

## **FOI 23/230 – data submitted to the MHRA by Pfizer in Covid-19 vaccine application**

### **REQUEST 26 March 2023**

I have read with interest, following a freedom of information document request, the assessment, by the Australian regulatory authority (the TGA), of the Pfizer Covid 19 mRNA vaccine application assessment (attached).

Can you please confirm;

1. Was the same Pfizer data utilised by the UK MHRA as the basis to support the authorization of the use of the same Pfizer covid 19 vaccinations for UK personnel
2. If this is not the case, what data was utilised by the UK MHRA to support the authorization of the use of the Pfizer covid 19 vaccinations

### **MHRA RESPONSE 21 April 2023**

Dear

Thank you for your email.

As we cannot see the data that was submitted to the TGA in its entirety, we cannot confirm that the same data has been submitted.

However, MHRA has published a Public Assessment Report (PAR) for the authorisation of the Pfizer vaccine under Regulation 174 and the European Medicines Agency (EMA) has published a PAR for the authorisation of the Pfizer/BioNTech vaccine (Comirnaty) following a European Commission (EC) decision on 21 December 2020 (PLGB 53632/0002). These PARs provide details of the study data that were submitted for the authorisation of this vaccine.

Links to these are provided below:

<https://www.gov.uk/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19>

<https://www.ema.europa.eu/en/medicines/human/EPAR/comirnaty>

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](mailto: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

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