Australian Government
Department of Health
Therapeutic Goods Administration

TRIM Ref: D21-2893765

Ms M[redacted]
By Email: [redacted]

Dear Ms [redacted],

FREEDOM OF INFORMATION REQUEST FOI 2533
Request Consultation Process

1. I refer to your request dated 12 July 2021 under the *Freedom of Information Act 1982* (**the FOI Act**) in which you sought access to the following documents:

   "1) The TGA has recently begun to provide a report of the adverse reactions and deaths following the Covid injections:
   1 January 2021 until 1st April 2021
   https://apps.tga.gov.au/PROD/DAEN/daen-report.aspx
   The DAEN report above states there are 33 deaths from the injection. However, these are not listed individually in the report. Why is this?
   Please provide the 33 individual reports of death from the injection.
   2) The weekly Covid vaccine reports (https://www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report-08-07-2021) states: "The TGA has received and reviewed 355 reports of deaths in people who have recently been vaccinated and found that only three were linked to immunisation." Please provide the documentation and evidence showing how it was concluded that the other 332 are not linked to vaccines.
   3) The latest reports from 7th July 2021 states that 8,255,473 vaccines have been administered. From this number, please confirm how many vaccines were distributed and how many were actually administered? Please confirm whether this number also includes vaccine wastage, and what the wastage was."

Decision Maker

2. I am the Therapeutic Goods Administration (TGA) officer authorised to make a decision on your request under the FOI Act.

Requirements for a valid FOI request

3. At the outset, I note that the purpose of the FOI Act is to request documents. It does not require the TGA to answer questions. Therefore, your questions do not meet the requirements of an FOI request under the FOI Act.

4. Sections 11 and 11A of the FOI Act explains a person's right to seek access to documents that are held by agencies, and subsection 15(1) of the FOI Act notes that persons may request access to the documents of an agency.

Publicly available and otherwise too voluminous to process

5. In relation to your request for documents in relation to items 1 and 2 of your request, namely, your request for *"the 33 individual reports of death from the injection"* and *"documentation and evidence showing how it was concluded that the other 332 are not linked to the vaccine"*, these items are too voluminous to process and are otherwise publicly available. As these items have been found to be too voluminous to process, the TGA has not continued processing your request.

Requirement to undertake a request consultation process

6. Under paragraph 24(1)(a) of the FOI Act, I, as a decision maker must consult you if I am satisfied that a "practical refusal reason" exists in relation to your request. A practical refusal reason exists if the work involved in processing the request would substantially and unreasonably divert the resources of the TGA from its other operations. As mentioned above, I am of the view that a practical refusal reason exists in relation to items 1 and 2 of your request.

7. A copy of the sections of the FOI Act that set out the consultation process (sections 24, 24AA and 24AB) is at **Attachment A**. In deciding whether the processing of your request would involve a substantial and unreasonable diversion of resources such that a practical refusal reason exists, I am required under section 24AA(2) of the FOI Act to consider the resources that would have to be used in the following activities:
   - identifying, locating and collating the documents;
   - deciding whether to grant or refuse access to each document and/or to provide an edited copy which would include examining each document and consulting with any person (including those that I would be required to consult under the FOI Act);
   - making a copy or edited copy of each document; and
   - notifying any interim or final decision on the request (including to any third party consulted in the event that a decision is made to give access to the documents despite the objections of the relevant third party).

8. In coming to a view that a practical refusal reason exists in relation to your request, I have had regard to the following:
   - the correspondence from you dated 12 July 2021, including the terms of your request.
   - the estimated volume of documents involved, and the work involved in processing them, namely, preliminary estimates from the relevant line areas of the TGA identified approximately 33 reports in relation to deaths investigated to determine any causal links to the COVID-19 vaccine. The total number of pages is conservatively estimated at 660 pages (at a conservative estimate of approximately 20 pages for each report). This is a particularly conservative estimate noting that some reports may have approximately 50 pages, where they include coroner's reports and correspondence with reporters.
   - the fact that each of the documents is likely to contain personal information, in relation to which 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.
   - this is particularly relevant as the data includes sensitive health information, including coroner's reports, that are likely to require consultation with the third parties or the representatives of deceased persons.
   - the number of affected third parties. To release this information would likely require the TGA to consult with at least 1–2 third parties per report, i.e. there is likely to be at least 66 third parties. In these circumstances, affected third parties may also include the reporters, family members of deceased persons and the coroners who were involved in determining any causal link between the COVID-19 vaccine and the death. 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 taking these submissions into account. Also, 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.

- 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 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.
- 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.

9. Taking into account these matters, I have:
   - considered the time required to undertake the consultation process with at least sixty-six (66) third parties;
   - considered the time already taken to perform searches for potentially relevant documents; and
   - estimated how long it might take to process the 33 reports containing approximately 660 pages (as a conservative estimate).

10. I consider that the number of pages estimated to fall within the scope of your request, combined with the fact that much of the information is sensitive health information, and the necessary consequential work associated with considering whether the documents may be lawfully disclosed, would have a substantial effect on the operations of the TGA.

11. I also find, for the following reasons, that the work involved in processing this request would be an unreasonable diversion of the TGA's resources, including TGA's officers engaged in safety monitoring of medicines and vaccines. As to the critical work that these officers perform, I note that analysis and investigation of medicine and vaccine safety issues, and associated regulatory actions, are of significant public health impact. As you would appreciate, if these officers are required to consider large FOI requests, this diverts their time and attention from undertaking their primary role as evaluators.

12. In addition, 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. Processing your request would tie up resources of those teams that would otherwise be involved in supporting evaluators, the broader operations of the TGA's medicines safety monitoring business and processing other FOI requests. In this regard, the FOI Guidelines state that a relevant matter in deciding whether 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 (my emphasis)** (see paragraph 3.117 of the FOI Guidelines).

13. I also note that there are likely to be significant charges imposed on you for processing your request (as calculated in accordance with the *Schedule to the Freedom of Information (Charges) Regulations 2019*) based on the number of documents and the number of third parties.

14. I note that 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.

15. The public interest is met through the publication of information in the supporting regulatory documents, including the Product Information (PI). 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.

16. In addition to the PI, the TGA publishes a weekly safety report for COVID-19 vaccines, and also makes adverse event information available to the public through the Database of Adverse Event Notifications (**DAEN**). All weekly safety reports remain available on the TGA website at this address: https://www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report. The DAEN can be accessed here: https://apps.tga.gov.au/Prod/daen/daen-entry.aspx.

17. Similar adverse event data is also made available by international regulators, for example:
    - The US Food and Drug Administration's Vaccine Adverse Event Reporting System: https://vaers.hhs.gov/
    - The UK Medicines and Healthcare products Regulatory Agency's Yellow Card reporting: https://www.gov.uk/government/publications/coronavirus-covid-19-vaccine-adverse-reactions
    - The European Medicines Agency EudraVigilance (European database of suspected adverse drug reaction reports): https://www.adrreports.eu/en/

18. I also note, in relation to item 2 of your request, that if a person dies or has a serious event needing hospitalisation within the days to weeks after vaccination, or there was an unusual unexpected event, there are further investigations undertaken. TGA staff gather as much information as possible about the person, including their medical history, risk factors, any medications they are prescribed, details and timing of the vaccine, hospitalisation records, any laboratory test results and whether they have recovered or have any ongoing issues.

19. This will usually involve liaising with the person's GP, specialists and the hospital. Many states and territories then convene an expert panel of doctors. These panels often include the treating doctor, discuss the case in detail, and may advise extra tests that may help them understand the event. A full clinical dossier is then provided to the TGA. The TGA further reviews the case and decides whether the Vaccine Safety Investigations Group (VSIG) is needed to review the case in detail and assess if the vaccine caused it. The VSIG often includes independent medical experts in vaccine safety, infectious diseases, haematology, public health and vaccine confidence, other medical specialists, and a consumer representative.

20. The VSIG reviews the clinical details of the event. It then uses an internationally accepted method to rate the level of certainty of a link between the serious event and the vaccine. For further information on this method, please see the link here:

    https://www.who.int/vaccine_safety/publications/CausalityAssessmentAEFI_EN.pdf?ua=1

21. The VSIG determines if there is enough clinical information to come to a decision, and if not, will request further information from the state/territory health department and may need to reconvene when that information is available. The group then determines if the case is classified as being caused by the immunisation process, uncertain if the vaccine or immunisation caused the event or a coincidence.

22. The TGA then publishes the results of this independent assessment on its website. This is accompanied by a summary of the cases and extra clinical advice for doctors. The TGA also feeds the results back to the state/territory health department and treating doctor. This information is also included in weekly updates published on the TGA website and is reviewed by other key advisory groups, including the Australian Technical Advisory Group on Immunisation (ATAGI) and the government, who monitor the progress of immunisation programs, including for COVID-19. Further information on the ATAGI is available here: https://www.health.gov.au/committees-and-groups/australian-technical-advisory-group-on-immunisation-atagi

23. When a safety signal is identified, the TGA will conduct a thorough investigation to determine what, if any, action is required. An adverse event may occur soon after immunisation, but that does not definitively indicate that the vaccine caused it. The TGA's investigations aim to determine whether vaccination could be the cause of the adverse event and includes assessment of the 'background rate' of the adverse event in the population to see if the reported rate is higher than expected. You may wish to consider accessing the following link for further information: https://www.tga.gov.au/sites/default/files/covid-19-vaccine-safety-monitoring-plan.pdf

24. In relation to item 3 of your request, this information is publicly available here:
    - this page provides data about Australia's COVID-19 vaccine rollout: https://www.health.gov.au/news/health-alerts/novel-coronavirus-2019-ncov-health-alert/coronavirus-covid-19-case-numbers-and-statistics
    - the COVID-19 vaccine rollout update presentation by Operation COVID Shield dated 21 July 2021 contains an update to Australia's COVID-19 vaccine rollout: https://www.health.gov.au/sites/default/files/documents/2021/07/covid-19-vaccine-rollout-update-21-july-2021.pdf
    - advice to COVID-19 vaccine providers is available here, including advice in relation to minimising vaccine wastage: https://www.health.gov.au/initiatives-and-programs/covid-19-vaccines/information-for-covid-19-vaccination-providers/covid-19-vaccine-advice-for-vaccine-providers

25. 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, as well as through publication of information regarding deaths and adverse events on the DAEN and the weekly safety reports.

26. I find that the balance of interests does not favour the expenditure of considerable resources by the TGA. The above diversion of TGA resources would, in my view, be substantial, and is likely to cause serious delays to, and potentially compromise, the TGA's performance of its regulatory functions under the *Therapeutic Goods Act 1989*. Having regard to the importance of the prompt and proper performance of the TGA's regulatory functions, I consider that this diversion of resources would be unreasonable in the circumstances.

Notification of request consultation process

27. I am notifying you of my intention to refuse to give access to the documents that come within the scope of your request.

28. Before deciding to refuse access to documents, I am required under paragraph 24(1)(a) of the FOI Act to undertake a request consultation process in accordance with section 24AB of the FOI Act and provide you with the opportunity to refine the scope of your request.

29. Accordingly, you are now afforded fourteen calendar (14) days from your receipt of this letter in which to contact the TGA to discuss a revision of the scope of your request.

30. Before the end of the 14-day consultation period, you must do one of the following:
    - withdraw your request;
    - make a revised request; or
    - indicate that you do not wish to revise your request.

31. You may wish to consider the following suggestion to revise the scope of your request (please note that this is a suggestion only and does not guarantee the practical refusal reason will no longer exist):
    a. wait until you have reviewed the links to the publicly available material to determine whether a further FOI request for documents is necessary (i.e. you may wish to make another FOI request once you have had an opportunity to review the material in the public domain, noting the regular updates to the COVID weekly safety report and the DAEN).

32. If you have not contacted the TGA within 14 days of receiving this letter to do one of the above or consulted the TGA to discuss revising its scope, your request is taken to have been withdrawn.

33. If you wish to refine the scope of your request, you may contact the TGA FOI team on (02) 6289 4630 or at TGA.FOI@tga.gov.au.

34. Please note that if you indicate that you do not wish to revise your request or revise your request in such a way that I am still of the view that processing it would substantially and unreasonably divert TGA resources from other operations, I may refuse your request under paragraph 24(1)(b) of the FOI Act.

Yours sincerely,

Authorised and electronically signed by

Phillipa Olrick
Acting Assistant Secretary
Pharmacovigilance & Special Access Branch
Therapeutic Goods Administration
29 July 2021