**Australian Government**

**Department of Health**
Therapeutic Goods Administration

TRIM Ref: D21-3152202

[redacted]
**By Email:** [redacted]

Dear Ms [redacted],

**FREEDOM OF INFORMATION REQUEST FOI 2901**
**Notice of Decision**

1. I refer to your request dated 10 August 2021 under the *Freedom of Information Act 1982* (**the FOI Act**) in which you sought access to the following documents:

   *"1) Please confirm if the TGA-funded laboratories have tested all current Covid vaccines licenced in Australia (or which will be licenced in Australia in the near future) for the presence of graphene oxide.*

   *2) If graphene oxide was found, what percentage of the total contents of each vial tested was found to be contaminated with this substance?"*

2. I also refer to subsequent correspondence between yourself and the TGA FOI team, specifically, the email from the FOI team dated 17 August 2021 which advised that much of the information you had requested is publicly available (and included the links to the publicly available information), and your subsequent emails dated 17 August 2021 and 24 August 2021 in which you clarified your request as follows:

   *"As there is growing concerns in Australia regarding worldwide evidence claiming there could be graphene oxide in the Covid vaccines, please provide the specific documentation/full analyses of the Pfizer vaccines arriving in Australia. For ongoing approval, this would surely need to be done by TGA scientists to ensure the accuracy of the ingredients list provided by Pfizer itself. Please include the documentation showing that the lipids themselves have been analysed as that is where scientists are claiming the graphene oxide is located."*

3. On 29 September 2021, you responded to the TGA's request consultation letter as follows:

   "*In response to your email, I would like to revise the scope of my request to the following:*
   *1) Please provide the documentation showing that the TGA has independently tested all vaccine ingredients in the Covid-19 vaccines to show that they align exactly with those listed by the manufacturer.*
   *2) Please provide documentation showing if any of the tests done by the TGA or the manufacturer has found graphene oxide in the Covid-19 vaccines.*
   *Neither of these requests should be onerous as they should be in one (or just a few documents).*
   *I look forward to hearing from the FOI team with the above documentation."*

4. In considering your request, I have taken "*the Covid-19 vaccines*" to refer to the following:
    - the COVID-19 Pfizer (Comirnaty) vaccine (**Pfizer vaccine**),
    - the COVID-19 Moderna (SpikeVax) vaccine (**Moderna vaccine**), and
    - the COVID-19 AstraZeneca (Vaxzevria) vaccine (**AstraZeneca vaccine**),

    being the vaccines current being administered as part of Australia's COVID-19 vaccination program.

**Decision maker**

5. I am the TGA officer authorised to make a decision on your request under the FOI Act.

**Decision**

6. I am notifying you of my decision under the FOI Act to refuse access to the documents that are the subject of your request.

7. You have amended the scope of your request to now be seeking access to "*documentation showing that the TGA has independently tested all vaccine ingredients in the Covid-19 vaccines"* and *"documentation showing if any of the tests done by the TGA or the manufacturer has found graphene oxide in the Covid-19 vaccines"*. The documents falling within the amended scope of your request continue to be too voluminous to process.

8. With respect to item 1 of your revised request, information from the relevant line area of the TGA indicates that each batch release assessment includes between five and nine documents, containing between 74 and 181 pages, which are associated **only** with tests related to the identity of ingredients. Each document contains commercially valuable material and would require consultation with the relevant vaccine sponsor, along with as overseas regulatory agencies.

9. Therefore, in order to process the documents contained within item 1 of your revised request, the TGA would still need to process between five and nine documents, containing between 74 and 181 pages, for each batch tested. There have been 114 batches of COVID-19, whether AstraZeneca, Pfizer or Moderna vaccines, tested by the TGA to date. This amounts to approximately 725 documents containing approximately 13,023 pages, each of which contains commercially valuable information. As a result, your request remains too voluminous to process.

10. Regarding item 2 of your request, for "*documentation showing if any of the tests done by the TGA or the manufacturer has found graphene oxide in the Covid-19 vaccines"*, the TGA does not hold any documents containing evidence that graphene oxide is present in the vaccines.

11. If the revised scope of your request was intended to include only a summary document which outlines the testing results of each batch, a table summarising the results of the TGA's batch testing is publicly available here: https://www.tga.gov.au/batch-release-assessment-covid-19-vaccines.

12. I am satisfied that, following a request consultation process undertaken in accordance with section 24AB of the FOI Act, a 'practical refusal reason' exists within the meaning of paragraph 24AA(1)(a)(i) of the FOI Act.

13. The reason for practical refusal is that the work involved in processing your request would substantially and unreasonably divert the resources of the TGA from its other operations. The reasons for my decision are set out in further detail below.

**Background**

14. On 10 August 2021, you submitted your original FOI request.

15. On 16 September 2021, I advised you of my intention to refuse to give access to documents within the scope of your request. As required by paragraph 24(1)(a) of the FOI Act, a request consultation process commenced in accordance with section 24AB of the FOI Act, to provide you with an opportunity to revise the scope of your request so that a practical refusal reason would no longer exist.

16. Specifically, you were advised that it was likely that your request would, among other things, create an unreasonable diversion of the TGA's resources because it involved the review and consideration of approximately 1,638 documents of approximately 17,500 pages, including 42 documents containing in excess of 924 pages specifically related to the testing of lipids by the TGA. The practical refusal reasons also included the following:
    - the fact that each of the documents is likely to include commercially valuable information, that is likely to have a commercial value to the sponsor that would be, or could reasonably be expected to be, destroyed or diminished if the information were disclosed. Consideration would need to be given about whether an exemption should be claimed and whether consultation with the relevant third party is required, and, if so, preparation of schedules for the third party detailing all relevant documents.
    - the number of affected third parties. There is likely to be at least three third parties to consult, including the vaccine sponsors.
    - that advice on the data and sensitivity of the information in these documents would need to be provided by specialised technical staff at the TGA (i.e., senior clinical medical officers, nurses, pharmacists and scientists) a majority of whom are presently engaged in analysis of adverse event data and investigation of safety issues relating to COVID-19 vaccines.
    - the assumption that even if a substantial number of those documents may be capable of being made available (even if in edited form with exempt material redacted), the time taken to appropriately edit each document and to make copies would be an unreasonable diversion of TGA resources; and
    - the fact that any decision letter would need to list each document in an attachment setting out the outcome of the consideration of whether exemptions apply.

17. The TGA also provided you with further publicly available materials in relation to your FOI request as follows:
    - the Australian Public Assessment Report (**AusPAR**) and the Product Information (**PI**) are available for each provisionally approved vaccine here: https://www.tga.gov.au/covid-19-vaccine-provisional-registrations.
    - 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: https://www.tga.gov.au/batch-release-assessment-covid-19-vaccines.
    - general information on how ingredients are recorded for medicines:
        - https://www.tga.gov.au/ingredients-therapeutic-goods and
        - https://www.tga.gov.au/what-ingredients-are-my-medicine.

18. You were also provided with the publicly available information from international regulators on the adverse event data.

19. You were invited to withdraw your request, refine the scope of your request or indicate that you did not wish to revise your request.

20. On 29 September 2021, you responded clarifying the scope of your FOI request, as described on page 1 of this letter.

21. I am now refusing access to your request, noting that the scope of item 1 of your request remains too voluminous to process, for the reasons discussed above.

**Material considered in Decision-Making**

22. In making my decision, I have had regard to:

- the terms of your FOI request and subsequent correspondence between you and the TGA;
- the TGA's assessment of the time and resources that would be required to process your request;
- documents falling within the scope of your request, including the time involved to consult with third parties;
- relevant provisions of the FOI Act, including sections 24, 24AA and 24AB. In particular, the mandatory considerations in section 24AA(2) of the FOI Act regarding whether a practical refusal reason exists, including the resources that would be required to:
    - identify, locate or collate documents falling within the scope of the FOI request;
    - examine the relevant documents and consult with any person or body in relation to the request;
    - make copies or edited copies of the documents; and
    - notify you of the final decision.
- the guidelines issued by the Information Commissioner under subsection 93A(1) of the FOI Act that I am required to have regard to under subsection 93A(2) of the FOI Act; and
- information from the relevant area of the TGA concerning the resources required to comply with your request, and the effect of the same on the TGA's operations, including the staffing resources available to the TGA and the extent to which processing this request would divert resources from other matters important to the TGA's functions of protecting public health and safety.

**Relevant provisions of the FOI Act**

23. Subsection 24AA(1) of the FOI Act defines when a 'practical refusal reason' will exist in relation to a request. A copy of the relevant sections of the FOI Act (sections 24, 24AA and 24AB) are available at **Attachment A**.

24. A practical refusal reason exists if the work involved in processing the request would substantially and unreasonably divert the resources of the agency form its other operations (see subparagraph 24(1)(a)(i) of the FOI Act).

25. Subsection 24AA(2) of the FOI Act sets out the matters to which I must have regard in deciding whether a practical refusal reason exists. Specifically, it states:

*(2) Subject to subsection (3), but without limiting the matters to which the agency or Minister may have regard, in deciding whether a practical refusal reason exists, the agency or Minister must have regard to the resources that would have to be used for the following:*

*(a) identifying, locating or collating the documents within the filing system of the agency, or the office of the Minister;*

*(b) deciding whether to grant, refuse or defer access to a document to which the request relates, or to grant access to an edited copy of such a document, including resources that would have to be used for:*

*(i) examining the document; or*

*(ii) consulting with any person or body in relation to the request;*

*(c) making a copy, or an edited copy, of the document;*

*(d) modifying any interim or final decision on the request.*

26. Subsection 24AA(3) of the FOI Act sets out the matters to which I must not have regard to and so I confirm that I have not had regard to any of those matters in coming to my decision.

**Reasons for Decision**

***Request remains too voluminous to process***

27. Notwithstanding that you have revised the scope of your request, the TGA maintains the view that your request remains too voluminous to process.

28. The scope of your revised request includes all documents "*showing that the TGA has independently tested all vaccine ingredients in the Covid-19 vaccines to show that they align exactly with those listed by the manufacturer*" and "*showing if any of the tests done by the TGA or the manufacturer has found graphene oxide in the Covid-19 vaccines".* This revised scope includes all documents previously requested.

29. The revised scope of your request includes at least 725 documents containing approximately 13,023 pages, each of which contains commercially valuable material and would require consultation with the relevant vaccine sponsor as well as overseas regulatory agencies.

30. I have taken into account the time required to determine whether to refuse or grant access to copies of at least 725 documents; edit and make copies of the documents; engage in third party consultation; prepare the third party decision letters and schedules required; and prepare the decision letter. It is estimated that the TGA would require in excess of 800 hours to process your request in its current form.

31. The documents are likely to require numerous redactions, as the documents contain commercially valuable information. This information is also likely to require consultation with multiple third parties, including the vaccine sponsors and overseas regulators. Regardless of the redactions to commercially valuable information, each document would need to be reviewed in order to ascertain whether consultation was required and with whom.

32. As you would appreciate, the TGA would need to write to each third party individually, attach copies of their documents, and consider the responses provided and any requested redactions. I would then need to make a decision on these documents considering these submissions.

33. In addition, if any of the third parties objected to release of documents and I disagreed with them, then I would need to provide them with a decision. The documents also could not be released to you, in those circumstances, until the third party's review rights had been exercised or had expired.

34. As mentioned previously, a range of the TGA's important public health functions would also be adversely affected by the continued processing of this request in its current form. In particular, the administrative team providing critical support to the TGA's evaluators and the other safety monitoring business of the TGA and the FOI team are also currently dealing with a high volume of COVID-19 related FOI requests.

35. Processing your request would engage resources of those teams that would otherwise be supporting evaluators, the broader operations of the TGA's medicines safety monitoring business and processing other FOI requests. In this regard, the FOI Guidelines states that a relevant matter in deciding a practical refusal reason exists is "the impact that processing a request may have on other work in the agency or minister's office, **including FOI processing (emphasis mine)** (see paragraph 3.117 of the FOI Guidelines).

**Further Information**

36. Paragraph 3.117 of the FOI Guidelines indicates another matter I may take into account in deciding whether a practical refusal reason exists is whether there is a significant public interest in the documents requested and what information is published. I consider that there is a public interest in evidence supporting the safety and efficacy of COVID-19 vaccines that will be used in Australia.

37. To a very large degree, that public interest is met by the publishing of the supporting regulatory documents, including the AusPAR and the PI. The PI and the AusPAR include the ingredients and excipients for the Pfizer and AstraZeneca vaccines, respectively. 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.

38. In particular, as mentioned in our previous correspondence, the TGA releases the testing results of each batch of COVID-19 vaccines which is administrated in Australia. You can find detailed information on how the TGA tests COVID-19 vaccines for purity as well the test results for each batch of COVID-19 vaccine that has been tested by the TGA at: https://www.tga.gov.au/batch-release-assessment-covid-19-vaccines.

39. Each vaccine available in Australia is thoroughly evaluated by the TGA for quality, safety and efficacy before it is allowed to be used in Australia. Part of the TGA process includes assessment of the manufacturing site(s) for the product, and the methods and checks used by the manufacturer to ensure the vaccine made appropriately and is free from contaminants. The TGA also reviews the ingredients used in production of the vaccine.

40. Once COVID-19 vaccines receive approval in Australia, the TGA performs a range of tests to ensure the ingredients comply with the registered product details on the Australian Register of Therapeutic Goods (ARTG). This testing includes visual assessment to ensure the product complies with the appearance description demonstrating the samples are free of contaminants. Other testing includes the assessment of lipid nanoparticles for size.

41. These methods are also able to detect other nanoparticles such as graphene oxide.

42. All batches of Pfizer released in Australia and tested by the TGA, have met the requirements for the nanoparticle size and have not shown any contamination with graphene oxide or metal particulates. 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). The TGA's own pre-market evaluation and post-market testing show that none of the COVID vaccines contain graphene oxide.

43. In addition to testing, the TGA reviews batch release documentation, including details of the manufacturers testing results. The manufacturers of COVID-19 vaccines conduct 100% visual inspections under strict conditions to ensure that every vial is tested to be free of any metal particulates and no contaminated batches are release to the public.

44. Therefore, I consider that insofar as any interest is served by the release of the documents in question, the public interest in evidence supporting the safety and efficacy of COVID-19 vaccines in Australia has already been met through the publication of the supporting regulatory documents and the publicly available materials outlined above.

45. I am satisfied that your request would substantially and unreasonably divert the TGA (as part of the Department of Health) from its other operations. It is also likely to cause serious delays to, and potentially compromise, the TGA's performance of its regulatory functions under the *Therapeutic Goods Act 1989*.

**Review and complaint rights**

46. 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/

47. Should you have any enquiries concerning this matter, please contact the FOI Team on (02) 6289 4630.

Yours sincerely

*Authorised and electronically signed by*

Lisa Kerr
Assistant Secretary
Laboratories Branch
Medical Devices and Product Quality Division
Therapeutic Goods Administration
30 September 2021