FOI 23/547

Dear

Thank you for your email, which we have processed under the Freedom of Information Act as request FOI 23/547.

Please find below answers to the questions you have raised.

> *1). What testing of the covid vaccines, both A-Z and Pfizer, was carried out on people -*
>
> *a) with long term illnesses?*
> *b) with compromised immune systems? and*
> *c) with autoimmune conditions?*

The data from clinical studies for the Pfizer vaccine (Comirnaty) and the AZ vaccine (Vaxzevria) is available from the EMA clinical repository, which is linked below:
https://clinicaldata.ema.europa.eu/web/cdp/home

Additionally, assessment of the vaccines (including any analyses of subgroups) by MHRA and the EMA, are available in the PARs that have been published.

MHRA PARs can be accessed through our Products Portal, linked below:
https://products.mhra.gov.uk/

EMA PARs can be accessed through the EMA website, links to these are provided below:
https://www.ema.europa.eu/en/medicines/human/EPAR/vaxzevria
https://www.ema.europa.eu/en/medicines/human/EPAR/comirnaty

> 2). What incidence is there of vaccine damage
> a) in the above three groups?
> b) in the general population?
> Please answer with both absolute and relative percentages

No medicine or vaccine is completely risk-free and hence the MHRA has continually monitored the safety of the COVID 19 vaccines through a comprehensive COVID-19 Vaccine Surveillance Strategy. This monitoring strategy is proactive and based on a wide range of information sources, with a dedicated team of scientists continually reviewing information to look for safety issues or any unexpected, rare events.

The Yellow Card scheme is one of these sources of information and is the UK system for collecting suspected adverse drug reactions (ADRs) to medicines and vaccines from healthcare professionals and patients. We have published a summary of Yellow Card reporting for the COVID-19 vaccines which summarises information received via the Yellow Card scheme along with details of our assessments of specific safety issues. This summary of Yellow Card reporting provides information

on suspected adverse reactions that have been reported to the MHRA via the Yellow Card scheme for all COVID-19 vaccines deployed in the UK. This includes all reports received from healthcare professionals, members of the public, and pharmaceutical companies.

Yellow Card data cannot be used to determine the incidence of a reaction or to compare the side effect profiles of different medicines or vaccines. Suspected 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.

The total number and the nature of the majority of Yellow Cards received reporting ADRs to the COVID-19 vaccines so far is not unusual for a new vaccine for which members of the public and healthcare professionals are actively encouraged to report any suspected adverse reaction. The reporting rate for spontaneous ADRs is variable and can depend on a multitude of factors.

The product information for the COVID-vaccines includes a list of the possible side effects of COVID-19 vaccines including information on the estimated frequency of adverse reactions where this can be estimated from the available data. The product information for COVID-19 for AstraZeneca and Pfizer COVID-19 vaccines, including the Summary of Product Characteristics (SmPC) for health professionals and the Patient Information Leaflet (PIL) for vaccine recipients, are available at the following links:

- https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-astrazeneca

- https://www.gov.uk/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19

Information on the frequency of side-effects can be found in ‘Section 4.8 Undesirable effects’ of the SmPC and under ‘Section 4 Possible side effects’ of the PIL.

The COVID-19 vaccine product information does not provide information on the frequency of possible side effects in particular patient groups however ‘Section 4.4 Special warnings and precautions’ of the SmPC provides advice for on use in patients with specific conditions or past medical history (e.g., for immunocompromised individuals).

This information is reflected in ‘Section 2 What you need to know before you receive the COVID-19 vaccine’ of the PIL which inform vaccine recipients when they need to talk to their doctor, pharmacist or nurse before they are given the vaccine.

For the vast majority of people, the benefits of the vaccines in preventing serious complications associated with COVID-19, far outweigh any currently known side effects. The safety of COVID-19 vaccines is continuously monitored; should a new safety issue be confirmed we will continue to act promptly to inform patients and healthcare professionals and take appropriate steps to mitigate any identified risk and protect public health.

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 you receive this response and addressed to: info@mhra.gov.uk

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

If you were to remain dissatisfied with the outcome of the internal review, you would have the right to apply directly to the Information Commissioner for a decision. Please bear in mind that the Information Commissioner will not normally review our handling of your request unless you have first contacted us to conduct an internal review. The Information Commissioner can be contacted at:

Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF

Yours sincerely

MHRA Customer Experience Centre
Communications and engagement team
Medicines and Healthcare products Regulatory Agency
10 South Colonnade, Canary Wharf, London E14 4PU