FOI 23/034

13th February 2023

Dear

Thank you for your Freedom of Information request dated 14th January 2023, where you asked for disclosure of the total number of adverse drug reactions (ADRs) submitted to the Yellow Card scheme concerning COVID-19 vaccines in Scotland, between 8th December 2020 and 14th January 2023. You also requested data on the proportion of reports submitted by healthcare professionals and an estimated rate of under-reporting.

Further to your request, I can confirm that the MHRA has received a total of 35,076 Yellow Card reports from Scotland, between the time period 8th December 2020 to 14th January 2023 in association with the COVID-19 vaccines. This data refers to all COVID-19 vaccines which are currently licensed for distribution in the UK. These reports contained a total of 119,117 adverse reactions. Please note that this value is significantly higher than the number of reports as one report can contain multiple adverse reactions.

Of these 35,076 Yellow Card reports, 200 reported a fatal outcome. Please be aware that a report with a fatal outcome does not necessarily mean that it was caused by the vaccine, only that the reporter has a suspicion it may have been. Underlying or previously undiagnosed illness unrelated to vaccination can also be factors in such reports. The relative number and nature of UK reports with a fatal outcome are subject to many factors that influence ADR reporting. A high proportion of people vaccinated early in the vaccination campaign were very elderly, and/or had pre-existing medical conditions. Older age and chronic underlying illnesses make it more likely that coincidental adverse events including those with a fatal outcome will occur, especially given the millions of people vaccinated. Fatal Yellow Card reports should therefore not be used to directly compare the safety of the different vaccines.

Furthermore, in the years 2021 and 2022 the MHRA received a total of 514,810 Yellow Card reports across all medicines and vaccines. Of these, 106,408 were reported directly by healthcare professionals. This gives an approximate percentage of 21% of Yellow Cards being reported by healthcare professionals. It is important to be aware that reporter qualification may not always be reported accurately.

Suspected ADRs to medicinal products and vaccines are reported to the MHRA on a voluntary basis by healthcare professionals and members of the public through the Yellow Card scheme. The MHRA has seen a significant increase in reports from members of the public over the past few years and

therefore, the ratio of healthcare professional to patient reports is quite different to historical reporting rates. This is attributed to the increased awareness and publicity of the MHRA and the Yellow Card scheme due to significant media attention following the start of the COVID-19 vaccination campaign and MHRA campaign work.

When considering this spontaneous ADR data, it is important to be aware of 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 been. Each year, millions of doses of routine vaccinations are given in the UK alone, and when any vaccine is administered to large numbers of people, some recipients will inevitably experience illness following vaccination.

The fact that symptoms occur after use of a vaccine or medicine, and are reported via the Yellow Card scheme, does not in itself mean that they are proven to have been caused by it. 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 vaccine, and may be stimulated by promotion and publicity about a 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 enclosed data should not be used as a basis for determining incidence of side effects.

Regarding your question on under-reporting, it is important to understand that the reporting rate for spontaneous ADRs is variable and can depend on a multitude of factors. Although some historical studies have estimated only 10% of ADRs are reported, the actual rate is unknown and variable because it is influenced by public awareness and seriousness of the event. In particular, this figure should not be used as the estimated rate of under-reporting for the COVID-19 vaccines in which there is a higher public awareness of reporting suspected side effects, for the reasons detailed below.

MHRA has in place a Yellow Card Strategy to promote the scheme and raise awareness amongst healthcare professionals and patients alike. 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.

Specifically, for COVID-19 vaccines, information about reporting suspected side-effects using the Coronavirus Yellow Card website and app is contained in the materials given to vaccine recipients which are also available on-line. We have also optimised website search functionality and worked with media outlets to encourage them to carry messages about reporting of side effects. We have also run a targeted social media campaign and would encourage anyone seeing this who has not already done so to report through the Coronavirus Yellow Card site.

Since the start of the vaccine campaigns, we have been working in close collaboration across the healthcare system to ensure healthcare professionals and patients are aware of the Yellow Card scheme and how they can report to us. Information on Yellow Card reporting has been included in NHS training materials, as well as the materials available to individuals both before and after vaccination. Both vaccine recipients and healthcare professionals are strongly encouraged to report any suspicion of a side effect to the MHRA.

I hope the information provided is helpful. 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