Australian Government

Department of Health and Aged Care
Therapeutic Goods Administration

Mr David Malcolm
Email: foi+request-11266-8dc048c0@righttoknow.org.au

Dear Mr Malcolm

FREEDOM OF INFORMATION REQUEST FOI 5043
Notice of Decision

1. I refer to your request dated 25 March 2024 under the *Freedom of Information Act 1982* (the FOI Act) and subsequent correspondence between you and the TGA, including a request consultation process undertaken under section 24AB of the FOI Act, in which the scope of your request was clarified as being for access to the following documents:

   'I would like to request that the public receive all of the information which the Australian Federal Government or any State/Territory Governments had regarding the MRNA COVID-19 "Vaccines" in the year 2021 at the time of the "vaccine" rollout, specifically on the subjects of:

   -The known and potential side effects (Eg. Myocarditis, Infertility), -Contamination of the contents of the shots with other substances (Eg. DNA), -Whether or not these "vaccines" prevented infection or transmission -Whether or not the "vaccines" in question remains in your body for any extended period of time (longer than two weeks) -Whether or not any properties of or caused by the vaccines in question are passed down to offspring of the covid-19 "vaccinated".

   This is a very important matter and serious follow-ups are required if any branches of Government had knowledge of negative or important factors and effects of these "vaccines" and still encouraged people to receive them and did not tell the citizens of the Commonwealth of Australia about these effects, or even lied about them (Eg. Saying the "vaccines" prevented transmission in advertisements when it is now known that there was NEVER any evidence of this whatsoever).

   I would like to make it clear that I wish to receive a detailed report on ALL of the knowledge the Australian Government had on these topics at the time of the COVID-19 vaccine rollout.'

2. Clarified 8 and 11 May 2024:

   'I would like to clarify my request. What I am asking for, is whether the Australian Government had any knowledge of side effects of or relevant issues with the MRNA COVID-19 Vaccines by Pfizer, Moderna, and Astrazenneca on the topics of:

   -The shots' potential to cause Myocarditis, Infertility, Blood Clots, Heart Arrhythmias or other cardiovascular conditions, Loss of Vision, Loss of other senses such as taste and smell

   -Contamination of the contents of the shots with other substances such as DNA, Heavy Metals, or whether they contained any such substances for any reason

-Whether or not these "vaccines" prevented infection or transmission

-Whether or not the "vaccines" in question remains in your body for any extended period of time (longer than two weeks)

-Whether or not any properties of or caused by the vaccines in question can be passed down to offspring of the covid-19 "vaccinated."

-Whether or not the shots may cause developmental issues or changes in children who received the shots as an infant, or whose mother received it whilst pregnant, or who received it at any point before adolescent development is finished, or who have not received but whose parents did receive it prior to the child's conception

-Whether the shots may cause or be a relevant factor to miscarriages, stillbirths, or infant mortality

-Whether the shots actually have any ability to prevent transmission from or initial infection in those who have received the shots.

I am not asking for companies such as Pfizer to be contacted, I am asking for what knowledge of these issues the Australian Government had at the beginning of the vaccine rollout, and has now.

I would ask that this request be given particular time and scrutiny, as it is one of great importance, especially to those who believe to have been harmed by the shots, or are worried they may develop issues caused by the shots.

Footnote: 'the shots' and "the vaccines" here refers to the MRNA COVID-19 Vaccinations made by Pfizer, Moderna, and Astrazenneca.'

Decision maker

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

Decision

4. I am notifying you of my decision under paragraph 24(1)(b) of the FOI Act to refuse access to the documents that come within the scope of your request.
5. I am satisfied that, following a request consultation process undertaken in accordance with section 24AB of the FOI Act, a 'practical refusal reason' within the meaning of section 24AA of the FOI Act still exists. Specifically, the work involved in processing your request would substantially and unreasonably divert the resources of the TGA from its other operations.
6. The reasons for my decisions are set out in further detail below.

Background

7. On 25 March 2024, the TGA received a request from you under the FOI Act.
8. On 2 May 2024, you were advised that the processing of your request would be an unreasonable diversion of TGA resources. You were invited to undertake a Request Consultation Process in an attempt to reduce the scope of your request to a manageable scope.
9. In my letter dated 2 May 2024, I notified you of my intention to refuse to give access to documents that come within the scope of your request. As required by paragraph 24(1)(a) of the FOI Act, I undertook a request consultation process in accordance with section 24AB of the FOI Act to provide you with the opportunity to contact a TGA officer to consult them about revising the scope of your request so that the practical refusal request would no longer exist.

10. Specifically, I informed you that you had fourteen (14) days from the date of receipt of my letter in which to contact the TGA to do one of the following:

    - withdraw your request;
    - make a revised request; or
    - indicate that you do not wish to revise your request.

11. In your correspondence of 8 and 11 May 2024 in response to my letter, you clarified the scope of your request, as outlined at paragraph 2 above.

12. On 8 May 2024, you agreed to a 15-day extension under section 15AA of the FOI Act for the processing of your FOI request.

Material considered in Decision-Making

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

    - the terms of your FOI request dated 25 March 2025 and the clarification you provided on 8 May 2025 and again on 11 May 2024 in relation to the scope of your request;
    - the TGA's assessment of the time and resources that would be required to process your request;
    - relevant provisions of the FOI Act, including sections 24, 24AA and 24AB;
    - 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;
    - your responses of 8 and 11 May 2024 to my letter of 2 May 2024; and
    - information from relevant areas of the TGA concerning the resources required to comply with your request, and the effect of same on the TGA's operations.

Reasons for Decision

14. Subsection 24AA(1) of the FOI Act defines when a 'practical refusal reason' will exist in relation to a request. Specifically, that provision states:

    (1) For the purposes of section 24, a *practical refusal reason* exists in relation to a request for a document if either (or both) of the following apply:
        (a) the work involved in processing the request:
            (i) in the case of an agency – would substantially and unreasonably divert the resources of the agency from its other operations; or
            (ii) in the case of a Minister – would substantially and unreasonably interfere with the performance of the Minister's functions;
        (b) the request does not satisfy the requirement in paragraph 15(2)(b) (identification of documents).

15. 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:

(iii) examining the document; or
(iv) 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.

16. Subsection 24AA(3) of the FOI Act also sets out the matters to which I must not have regard to:

> (3) In deciding whether a practical refusal reason exists, an agency or Minister must not have regard to:
> (a) any reasons that the applicant gives for requesting access; or
> (b) the agency's or Minister's belief as to what the applicant's reasons are for requesting access; or
> (c) any maximum amount, specified in the regulations, payable as a charge for processing a request of that kind.

17. I confirm that I have not had regard to any of the matters set out in subsection 24AA(3) in coming to my decision.

18. Following the clarification you provided in relation to the scope of your request during the request consultation process undertaken under section 24AB of the Act, the TGA has still identified approximately 1,809 relevant documents containing 113,631 pages in relation to your request that would have to be processed for your request to be finalised.

19. Based on the estimated hours it would take to process your request (currently estimated at in excess of 1000 hours) and the need to involve staff from the TGA's regulatory areas to assist in processing the request, I am satisfied that your request would substantially and unreasonably divert the TGA (a part of the Department of Health and Aged Care) from its other operations.

20. Specifically, staff from the Prescription Medicines Authorisation Branch within the TGA would need to spend a substantial amount of time working on your FOI request to assist in processing and finalising it within the timeframes set by the FOI Act. While undertaking this FOI work, these staff would not be performing their ordinary regulatory functions.

21. 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.

Guidance on accessing the TGA's publicly available information

22. As outlined in my correspondence of 2 May 2024, paragraph 3.117 of the FOI Guidelines indicates a 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 of COVID-19 vaccines that are being used in Australia and much of this information has been made publicly available, as outlined below.

23. In addition to this information, you may wish to review the TGA's responses to various Senators on the matters raised in your scope through the Senate estimates process. This is available at www.aph.gov.au/Parliamentary_Business/Senate_Estimates/eqon.

The TGA's provisional approval of the COVID-19 vaccines

24. The TGA has published a range of regulatory documents relating to the provisional approval of the mRNA COVID-19 vaccines, which provide detailed information regarding the evaluation process and the data that were considered. These include Australian Public Assessment Reports (AusPARs), Product Information (PI) and Consumer Medicine Information (CMI) documents, and they are available at: www.tga.gov.au/products/covid-19/covid-19-vaccines/covid-19-vaccines-regulatory-status. Click on the vaccine of interest's name; the links to these documents are listed under the '*Supporting regulatory documents*' subheading.

25. The TGA also published several documents in response to previous FOI requests for information at the time of the vaccines' roll-out and these are available at www.tga.gov.au/foi-disclosure-log. These documents offered a useful summary and analysis of the data submitted to the TGA for the purposes of making a regulatory decision regarding the provisional approval of the mRNA COVID-19 vaccines.

Clinical trials

26. Clinical trials supporting the safety and effectiveness of the COVID-19 vaccines have been peer-reviewed, published in reputable medical journals and are publicly available. Please see the list, below:

    - Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine
    - Efficacy and Safety of the mRNA-1273 SARS-CoV-2 Vaccine
    - Safety, Immunogenicity, and Efficacy of the BNT162b2 Covid-19 Vaccine in Adolescents
    - Evaluation of the BNT162b2 Covid-19 Vaccine in Children 5 to 11 Years of Age
    - Evaluation of mRNA-1273 Vaccine in Children 6 Months to 5 Years of Age
    - Safety and effectiveness of vaccines against COVID-19 in children aged 5–11 years: a systematic review and meta-analysis
    - Evaluation of mRNA-1273 Covid-19 Vaccine in Children 6 to 11 Years of Age
    - Evaluation of mRNA-1273 SARS-CoV-2 Vaccine in Adolescents
    - COVID-19 vaccine BNT162b1 elicits human antibody and TH1 T cell responses
    - Safety and efficacy of the ChAdOx1 nCoV-19 vaccine (AZD1222) against SARS-CoV-2: an interim analysis of four randomised controlled trials in Brazil, South Africa, and the UK
    - Single-dose administration and the influence of the timing of the booster dose on immunogenicity and efficacy of ChAdOx1 nCoV-19 (AZD1222) vaccine: a pooled analysis of four randomised trials.

27. Further, accurate, evidence-based answers to questions about COVID-19 vaccines can be found on the Department of Health and Aged Care's website Is it true? Get the facts on COVID-19 vaccines. This includes advice that the COVID-19 vaccines cannot alter your DNA.

Safety and efficacy of COVID-19 vaccines

28. Since the COVID-19 vaccines were provisionally approved, more than 13 billion doses of COVID-19 vaccines have been administered worldwide. The safety and efficacy of the COVID-19 vaccines demonstrated in clinical trials has therefore been substantiated by real world use, providing reassurance about the safety of these vaccines. This includes that vaccination is highly effective at preventing serious illness, hospitalisation, and death from COVID-19 in all age groups.

29. Further, this real-world data has shown that vaccines are as safe in special populations, such as people with underlying medical conditions, immunocompromised patients and pregnant women, as they are in the general population. Vaccination of

these groups is strongly recommended because they are at higher risk of complications from COVID-19. Vaccination during pregnancy protects both the mother and the baby. Please refer to the ICMRA statement on the safety of COVID-19 vaccines published in July 2023 on the TGA's website at www.tga.gov.au/news/media-releases/icmra-statement-safety-covid-19-vaccines.

Transmission

30. While dampening transmission of COVID-19 is important, the purpose and approved indication of COVID-19 vaccines is to prevent COVID-19 disease caused by SAR-COV-2.

31. Over the course of the pandemic, numerous studies have been published which show that the vaccines did have an effect on transmission of earlier variants. For example:

    - Infectiousness of SARS-CoV-2 breakthrough infections and reinfections during the Omicron wave.
    - Effect of COVID-19 vaccination on household transmission of SARS-CoV-2 in the Omicron era: The Vaccine Effectiveness, Networking, and Universal Safety (VENUS) study
    - BNT162b2 vaccination reduced infections and transmission ina COVID-19 outbreak in a nursing home in Germany, 2021.

Safety monitoring

32. The TGA, like other regulatory agencies around the world, continues to monitor the safety of vaccines and medicines after they are approved to contribute to a better understanding of their safety profile. General information about the safety of medicines and how the TGA monitors safety is available here: www.tga.gov.au/medicines-safety.

33. The existing safety monitoring system for vaccines involves:

    - reviewing and analysing reports of suspected side effects (also known as adverse events) submitted by health professionals and consumers.
    - requiring pharmaceutical companies to have risk management plans for the vaccines they supply.
    - proactively reviewing medical literature and other potential sources of new safety information.
    - working with international regulators to assess significant side effects detected overseas.
    - working with State and Territory health departments and clinical experts to ensure a coordinated approach.

34. Pharmaceutical companies also have legal obligations to monitor, collect, manage and report on safety data, known collectively as their 'pharmacovigilance responsibilities'. Prior to the COVID-19 vaccine rollout, the TGA implemented a number of enhancements to strengthen the *existing* vaccine safety monitoring system, to allow for early detection and investigation of possible safety issues associated with COVID-19 vaccines, and rapid communication of any confirmed safety issues. These enhancements are described in the COVID-19 vaccine safety monitoring plan, published on the TGA website at: www.tga.gov.au/resources/resource/guidance/covid-19-vaccine-safety-monitoring-plan. If our monitoring confirms a safety issue, we take prompt action to make this information available to health professionals and the public.

Adverse event reports

35. The TGA encourages the reporting of all adverse events, even when the individual is not sure if their medicine or vaccine has been the cause. The information in those reports is uploaded to the Database of Adverse Event Notifications (DAEN). The DAEN contains information on adverse events reported following administration of a medicine, including the COVID-19 vaccines. You can search the DAEN for "COVID" in the medicines report section, available here: apps.tga.gov.au/PROD/DAEN/daen-report.aspx.

36. In addition to the vaccine safety monitoring conducted by the TGA, AusVaxSafety, which is led by the National Centre for Immunisation Research and Surveillance (NCIRS) and funded by the Australian Government Department of Health, conducts active vaccine safety surveillance of the COVID-19 vaccines in use in Australia to ensure their ongoing safety. This information is updated regularly and is accessible here: www.ausvaxsafety.org.au/safety-data/covid-19-vaccines.

37. AusVaxSafety has published articles explaining how current data gives us confidence about the long-term safety of COVID-19 vaccines and how the TGA monitors side effects. If you would like to learn more, we refer you to: www.ausvaxsafety.org.au/how-do-we-know-covid-vaccine-wont-have-long-term-side-effects.

38. The approved PIs and CMIs for each of the COVID-19 vaccines contain information about the recognised side effects of COVID-19 vaccines and are updated as new information becomes available. As mentioned above, you can find these documents on our website at: www.tga.gov.au/products/covid-19/covid-19-vaccines/covid-19-vaccines-regulatory-status.

Contamination of the COVID-19 mRNA vaccines

39. The COVID-19 mRNA vaccines are not contaminated. All batches of mRNA vaccines supplied in Australia have met the established acceptable limits of residual DNA. This is confirmed as part of the vaccine batch release process prior to the release of the batch.

40. The TGA's assessment is that there are no indications of DNA contamination of any of the COVID-19 mRNA vaccines. Residual DNA is a manufacturing impurity found in very low level in many biotechnology medicines and vaccines including mRNA vaccines. The safe use of biological medicines in millions of patients for over 40 years shows that this technology is safe and residual DNA presents a low safety risk. All mRNA vaccines registered in Australia comply with the established acceptable limits of residual DNA. The World Health Organisation (WHO), European Pharmacopeia and regulators including the US FDA and TGA have provided guidance on the acceptable limits of total residual DNA and all mRNA vaccines registered in Australia comply with these limits.

Assistance with making a revised FOI application

41. Should you choose to submit a further FOI request, the TGA would be happy to assist you in forming your request for access to specific documents you may seeking. Please note that Section 15 of the FOI Act requires that a request for documents meets certain requirements, including the provision of sufficient information about specific *document(s)* held by an agency to allow an agency to process a request.

42. Should you wish to seek answers to specific questions, you may wish to write to our regulatory assistance team in the first instance. Further information is available at Contact us | Therapeutic Goods Administration (TGA).

43. 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/your-freedom-of-information-rights/freedom-of-information-reviews.

Review and complaint rights

44. 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/your-freedom-of-information-rights/freedom-of-information-reviews.

45. Should you have any enquiries concerning 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

Andrew Simpson
Assistant Secretary
Prescription Medicines Authorisation Branch
Therapeutic Goods Administration
22 May 2024