Medicines & Healthcare products
Regulatory Agency

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[redacted]

9 May 2024

MHRA reference: FOI2024/00059

Dear [redacted],

Thank you for your information request, which we received on 10 April. You asked for:

> *Does Covid -19 vaccine, produced by Phizer [Sic], contain any graphene oxide or other toxic, dangerous components?*
> *Where in UK done independent tests prior to offering vaccine as safe to elderly, gravely sick people? Later- younger prople, pregnant women?*
> *Are there investigations, what side effects noted? What illnesses vaccinated people developed in 2 following years after vaccination?*
> *Where could people, living in UK, find this kind of statistics?*

We have dealt with your request under the Freedom of Information Act 2000 (FOIA).

We have identified the below questions in your message, and have provided our answers beneath each question.

1. *Does Covid -19 vaccine, produced by Phizer [Sic], contain any graphene oxide or other toxic, dangerous components?*

   Our response:
   The Pfizer/BioNTech (Comirnaty) vaccines do not contain graphene oxide or any other dangerous components.

   The ingredients included in each authorised Comirnaty vaccine are recorded in Section 2 and 6.1 of the Summary of Product Characteristics (SmPC) and the Patient Information Leaflet (PIL). These documents are available on the

MHRA products website. Therefore, this information is exempt under Section 21 (Information Reasonably Accessible to the Applicant by Other Means). A link to the PIL and SmPC for each authorised Comirnaty vaccine published on the MHRA website is provided below:

https://products.mhra.gov.uk/search/?search=Comirnaty&page=1&doc=Pil%7CSpc&rerouteType=0

2. *Where in UK done independent tests prior to offering vaccine as safe to elderly, gravely sick people? And later younger prople [Sic], pregnant women?*

Our response:
We have interpreted your question to mean were elderly and/or gravely sick people included in clinical trials conducted in the UK completed prior to offering the vaccine to these populations/groups.

This information is also exempt under Section 21 (Information Reasonably Accessible to the Applicant by Other Means), however, for ease we have provided the response below.

The clinical trial sites were not located in the UK. The main trial undertaken to support the first authorisation of the Comirnaty vaccine is published online, see link below. The median age was 52 years, and 42% of participants were older than 55 years of age. Of participants, 21% had at least one coexisting condition. Overall, 46% of the participants had at least one comorbidity that increases the risk of severe COVID-19 disease: e.g. asthma, BMI ≥ 30 kg/m2, chronic pulmonary disease, diabetes mellitus, hypertension; 35% of the participants were obese and another 35% were overweight.

Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine | New England Journal of Medicine (nejm.org)

Public Assessment Report (publishing.service.gov.uk)

The Pfizer/BioNTech vaccine is currently authorised by the Reliance procedure, therefore, the EMA PAR may also be of interest.

ema.europa.eu/en/documents/assessment-report/comirnaty-epar-public-assessment-report_en.pdf

About Our Landmark Trial | Pfizer

3. *Are there investigations, what side effects noted?*

Our response:
We have interpreted your question to mean, based on clinical trials conducted for the first authorisation of the Comirnaty vaccine were any investigations conducted on trial participants and if so, which side effects were noted.

In clinical trials, the Comirnaty vaccine was generally well-tolerated. The overwhelming majority of reports relate to injection-site reactions (sore arm for example) and generalised symptoms such as 'flu-like' illness, headache, chills, fatigue (tiredness), nausea (feeling sick), fever, dizziness, weakness, aching muscles, and rapid heartbeat. Generally, these happen shortly after the vaccination and are not associated with more serious or lasting illness.

The full information is also exempt under Section 21 (Information Reasonably Accessible to the Applicant by Other Means). The Public Assessment Reports (PARs) listed in the above response to question 2 include tables of side effects listed in the clinical trials.

4. *What illnesses vaccinated people developed in 2 following years after vaccination? Where could people, living in UK, find this kind of statistics?*

Our response:
Following approval of a vaccine for the UK market, the MHRA's role is to continually monitor its safety, particularly during widespread use of a vaccine. Prior to the UK COVID-19 vaccination roll out, the MHRA put in place a comprehensive proactive vigilance strategy to enable us to maximise rapid collection of safety data and proactively monitor the safety of the vaccines. Part of our monitoring role includes reviewing reports of suspected side-effects, and this has been continuously carried out since the beginning of the vaccination campaign. Any member of the public or health professional can submit reports of suspected side effects after vaccination through the Yellow Card Scheme.

The MHRA publishes information on suspected side effects being reported for COVID-19 vaccines through the Yellow Card Scheme in the form of interactive Drug Analysis Profiles (iDAPs) which can be accessed using the following link: https://yellowcard.mhra.gov.uk/iDAPs. Each iDAP contains a complete listing of all suspected adverse reactions that have been reported to the MHRA via the Yellow Card scheme. This includes all reports received from healthcare professionals, members of the public, and pharmaceutical companies. It is important to note that reported adverse reactions have not been proven to be related to the vaccine and should not be interpreted as a list of known side effects. Please also note that a reporter can report a suspected adverse reaction occurring at any time point following vaccination.

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Additionally, during the pandemic the MHRA published a summary of the reports we received alongside our assessment of specific issues, which can be found in the links below:

ARCHIVED - Coronavirus vaccine - summary of Yellow Card reporting - GOV.UK (www.gov.uk)

Coronavirus vaccine - summary of Yellow Card reporting - GOV.UK (www.gov.uk)

The MHRA continues to evaluate emerging safety information on the COVID-19 vaccines and will take action to minimise risks to patients should a new safety concern be identified. The benefits of the vaccines in preventing serious complications associated with COVID-19 outweigh any currently known side effects in the majority of patients.

We hope this information is useful for you.

This concludes our response to your request.

If you have a query about this response, please contact us at

Please remember to quote the reference number at the top of this letter in any future communications. Details of your appeal rights are below.

Yours sincerely,

Healthcare, Quality and Access Group
Medicines and Healthcare products Regulatory Agency

Appeal rights

If you are dissatisfied with the handling of your request, you can ask us to conduct an internal review. Internal review requests should be submitted within two months of the date you receive this response and addressed to: foi.request@mhra.gov.uk

If you remain dissatisfied with the outcome of the internal review, you 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 a request unless the requester has first asked us to conduct an internal review.

The Information Commissioner can be contacted through their online webform at: https://ico.org.uk/make-a-complaint/foi-and-eir-complaints/foi-and-eir-complaints/

Or in writing to: Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire, SK9 5AF

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Re-use of our information