Australian Government

Department of Health and Aged Care
Therapeutic Goods Administration

Ms Deborah-May Torrens
Email: foi+request-11591-fcb5dba7@righttoknow.org.au

Dear Ms Torrens

FREEDOM OF INFORMATION REQUEST FOI 5243
Notice of Decision

1. I refer to your request dated 1 July 2024 under the *Freedom of Information Act 1982* (the FOI Act) and subsequent correspondence between you and the TGA in which the scope of your request was clarified as being for access to the following documents:

   'Under the FOI Act, I request a copy of the 'Request for Release Form' which was submitted by Anthony Fauci to Advisory Committee on the Safety of Medicines.'

Decision Maker

2. I am the Therapeutic Goods Administration (TGA) officer authorised to make this decision under section 23 of the FOI Act.

Decision

3. Unfortunately, I am unable to continue to process your request because the documents you have requested do not exist. Therefore, I am notifying you of my decision to refuse your request for access under section 24A of the FOI Act.

Background

4. On 1 July 2024 the Department of Health and Aged Care, which the TGA is part of, received a request from you under the FOI Act. The scope of your request was for the following documents:

   'I am contacting the Advisory Committee on the Safety of Medicines, to ask for a copy of the 'Request for Release Form' which was submitted by Anthony Fauci to Advisory Committee on the Safety of Medicines, as well the complete summary of protocols for manufacture and QC, including all steps in production in the agreed format; and documentation on at least twenty vials (samples) of each manufacturing batch of BNT162b2 (mRNA) COVID-19 vaccine with the Australian labels, PI and packaging representative of all batches of product proposed to be distributed in Australia; and if the manufacturing batch has been released in Europe or United Kingdom (UK) a copy of those EU Official Control Authority Batch Release (OCABR) certificate (or equivalent from the UK) and any reagents, reference material and standards required to undertake testing.

   I also request for a copy of the Certified Product Details (CPD) as described in Guidance 7: Certified Product Details of the Australian Regulatory Guidelines for Prescription Medicines (ARGPM).'

5. On 11 July 2024 you were advised that the scope of your request was considered too voluminous to process and you were subsequently asked to consider revising your scope to a manageable size. You were further advised that the TGA has published a number of documents on the FOI disclosure log related to your request. In addition, you were provided with publicly available information regarding the batch release assessment for every batch of COVID-19 vaccine supplied in Australia. The TGA provided you with a suggested scope revision for your consideration so that the TGA may continue processing your request.
6. On 15 July 2024 you provided a revised scope as set out in paragraph 1 of this letter.

Reasons for Decision

7. Despite a thorough and complete search, the documents you have requested do not exist. In these circumstances, section 24A of the FOI Act states that an agency is able to refuse (discontinue processing) the request. Specifically, section 24A states:

   requests may be refused if all reasonable steps have been taken to find a document and the document does not exist.

8. Please be assured that the TGA's electronic databases, files and corporate file lists have been searched, and, following these searches, I am satisfied that all reasonable steps have been taken to find the documents requested. However, the documents you have requested do not exist.
9. The reasons the documents you have requested do not exist is because Anthony Fauci has not submitted any such form to the TGA or any of its committees.

Access to Publicly Available Information

10. As advised to you on 11 July 2024, the TGA has published a number of documents on the FOI disclosure log. They are as below:

    - **FOI 4878 –** the TGA Laboratory's standard operating procedure for analysis of batch samples and full test results documentation for the analysis of 3 batches of Comirnaty. This also contains OCABR certificates for various batches of Comirnaty.
    - **FOI 4382 -** Laboratory testing results of multiple Comirnaty COVID-19 vaccine batches.
    - **FOI 3471 -** TGA laboratory analysis documentation of the following batches of Comirnaty vaccine: FL5333, FK8917, FH3221, FL3560, FE3430.
    - **FOI 3390** - TGA's batch release assessment for the batch FL7649 of Comirnaty COVID-19 vaccine.

11. In addition, the TGA conducts a batch release assessment for every batch of vaccine supplied in Australia. Batch release assessments for the BNT162b2 (mRNA) COVID-19 vaccine (also referred to as Comirnaty) are publicly available here: https://www.tga.gov.au/batch-release-assessment-covid-19-vaccines. This link provides guidance on the batch assessment process as well as a table of information showing the test results for each batch of COVID-19 vaccine that has been tested by the TGA.
12. Finally, Guidance 7: Certified Product Details of the Australian Regulatory Guidelines for Prescription Medicines (ARGPM) is available on the TGA website at the following link: https://www.tga.gov.au/sites/default/files/pm-argpm-guidance-7.pdf.

Review and Complaint Rights

13. If you are not satisfied with this decision, you can either seek internal review or apply to the Office of the Australian Information Commissioner (OAIC) for review of the decision. Further information can be found on the OAIC website at the following link: www.oaic.gov.au/freedom-of-information/your-freedom-of-information-rights/freedom-of-information-reviews.
14. If you have any queries regarding this matter, please contact the FOI Team via email at TGAFOI@health.gov.au or telephone (02) 6289 4630.

Yours sincerely

Authorised and electronically signed by

Leisa Whitby
A/g Assistant Secretary
Laboratories Branch
Therapeutic Goods Administration
29 July 2024