FOI 23/009

17th January 2023

Dear

Thank you for your FOI request dated 7th January 2023 in which you asked 'information with regard to Steven-Johnson Syndrome cases and the Covid-19 Vaccine'.

For suspected side effects being reported, the MHRA publishes this information in the form of interactive Drug Analysis Profiles (iDAPs), of which the one for the COVID-19 Vaccines can be accessed here: https://yellowcard.mhra.gov.uk/idaps. This shows that we have received 7 Yellow Card reports of Stephen-Johnson Syndrome in relation to the Pfizer/BioNTech vaccine, 7 reports in relation to the AstraZeneca vaccine, fewer than 5 reports in relation to the Moderna vaccine, and 0 reports in relation to the Novavax and brand unspecified or not routinely used in the UK vaccines.

There is an iDAP for each licensed medicine by drug substance. Within an iDAP you can see all suspected side effects, known as suspected adverse drug reactions, that have been reported to the MHRA and you may filter by type of reaction, level of reaction and year of report. It is important to note that reported adverse reactions have not been proven to be related to the drug and should not be interpreted as a list of known side effects.

Conclusions on the safety and risks of the vaccines cannot be made on the data shown in the report alone. When viewing the report, you should remember that:

- Reporters are asked to submit Yellow Card reports even if they only have a suspicion that the vaccine may have caused the adverse reaction. The existence of an adverse reaction report does not necessarily mean that the vaccine has caused the reaction.
- It may be difficult to tell the difference between something that has occurred naturally and an adverse reaction. Sometimes reactions can be part of the condition being treated rather than being caused by the vaccine.
- Many factors have to be considered when assessing whether a vaccine has caused a reported adverse reaction. When monitoring the safety of medicines and vaccines, MHRA staff carry out careful analysis of these factors.
- It is not possible to compare the safety of different vaccines by comparing the numbers presented in the vaccine reports. Reporting rates can be influenced by many factors including the seriousness of the adverse reactions, their ease of recognition and the extent of use of a particular vaccine. Reporting can also be stimulated by promotion and publicity about a product.

For a vaccine to be considered safe, the expected benefits will be greater than the risk of having harmful reactions. It is important to note that most people receive vaccinations without having any serious side effects.

I hope the information provided is helpful; however, 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.

Please remember to quote the reference number above in any future communications.

Kind regards,

FOI Team