaccines rather than with unexposed patients. Further, the MHRA can also apply additional sensitivity analyses into its statistical evaluation of a potential safety concern which takes account of a range of levels of possible reporting.

Since December 2020, over 151 million doses of COVID-19 vaccines have been administered in the UK in the largest ever vaccination programme. As part of this, we have taken a number of steps to increase public awareness of Yellow Card reporting and therefore the numbers of reports for these products is expected to be higher than for other medicines and vaccines which are not given to such a large number of people over a short time period. Of note, reporting to the scheme across all medicines and vaccines has generally increased since the pandemic demonstrating a wider public awareness compared to previous years.

The MHRA actively worked across the healthcare sector to increase access to reporting systems during the vaccination campaign and specifically integrated information regarding the reporting of side effects to materials provided at the point of care to people receiving vaccination. In addition to social media campaigns, the MHRA issued a Drug Safety Update and a press release informing healthcare professionals and members of the public that reporting to the Coronavirus Yellow Card reporting site will enable the MHRA to rapidly identify new and emerging side effects. The general public were also encouraged to report any suspected side effects to the vaccine to the MHRA via a Yellow Card on the televised press briefings throughout the pandemic. Information on the number of Yellow cards reported and the reporting rates associated with the COVID-19 vaccines was made publicly available throughout the pandemic in our Coronavirus vaccine - summary of Yellow Card reporting - GOV.UK (www.gov.uk).

As background to the second part of your request, you will be aware that the MHRA holds information on suspected adverse reactions and runs the Yellow Card scheme, which collects and monitors information on suspected safety concerns involving healthcare products. The scheme relies on voluntary reporting from the public as well as from healthcare professionals. There are also legal requirements for pharmaceutical companies to report to us. Reports of adverse reactions to COVID-19 vaccines can be found via COVID-19 vaccine reports published on the Yellow Card website.

It is important to be aware that while Yellow Card reports with a fatal outcome are reviewed by MHRA assessors to determine which additional information will be requested from the reporter, in the assessment of a safety issue, Yellow Card reports are evaluated cumulatively, alongside other information and evidence. Causality is not assigned to individual reports, nor is an assessment recorded for individual reports. All the information is assessed on a continual basis to see whether a new side effect is identified, or the safety profile has changed. In addition, we also apply statistical techniques which can tell us if we are seeing disproportionately more cases than we would expect to see based on what is known about background rates of illness in the absence of vaccination. If it is considered that a medicine may be causing the side effect, we will look at the risk of the side effects in relation to its benefits to consider whether regulatory action is needed.

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
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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
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