WhatDoTheyKnow

Pfizer/BioNTech Covid 19 Vaccine Exposure During Pregnancy

Nicholas Wells made this Freedom of Information request to Medicines and Healthcare products Regulatory Agency

We're waiting for Nicholas Wells to read a recent response and update the status.

Nicholas Wells 4 May 2021
Delivered

Dear Medicines and Healthcare products Regulatory Agency,

In the clinical trial protocol for the Pfizer/BioNTech study with the short title "A Phase 1/2/3 Study to Evaluate the Safety, Tolerability, Immunogenicity, and Efficacy of RNA Vaccine Candidates Against COVID-19 in Healthy Individuals" (EudraCT No. 2020-002641-42; Protocol No. C4591001) the following is stated in Section 8.3.5.1. Exposure During Pregnancy:

"An EDP occurs if:
[...]
• A male participant who is receiving or has discontinued study intervention exposes a female partner prior to or around the time of conception.
• A female is found to be pregnant while being exposed or having been exposed to study intervention due to environmental exposure. Below are examples of environmental exposure during pregnancy:
• A female family member or healthcare provider reports that she is pregnant after having been exposed to the study intervention by inhalation or skin contact.
• A male family member or healthcare provider who has been exposed to the study intervention by inhalation or skin contact then exposes his female partner prior to or around the time of conception[...]"

Under the FOI I request the MHRA to please clarify:
1) what it understands the above-protocol to mean where it states "...exposed to the study intervention by inhalation or skin contact...";
2) In relation to 1) above whether you understand this to mean that there is potential for the vaccine active ingredient(s) or excipients, or any protein or other material produced as a direct result of the active ingredient(s) (i.e. spike protein) to be released either orally or through any form of excretion from the recipient (shedding);

3) what you determine the potential effect to any person, whether pregnant or not resulting from exposure to anything referred to in your answer to 2) above.

Yours faithfully,

Nicholas Wells

MHRA Customer Services, Medicines and Healthcare products Regulatory Agency 4 May 2021

Thank you for your email. This auto-response is to inform you that your email has been received and will be reviewed by our Customer Service Team. We will respond to you as soon as possible.

Please note that we may not respond if your query:

- contains offensive language
- has already been answered in a previous reply to you
- is illegible
- is selling or promoting a product
- is for information only

Medicines and Healthcare products Regulatory Agency
10 South Colonnade,
Canary Wharf,
London
E14 4PU
gov.uk/mhra
Stay connected

For information on how the Agency uses your personal data and your data protection rights, please see our three centres' Privacy Notices: MHRA, CPRD and NIBSC.

The UK has left the EU, and the transition period ends on 31 December 2020. Our [1]guidance and information can be accessed here.

References

Visible links
1. https://www.gov.uk/government/collection...

MHRA Customer Services, Medicines and Healthcare products Regulatory Agency 4 May 2021

Our Ref: FOI 21/479

Dear Nicholas Wells,

RE: REQUEST UNDER THE FREEDOM OF INFORMATION ACT 2000

Thank you for your enquiry which we received on 4^th May 2021.

I confirm that your request is now being handled under the Freedom of Information Act and you should receive a reply within 20 working days from our date of receipt.

If you need to contact us again about this request, please quote the reference number above.

Please be aware that we publish FOIs replies and these are redacted and are located on our website at the following link below.

[1]https://www.gov.uk/government/collection...

Kind Regards,

MHRA Customer Service Centre

Medicines and Healthcare products Regulatory Agency

10 South Colonnade, Canary Wharf, London E14 4PU

Telephone 0203 080 6000

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MHRA Customer Services, Medicines and Healthcare products Regulatory Agency 19 May 2021

FOI 21/479

Dear Nicholas Wells

Thank you for your Freedom of Information (FOI) request (dated 4 May 2021), where you asked for information pertaining to the trial protocol for the following trial:

- EudraCT: 2020-002641-42
- Protocol title: "A Phase 1/2/3 Study to Evaluate the Safety, Tolerability, Immunogenicity, and Efficacy of RNA Vaccine Candidates Against COVID-19 in Healthy Individuals"
- Protocol number: C4591001

As the above trial was not conducted in the UK, the MHRA did not assess its content and are therefore not in a position to answer specific questions relating to it.

We now consider this request closed.

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: [1][MHRA request email] .

Please remember to quote the reference number above in any future communications. Please note, due to the ongoing Covid-19 situation, we are not able to accept delivery of any documents or

correspondence by post or courier to any of our offices.

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 Service Centre

Medicines and Healthcare products Regulatory Agency

10 South Colonnade, Canary Wharf, London E14 4PU

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Nicholas Wells 19 May 2021

Delivered

Dear Medicines and Healthcare products Regulatory Agency,

Please pass this on to the person who conducts Freedom of Information reviews.

I am writing to request an internal review of Medicines and Healthcare products Regulatory Agency's handling of my FOI request 'Pfizer/BioNTech Covid 19 Vaccine Exposure During Pregnancy' (your reference FOI 21/479).

In your response to FOI 21/479 you state that "[a]s the [trial with EudraCT number 2020-002641-42 and Protocol number C4591001] was not conducted in the UK, the MHRA did not assess its content and are therefore not in a position to answer specific questions relating to it." However, in your own Public Assessment Report titled "Authorisation for Temporary Supply COVID-19 mRNA Vaccine BNT162b2 (BNT162b2 RNA) concentrate for solution for injection" (published here - https://www.gov.uk/government/publicatio...) you refer to the above-mentioned study no less than 21 times and indeed the results of the study are used to support the clinical safety and efficacy of BNT162b2 RNA and therefore one must presume the granting of the temporary authorisation in the UK by the MHRA.

In light of your response to FOI 21/479 and admission contained within it, please clarify: Did the MHRA fail to assess the content of the above-mentioned pivotal trial prior to granting a temporary authorisation for the use of BNT162b2 RNA in millions of UK citizens?

If the answer to the above question is "no" and you have provided an insufficient response to FOI 21/479 then I request that you conduct a thorough review of my FOI request and provide answers to the questions immediately (no later than 5 days from today).

If the answer to the above is "yes" and the MHRA has not assessed the content of the pivotal clinical trial in support of BNT162b2 RNA prior to granting a temporary authorisation, then I request that you immediately withdraw the temporary authorisation and make an immediate public announcement to the UK via the Government and mainstream media explaining this oversight.

A full history of my FOI request and all correspondence is available on the Internet at this address: https://www.whatdotheyknow.com/request/p...

Yours faithfully,

Nicholas Wells

MHRA Customer Services, Medicines and Healthcare products Regulatory Agency 19 May 2021

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References

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1. https://www.gov.uk/government/collection...

MHRA Customer Services, Medicines and Healthcare products Regulatory Agency 21 May 2021

Dear Nicholas Wells,

Thank you for your email.

We confirm that an internal review will be carried out on FOI 21/479. We aim to respond to requests for internal review within 20 days of receipt.

Kind Regards

MHRA Customer Service Centre

Medicines and Healthcare products Regulatory Agency
10 South Colonnade, Canary Wharf, London E14 4PU

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