FOI 24/213 following Internal review of FOI 23/985

MHRA Customer Services <MHRACustomerServices@mhra.gov.uk>
Wed 20/03/2024 20:05
To [redacted] >
Cc:MHRA Customer Services <MHRACustomerServices@mhra.gov.uk>

Dear [redacted]

We are writing in response to your email of 25 February 2024, where you asked, "*Please can you confirm the following*" and listed a number of statements.

We should explain that the Freedom of Information Act (FOIA), grants access to the recorded information held by public authorities. Questions which ask for views, opinions or commentary are not valid under section 8 of the FOIA, unless those views are already held in recorded form at the time that the request is made. There is no requirement for a public authority to create new information in order to respond to a request.

As your question asks us to give a view or opinion on the statements you have made, rather than asking for recorded information, there is no requirement for us to respond as it falls outside the scope of the FOIA.

On this occasion, we have provided answers in response to these statements in order to assist you under the section 16 duty. We also include a further link to the Information Commissioner's website, where you can find guidance about what is and is not in scope of the FOIA, and advice on how to word an effective and valid information request. You can access this guidance at: https://ico.org.uk/your-data-matters/official-information/

Please see further explanation in response to your statements below. Your statements are in bold.

There is only 1 study undertaken on 5-11 year olds who were injected with mRNA 'vaccine'
For the authorisation of Comirnaty 10 micrograms/dose concentrate for dispersion for injection COVID-19 mRNA Vaccine (nucleoside modified; PLGB 53632/0006), which was authorised following a European Commission (EC) decision on 26 November 2021 (EMEA/H/C/005735/X/0077), Study C4591007 was a Phase 1/2/3 randomised, observer-blind, placebo-controlled, safety, immunogenicity and efficacy study in children aged 6 months to less than 12 years.

Phase 1 of the study was dose finding and included 48 subjects aged 5-11 years. This identified the 10-microgram dose taken forwards into Phase 2/3. Phase 2/3 of the study consists of 2 cohorts:

- An initial enrolment group of 5 to 11-year olds: 2268 subjects that were randomised 2:1 to vaccine (BNT162b2) or placebo – the median follow-up time in this group is 3.3 months post dose 2 (data cut-off 08 October 21)
- An additional safety expansion of 5-11-year olds (US only): 2379 subjects that were randomised 2:1 to vaccine (BNT162b2) or placebo – the median follow-up time in this group is 2.4 weeks post dose 2 (data cut-off 08 Oct 21).

Further information from this study can be found in the Public Assessment Reports (PARs) published by the European Medicines Agency (EMA) and MHRA, as well as the clinical data published on the EMA clinical repository. Links to these are provided below:
https://mhraproducts4853.blob.core.windows.net/docs/7af712d3dbf23fe5553374be32c5ff4cdbca6d97
https://www.ema.europa.eu/en/documents/variation-report/comirnaty-h-c-5735-x-0077-epar-assessment-report-extension_en.pdf

https://clinicaldata.ema.europa.eu/web/cdp/home
https://clinicaldata.ema.europa.eu/web/cdp/search?p_p_id=cdpdossierviewportlet_WAR_cdpdossierviewportlet&p_p_lifecycle=0&p_p_state=maximized&p_p_mode=view&folderName=EMEAHC005735X0077

The EMA have also stated in their ePAR that the marketing authorisation holder will evaluate safety in the following number paediatric 5 to <12 year-old subjects in the following studies:
C4591021(EU) source population about 2.5 million
C4591038 (former C4591021 substudy) (EU) not known (protocol submission Jan2022)
C4591009 (US) source population about 2 million
C4591011 (US) source population about 750,000
C4591036 (US and Canada) not known (protocol submission 30Nov2021)
C4591024 (global) 60
C4591007 4000
The recruitment of this population in the studies will be reported in the Periodic Safety Update Reviews.

This study was undertaken by the manufacturers of the product being tested Pfizer/BioNTech the company who would sell the product
The study sponsor was BioNTech and the study was conducted by Pfizer.

There are no impartial studies by anyone without a conflict of interest
The centres, investigators and ethics committees involved in the study ensure that the study is conducted impartially. Blinding of participants, investigators and study sponsors also ensured that no bias could take place in the recording of results for the Cominaty group versus the placebo group.

The study was only testing efficacy against Covid-sars 19. As stated in letters to the editor, 'However this trial was not powered to detect potential serious side effects of mRNA vaccines'
All clinical trials include an analysis/evaluation of safety. Study C4591007 included the collection and analysis of adverse events, as well as analysis from physical examinations and laboratory based analysis of blood samples at specific intervals during the study.

There was no follow up data beyond 2.3 months after the second dose
The ePAR published by the EMA, linked above, states that Adverse events (AEs) are collected from Dose 1 to 1 month after Dose 2 and serious AEs (SAEs) are collected from Dose 1 to 6 months after Dose 2.

This study states that data on serious adverse events will be collected from the first dose through 6 months after the second dose but these are not published in this study . Were these collected and if so how are they available?
The data on serious adverse events experienced during Study C4591007 are published in the ePAR that has been prepared by the EMA and the Clinical Study Report that is available in the EMA clinical repository. Both of these are linked above.

The study states that further study is required to understand the following; Longer term immune responses , safety and efficacy of the BNT162b2 and Covid -19 vaccine in this age group and the potential for 'rare' adverse events. The cut-off date for this study was September 2021. The study states 'that participants will be followed up for the 2 years after the receipt of the first dose ….' . When will this study be published?
A list of changes to the Comirnaty vaccine, including new data that has been submitted, is published by the EMA and is available via the link below:
https://www.ema.europa.eu/en/documents/procedural-steps-after/comirnaty-epar-procedural-steps-taken-and-scientific-information-after-authorisation_en.pdf

The yellow card reporting system is the only way by which Health/Medical professionals /parents would report any serious side effects of the vaccine post this

published study medium and long term.
To confirm, the Yellow Card scheme is the UK's spontaneous reporting scheme where patients, parents/carers and healthcare professionals can report any suspected ADRs to MHRA **at any time** once a product is authorised in the UK. However, there may be formal safety studies undertaken, although these generally look at specific predefined events which are captured in the study protocol. Details of all ongoing studies including paediatric subjects are listed in the Comirnaty Risk Management Plan (RMP) Comirnaty | European Medicines Agency (europa.eu)

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

From: [redacted]
Sent: Sunday, February 25, 2024 2:15 PM
To: MHRA Customer Services <MHRACustomerServices@mhra.gov.uk>
Subject: FOI 24/213 following Internal review of FOI 23/985

Thank you for completing the internal review of my queries.

I have now had time to read the information you have sent me.

Please can you confirm the following

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- There is only 1 study undertaken on 5-11 year olds who were injected with mRNA 'vaccine'
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- This study was undertaken by the manufacturers of the product being tested Pfizer/BioNTech the company who would sell the product
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