Australian Government
Department of Health
Therapeutic Goods Administration

TRIM Ref: D21-3224605

[redacted]

By email: [redacted]

Dear [redacted]

FREEDOM OF INFORMATION REQUEST FOI 3215
Notice of Decision

1. I refer to your request dated 7 October 2021 under the *Freedom of Information Act 1982* (**the FOI Act**) in which you sought access to the following documents:

    1. *"Documents and information detailing any and all testing processes conducted by the TGA specifically testing for the presence of Graphene Oxide in any COVID-19 vaccination currently approved for administration to people within Australia.*

        1.1. *The information requested may be in relation to one or more specific brand of vaccination currently approved.*

        1.2. *The information requested is in regards to testing carried out at any stage before or after any type of approval for Australian administration of the products was issued."*

2. I also refer to subsequent correspondence from you dated 5 September 2021 in which the scope of your request was clarified as being in the context of the following:

    "Under the TGA's publicly released laboratory testing reports, it appears that no testing has been carried out by the TGA on any COVID-19 vaccinations according to the TGA testing reports held at the following parts of the TGA website https://www.tga.gov.au/ws-labs-index?search_api_views_fulltext=covid-19&field_ws_labs_product_type=All&field_ws_labs_publication_releas=All&sort_by=field_sponsor_name&sort_order=ASC&items_per_page=10 https://www.tga.gov.au/tga-laboratory-testing-reports#y2021

    I also note that the link kindly provided by yourself does not appear to show any test results for graphene oxide in any COVID-19 vaccinations performed by the TGA. Though my request is not for third party testing results relied on by the TGA for the presence of Graphene Oxide, this link does not appear to show this either. Whilst I would welcome the provision of such third party testing results detailing this information, this is not within the scope of my FOI request at this time.

    Accordingly, it does not appear that there is any publicly available information addressing the question asked, being for all results of the TGA testing specifically for the presence of Graphene Oxide in any COVID-19 Vaccination.

To clarify, I am seeking all documents detailing testing carried out specifically by the TGA, specifically testing for the presence of Graphene Oxide in any COVID-19 vaccination approved for administration in Australia, whether provisionally or otherwise . If you could kindly point to where this information is, I will understand this request under FOI to be validly withdrawn."

Decision maker

3. I am the Therapeutic Goods Administration (**TGA**) officer authorised to make this decision under section 23 of the FOI Act. What follows is my decision under the FOI Act.

Decision

4. I am unable to continue to process your request because the documents you have requested do not exist.

5. As outlined in previous correspondence to you on 11 October 2021, the TGA conducts independent quality assessment on every batch of COVID-19 vaccine supplied in Australia. The TGA's laboratory testing includes testing the product for absence of impurities (purity and integrity, and endotoxins). This testing involves visual assessment and the assessment of lipid nanoparticles to ensure the samples are free of contaminants.

6. The tests applied by the TGA are for impurities, not specifically for graphene oxide. Graphene oxide has not been detected and the TGA has no reason to suspect graphene oxide is present based on the thorough provisional approval process and post-market monitoring. Therefore, the TGA holds no documents within the scope of your request for "*documents detailing testing carried out specifically by the TGA, specifically testing for the presence of Graphene Oxide in any COVID-19 vaccination".*

7. With respect to your statement that "*Under the TGA's publicly released laboratory testing reports, it appears that no testing has been carried out by the TGA on any COVID-19 vaccinations according to the TGA testing reports*", I wish to clarify that the TGA regularly publishes the results of laboratory testing on COVID-19 vaccine batches, available at: https://www.tga.gov.au/batch-release-assessment-covid-19-vaccines.

8. As the TGA holds no documents "*detailing testing carried out specifically by the TGA, specifically testing for the presence of Graphene Oxide in any COVID-19 vaccination"*, I am notifying you of my decision to refuse your request for access under section 24A of the FOI Act.

Reasons for Decision

9. The reasons for my decision are set out above. Despite a thorough and complete search, the documents you have requested do not exist. In these circumstance, section 24A of the FOI Act states that an agency is able to refuse (discontinue processing) the request. Specifically, paragraph 24A(1)(a) and subparagraph 24(1)(b)(ii) of the FOI Act state:

(1) An agency or Minister may refuse a request for access to a document if:

(a) all reasonable steps have been taken to find the document; and

(b) the agency or Minister is satisfied that the document:

(ii) does not exist.

10. Please be assured that the TGA's electronic databases, files and corporate file lists have been thoroughly 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.

Publicly available information

11. In order to further assist you, I wish to provide you with publicly available information relating to the safety of the COVID-19 vaccines approved for use in Australia.

12. The TGA has published a range of documents which provide detailed information on the safety and provisional approval of the COVID-19 vaccines. These include the Australian Public Assessment Report (**AusPAR**), the Product Information (**PI**), and Consumer Medicine Information (**CMI**). If you wish to see the AusPAR, PI and CMI for the individual vaccines, please see: https://www.tga.gov.au/covid-19-vaccine-provisional-registrations and the links provided therein.

13. The PI is the key source of information for health professionals as it provides a summary of the scientific information relevant to the safe and effective use of a prescription medicine, including vaccines. The PI is approved by the TGA, and sponsors must submit an application to the TGA to make any change to the PI. The PI includes information on adverse events which were observed in clinical trials, as well as those observed from post-market surveillance. The TGA works with COVID-19 vaccine sponsors to ensure the PI remains up to date and can mandate updates to the safety information included in the PI.

14. As explained previously, the TGA ensures there is an independent quality assessment of every batch of vaccine supplied in Australia through the vaccine batch release assessment process. A batch release assessment involves either TGA review of an overseas certification; or TGA's review of documents supplied by the sponsor which describe the manufacturing process (how the vaccine is made, tested, shipped and stored) and TGA laboratory testing. Overseas certification includes independent testing and assessment by a recognised National Control Laboratory, such as the Official Control Authority Batch Release (OCABR) process in Europe. The OCABR guidance on batch release for vaccines is available at https://www.edqm.eu/en/batch-release-human-biologicals-vaccines-blood-and-plasma-derivatives. The results of TGA batch release assessments are publicly available here: https://www.tga.gov.au/batch-release-assessment-covid-19-vaccines.

15. The TGA is aware of media claims that the Pfizer vaccine contains graphene oxide, however these claims have been heavily rejected by a number of fact checking websites (for example: https://www.reuters.com/article/factcheck-grapheneoxide-vaccine-idUSL1N2OZ14F).

Review and Complaint Rights

16. If you are not satisfied with this decision, you can either seek internal review or apply to the 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/reviews-and-complaints/

17. If you have any queries regarding this matter, please contact the FOI Team at tgafoi@health.gov.au.

Yours sincerely

Authorised and electronically signed by

Lisa Kerr PhD MBA
Assistant Secretary, Laboratories Branch
Medical Devices and Product Quality Division
Therapeutic Goods Administration
29 October 2021