Medicines & Healthcare products
Regulatory Agency

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United Kingdom
gov.uk/mhra

[redacted]

21 September 2023

FOI **23/583**

Dear [redacted]

Thank you for your information request, dated 07 August 2023, where you asked for:

'*Under the Freedom of Information Act 2000 to request the following information from the Medicines & Healthcare products Regulatory Agency*

Please may you provide me with information relating to the following two clinical trials.

1) The clinical trial to Evaluate the Safety, Tolerability, and Immunogenicity of BNT162b2 Against COVID-19 in Healthy Pregnant Women 18 Years of Age and Older (C4591015) (NCT04754594) REC ref 21/YH/0071

2) The Phase 1/2, Randomized, Placebo-Controlled, Observer-Blinded Trial to Evaluate the Safety, Tolerability, and Immunogenicity of a Multivalent Group B Streptococcus Vaccine in Healthy Nonpregnant Women and Pregnant Women 18 to 40 Years of Age and their Infants (C1091002) (NCT03765073) REC ref 21/LO/0240

For each trial please provide information relating to safety studies of the investigational product in pregnant animals, including non-human primates, particularly relating to maternal and neonatal outcome, provided by the sponsors to your agency, as part of their applications for clinical trials of investigational medicinal products to support their safe use in pregnant humans.'

I am pleased to provide you with the information requested, attached to this email.

1) Investigator's Brochure (IB), BNT162/PF-07302048
2) Investigator's Brochure (IB) for C1091002, PF-06760805 (GBS6)

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These documents are provided with personal information withheld under section 40(2), and information considered commercially sensitive withheld under section 41 and 43 of the Freedom of Information Act

Section 41(1) (information provided in confidence) is an absolute exemption and no consideration of the public interest is required. The withheld information was provided to the MHRA in confidence by a third-party for the purposes of assessment. This information has the necessary quality of confidence as it is more than trivial and not otherwise accessible; the preservation of confidences is recognised by the courts to be an important matter and one in which there is a strong public interest. In this case, the information was provided to the MHRA with explicit conditions on its use by the MHRA (including further disclosure) and an obligation of confidence therefore exists. For these reasons, disclosure would be likely to have a detrimental impact on the party who provided the information. In such circumstances, our view is that disclosure would be an actionable breach of that confidence, and this engages the section 41(1) exemption.

Section 43(2) applies in similar circumstances, when disclosure of the requested information would be likely to prejudice the commercial interests of any third party. We note here the ICO's guidance, which advises that public authorities who "*undertake regulatory activity (for example, if you issue licences or accreditations)*", may hold commercially sensitive information obtained from third-party companies through the course of assessments, investigations or otherwise related to our functions. This exemption is qualified, and so requires consideration of the public interest in disclosure and in maintaining the exemption. In this case, there is a public interest in transparency and disclosure where this would enable public scrutiny of the information; however, in this case, this public interest is met to a greater degree by the disclosure of a large amount of relevant information within the two documents. In this case, the stronger public interest favours maintaining the exemption for those parts of the information where the third-party has expressed commercial concerns about the harm in disclosure.

The Freedom of Information Act only entitles you access to information – the information supplied is subject to Crown copyright, and there are some restrictions on its re-use. For information on the reproduction or re-use of MHRA information, please visit https://www.gov.uk/government/publications/reproduce-or-re-use-mhra-information/reproduce-or-re-use-mhra-information.

If you have a query about the information provided, please reply to this email.

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

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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,

Clinical Investigations and Trials

(Science, Research and Innovation Group)