Medicines & Healthcare products Regulatory Agency

MHRA

Dr Tess Lawrie
By Email: tess@e-bmc.co.uk

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Medicines & Healthcare products Regulatory Agency

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Dear Dr Lawrie,

Analysis of COVID-19 vaccines Yellow Card data

Thank you for your email dated 9th June 2021 regarding the data published in the weekly Yellow Card reporting summary for COVID-19.

Firstly, whilst you have mentioned this in your letter, I would like to emphasise that the nature of Yellow Card reports means that reported events are not always proven side effects. Some events may have happened coincidentally, regardless of vaccination. This is particularly the case when millions of people are vaccinated. Individual reports to the scheme are highly likely to contain more than one reaction and therefore it is not always appropriate to sum the number of reactions from the published analysis prints. It is important to evaluate reports in context of any other information provided within the report and alongside evidence from other sources.

We have in place a proactive strategy to continually monitor the safety of COVID-19 vaccines, and through this strategy we are able to rapidly detect, confirm, and quantify any new risks and weigh these against the expected benefits. The strategy is available to view here: https://www.gov.uk/government/publications/report-of-the-commission-on-human-medicines-expert-working-group-on-covid-19-vaccine-safety-surveillance. We also receive independent advice from the Commission on Human Medicines (CHM) which is responsible for advice on the impact of any safety issues and on the balance of risks and benefits of COVID-19 vaccines. For further information on the CHM please follow this link: https://www.gov.uk/government/organisations/commission-on-human-medicines/about. Additionally, we work closely with our public health partners in reviewing the effectiveness and impact of the vaccines to ensure the benefits continue to outweigh any possible side effects. Data are now available on the impact of the vaccination campaign in reducing infections and illness in the UK.

Regarding your questions specifically regarding reports received for COVID-19 vaccine use in pregnancy please see our response to your FOI request 21/594 which also includes information on the reports received for Paroxysmal Extreme Pain Disorder.

You have mentioned in your correspondence that you have not yet compared adverse drug reaction (ADR) reports between the COVID-19 vaccinations currently in use in the UK. Yellow Card reports cannot be used to compare safety between vaccines as many factors can influence reporting to the

scheme, no robust inferences can be drawn from such comparisons. Overall, the number and nature of suspected ADRs reported so far is not unusual for an immunisation programme of this scale and the data we have analysed and published indicates that the safety of the COVID-19 vaccines is as expected based on the robust clinical trial data that supported the authorisations.

With regards to your points on under-reporting in pharmacovigilance data, the reporting rate for ADRs is variable and can depend on a multitude of factors. These estimates should not be used as indicators of the reporting rate for COVID-19 vaccines, for which there is high public awareness of the Yellow Card scheme and the reporting of suspected reactions. Additionally, we take into account of the variable levels of reporting as part of our monitoring procedures.

You have also asked three specific questions to which the responses are provided below:

1. **How many people have died within 28 days of vaccination?**
2. **How many people have been hospitalised within 28 days of vaccination?**

We collect information on suspected adverse reactions, including those with a fatal outcome, in association with medicines including COVID-19 vaccines. Reports received via the Yellow Card scheme can be reported at any time after a suspected side effect has occurred. Additionally, the timeframe from when the patient received the COVID-19 vaccine to experiencing a suspected side effect is not always provided by the reporter. The Office for National Statistics (ONS) may be able to help further with this request.

We take all reports received via the Yellow Card scheme seriously and review all reports of suspected ADRs with a fatal outcome regardless of the time to onset from receiving a medicine or vaccine. We follow up reports including all fatalities where permission has been provided to do so for further information including the length of time since the deceased received the vaccine if that has not already been provided. As with any serious suspected ADR, we fully evaluate reports with a fatal outcome to consider whether the vaccine (or medicine) may have caused the event, or whether the event and fatal outcome were likely to be purely coincidental and due to underlying illness.

3. **How many people have been disabled by the vaccination?**

We are unable to comment on the number of people left disabled as a result of a COVID-19 vaccination as Yellow Card reports do not detail functional outcomes for patients, particularly in the medium to long term, to be able to assess the level of disability for any patient that might have been experienced ADRs following COVID-19 vaccination. You will be best placed to direct this particular question to Public Health England (PHE).

Lastly, you requested access to the Yellow Card database. This would require a Category II data request which are considered by the Pharmacovigilance Expert Advisory Group (PEAG) of the Commission on Human Medicines. The remit of PEAG is to consider the method of study, its appropriateness, the implications of the Freedom of Information Act and Data Protection Act on data release and how use of other data would interact with Yellow Card data. PEAG also advises on the relevance of seeking ethics review of a proposal from the NHS Research Ethics Committee. Please follow this link to our website where you can find out more, including the application form which needs to be completed.

https://www.gov.uk/government/organisations/commission-on-human-medicines/about/membership#pharmacovigilance-eag

Yours sincerely

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