FOI 23/603

Dear

Thank you for your information request dated, 14 August 2023, where you asked the below. We have included our answers to your request below each bullet point.

> "*Would you be able to provide the following documents provided by the applicant :*
>
> - *A full inspection report from GCP inspection by Regierungspräsidium Karlsruhe and PaulEhrlich-Institut conducted at one of the investigator sites and at a CRO in Germany for the study BNT 162-01;*
>
> *After an appropriate and thorough search of our records we have established that this information is not held by MHRA. However, this information was held for a period but the data transfer package has since expired.*
>
> - *Establishment Inspection Reports from GCP inspection by Food and Drug Administrations (USA Regulatory Authority) of six investigator sites in USA for study C4591001 (BNT 162-02);*
>
> *We confirm that this information is held, however, this information is exempt under Sections 41* and 27* of FOI*
>
> - *A full inspection Report and the summaries of the outcome from two GCP inspections by the National Administration of Drugs, Foods and Medical Devices (Argentinian Regulatory Authority) conducted at the single site located in Argentina for the study C4591001(BNT 162-02)."*
>
> *After an appropriate and thorough search of our records we have established that this information is not held by MHRA.*
>
> *as referenced in this document Comirnaty, INN-COVID-19 mRNA Vaccine (nucleoside-modified) (europa.eu)."*

*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 an understanding that trust between the international regulators and the MHRA would be maintained, and an obligation of confidence therefore exists. For these reasons, disclosure would be likely to have a detrimental impact on the relationship with the third 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 27 (International relations): we consider that disclosure of this information is likely to damage the MHRA's relationship with a regulator from another country, and thus could damage the UK's interests abroad. Section 27 is a qualified exemption, which means that we have considered whether the public interest in releasing the information is outweighed by the public interest in withholding the information. In favour of disclosure, we consider that there is a general public benefit from release of inspection reports. However, we consider that the public interest will be better served by not releasing the information because these reports were not produced by the MHRA and are not MHRA's property, therefore, it is not in the overall interest of the public to strain relationships between regulators and breach existing arrangements; this could be detrimental to the work completed at the Agency which is undertaken to protect public safety.

If you disagree with how we have interpreted the Freedom of Information Act 2000 in answering your request, you can ask for an internal review. Please reply to this email, within two months of this reply, specifying that you would like an Internal Review to be carried out.

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 online via an electronic form: https://ico.org.uk/make-a-complaint/foi-and-eir-complaints/foi-and-eir-complaints/
The Information Commissioner can be contacted at:

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

Yours sincerely

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Communications and engagement team
Medicines and Healthcare products Regulatory Agency
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