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
Request Consultation Process

1. I refer to your request dated 25 March 2024 under the *Freedom of Information Act 1982* (the FOI Act) 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 advertismens 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.'

Decision Maker

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

Requirement to undertake a request consultation process

3. The TGA has now undertaken a preliminary search and retrieval for documents coming within the scope of your request. As a result, TGA officers have indicated that there are approximately 1,809 relevant documents that would have to be processed for your request to be finalised.
4. 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.
5. A copy of the sections of the FOI Act that set out the consultation process (sections 24, 24AA and 24AB) is at **Attachment A**.

6. 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 subsection 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 document).
7. 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 25 March 2024, including the terms of the FOI request;
    - the estimated volume of documents within scope of your request and the work involved in processing them. Namely, preliminary estimates from the relevant line areas of the TGA identified approximately 1,809 documents containing 113,631 pages in relation to your request.
    - there are other areas where searches have not been completed which are likely to hold additional relevant documents and therefore the total number of relevant documents is likely to be higher than the estimate;
    - the need to prepare a schedule detailing all relevant documents;
    - the documents may contain 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;
    - the affected third parties, being Pfizer and Moderna:
        - as you would appreciate, the TGA would need to write to Pfizer and Moderna, 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. If Pfizer and Moderna objected to release of documents and I disagreed with them, then I would need to provide them with a decision.
    - the assumption that the 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; and
    - any decision letter would need to list each document in an attachment setting out the outcome of the consideration of whether exemptions apply.
8. I consider that the number of pages estimated to fall within the scope of your request and the fact that most of the information is potentially commercially valuable information, in addition to 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.
9. I also find that the work involved in processing this request would be an unreasonable diversion of the TGA's resources. If these officers are required to consider large FOI requests, this diverts their

time and attention from undertaking their primary role as evaluators. In addition, the administrative team providing critical support to the TGA's evaluators and the other safety monitoring business of the TGA.

10. 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 (see paragraph 3.117 of the FOI Guidelines).

Guidance on accessing the TGA's publicly available information

11. 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 of COVID-19 vaccines that are being used in Australia.

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

12. 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.

13. 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

14. 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.

15. 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

16. 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.

17. 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

18. 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.

19. 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

20. 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.

21. 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.

22. 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/resource/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.

23. During the roll-out, the TGA published the outcomes of our ongoing monitoring and safety investigations of the COVID-19 vaccines available at: https://www.tga.gov.au/resources/resource/guidance/covid-19-vaccine-safety-monitoring-plan.

Averse event reports

24. 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: https://apps.tga.gov.au/PROD/DAEN/daen-report.aspx.

25. 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: https://www.ausvaxsafety.org.au/safety-data/covid-19-vaccines.

26. 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: https://www.ausvaxsafety.org.au/how-do-we-know-covid-vaccine-wont-have-long-term-side-effects.

27. 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

28. 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.

29. 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.

Notification of request consultation process

30. I am notifying you of my intention to refuse to give access to the documents that come within the scope of your request.
31. 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.
32. Accordingly, you are now afforded fourteen (14) calendar days from your receipt of this letter in which to contact the TGA to discuss a revision of the scope of your request. The processing time for your request has been set aside to allow for the request consultation period.
33. 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.
34. Should you require further time to consider submitting a revised scope, you are welcome to request an extension to the consultation period in writing to the TGA, in accordance with subsection 24AB(5) of the FOI Act.
35. 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 your scope, your request is taken to have been withdrawn.
36. If you wish to refine the scope of your request, you may contact the FOI team on (02) 6289 4630 or at TGAFOI@health.gov.au.
37. 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

Elizabeth Santolin
Director
Prescription Medicines Authorisation Branch
Therapeutic Goods Administration
24 April 2024