Australian Government

Department of Health

Department Reference: FOI 3250

Andria Vincekovic
via email: foi+request-8005-6f8bfd97@righttoknow.org.au

Dear Ms Vincekovic

NOTICE OF DECISION UNDER SECTION 24A
OF THE FREEDOM OF INFORMATION ACT 1982

I refer to your request of 23 October 2021 to the Department of Health (the department) seeking access under the *Freedom of Information Act 1982* (Cth) (the FOI Act) to documents related to COVID-19. Your request is in the following terms:

1. *Documentation proving isolation of the SARS COV2 Delta strain which is confirmed by means of a purified viral sample being imaged with an electron microscope.*
2. *Documentation where the isolated SARSCOV2 Delta virus sample mentioned in point (1) is exposed to healthy humans or animals and shown to cause the disease COVID-19.*
3. *Documentation where the COVID-19 vaccination has been proven to prevent individuals from contracting or spreading the disease COVID-19.*
4. *Documentation of the full list of ingredients as well as the adverse affects recorded from the COVID-19 vaccination since its introduction.*

Information about COVID-19

SARS-CoV-2, the virus which causes COVID-19, is real. Multiple scientific studies across the world demonstrate that highly reputable laboratory medicine experts have isolated and sequenced the virus that causes COVID-19, demonstrating that the virus exists, that it exists in variant forms, that it is different from the influenza virus, and that it causes a disease that has resulted in over 5 million deaths worldwide in just over 22 months.

While the department is not the custodian of the scientific studies establishing the existence of SARS-CoV-2, this research has informed the Australian Government's response to the pandemic. You can find those scientific studies in the public domain.

The department is a government agency and does not conduct scientific studies or laboratory testing for the SARS-CoV-2 in a laboratory. Diagnostic assays using reverse transcriptase polymerase chain reaction (RT-PCR) are conducted by testing laboratories throughout Australia. For more information, please see the Public

Health Laboratory Network guidance on laboratory testing for SARS-CoV-2, which is available online:
https://www.health.gov.au/resources/publications/phln-guidance-on-laboratory-testing-for-sars-cov-2-the-virus-that-causes-covid-19

In Australia, scientists at the Victorian Infectious Diseases Reference Laboratory at The Peter Doherty Institute for Infection and Immunity were the first to isolate SARS-CoV-2 outside of China, winning the 2020 MJA/MDA National Prize for Excellence in Medical Research. This critical information was immediately shared with local and overseas reference laboratories and major North American and European virus culture collections. These peer-reviewed, evidence-based publications provide scientific evidence for the existence of this deadly virus.

All viruses, including SARS-CoV-2, change over time as part of their natural evolution. A change may or may not give the virus a biological advantage. Existing and emerging variants are constantly monitored using genomic surveillance to detect those that pose or may pose an increased risk to human health.

In Australia, whole genome sequencing of the SARS-CoV-2 genome is the preferred way to determine the variant and mutation patterns of the virus, e.g. Alpha, Delta, and Kappa variants. Some RT-PCR tests have been designed to detect specific SARS-CoV-2 variants of concern. These tests can only identify the specific variants they have been designed for.

Attached to this email is an article published in the Daily Telegraph on 13 August 2021 that may be of interest to you.

Information about COVID-19 Vaccines

Before a prescription medicine (including a COVID-19 vaccine) can be legally supplied in Australia, the Therapeutics Goods Administration (TGA) rigorously assesses the safety, quality and effectiveness to determine if the benefits outweigh the risks. The risk-benefit approach assures consumers that the products they take are safe for their intended use, while still providing access to products that are essential to their health needs. More information can be found here: https://www.tga.gov.au/how-tga-regulates.

The TGA provisionally approved the Pfizer, AstraZeneca and Moderna COVID-19 vaccine candidates after a complete assessment of all available data using the same process that is used for other vaccines approved in Australia. With rolling submission, collaboration with international regulators, and proactively working with sponsors, the evaluation of COVID-19 vaccines has been, and continues to be, expedited without compromising on strict standards of safety, quality and efficacy.

The COVID-19 vaccines which have received provisional approval in Australia have each been shown to be highly effective in preventing severe illness, hospitalisation, and death from COVID-19, caused by SARS-CoV-2. The risk of a person infected

with the SARS-CoV-2 virus developing symptomatic illness and becoming seriously unwell with COVID-19 is significantly reduced if that person has received a COVID-19 vaccine. For each provisionally approved vaccine, the TGA has established the acceptable safety, quality and efficacy of the vaccine based on a comprehensive evaluation of a wide range of information.

Further information relating to the safety and efficacy of the COVID-19 vaccines available in Australia, including the Pfizer, AstraZeneca and Moderna vaccine candidates, is publicly available on the TGA website:
https://www.tga.gov.au/covid-19-vaccine-safety-monitoring-and-reporting

Information about reported adverse events following vaccination

The Therapeutic Goods Administration (TGA) maintains a Database of Adverse Event Notifications (DAEN) of reports of adverse events following the use of medicines in Australia, including the COVID-19 vaccines. The fact that an adverse event is reported on the DAEN following administration of a medicine does not mean the adverse event was related to the medicine. There might be no relationship between the adverse event and the medicine or vaccine – it may be a coincidence that the adverse event occurred when the medicine or vaccine was taken, and the symptom may be related to the underlying illness or to other factors.

Expert analysis and review of adverse event reports is needed to determine whether there may be a link between reported event and the use of a medicine, such as a vaccination. The TGA analyses the data and reviews individual reports to identify possible safety issues for investigation. If these investigations confirm a safety signal, the TGA takes appropriate action. There is not a predefined number of adverse event reports that leads to removal of a product from the market because the type of action depends on the nature of the safety issue identified, including its likelihood and severity and the potential to mitigate the risk (such as through patient selection or monitoring), and the impact of the safety issue on the balance of benefits and risks for the product.

The DAEN is available on the TGA website here:
https://www.tga.gov.au/database-adverse-event-notifications-daen)

Information about vaccine ingredients

A Product Information document (PI) provides a summary of the scientific information relevant to the safe and effective use of a prescription medicine, some non-prescription medicines and some biologicals. It provides objective information about the quality, safety and effectiveness of the medicine, as demonstrated in the data provided to the TGA by the pharmaceutical company. PI documents are written by the pharmaceutical company responsible for the medicine and must be approved by the TGA before publication.

The PI includes information about adverse events observed in clinical trials and from post-market surveillance. The TGA works with pharmaceutical companies to ensure the PI remains up to date and can mandate updates to the safety information included in the PI.

The PI documents, which include the ingredient lists for all vaccines available in Australia, can be found online: https://www.tga.gov.au/covid-19-vaccine-information-consumers-and-health-professionals

In addition, an Australian Public Assessment Report for prescription medicines (AusPAR) provides information about the evaluation of a prescription medicine and the considerations that led the TGA to approve or not approve an application. More information about AusPARs is available here:
https://www.tga.gov.au/australian-public-assessment-reports-prescription-medicines-auspars

Information about the vaccines that have provisional approval in Australia are available here:
https://www.tga.gov.au/covid-19-vaccine-astrazeneca-chadox1-s
https://www.tga.gov.au/covid-19-vaccine-pfizer-australia-comirnaty-bnt162b2-mrna
https://www.tga.gov.au/covid-19-vaccine-spikevax-elasomeran)

FOI decision

I am authorised under subsection 23(1) of the FOI Act to make decisions in relation to Freedom of Information requests. I am writing to notify you of my decision in response to your request.

The FOI Act provides a mechanism for individuals to request access to documents held by relevant entities. It is not a mechanism for asking questions or seeking information that the entity does not hold in documents.

Appropriate steps have been taken to find documents you have requested including consultation with relevant departmental officers and searches of departmental file management systems.

I am satisfied, based on the consultation undertaken and the searches conducted, that the department, including the Therapeutic Goods Administration, does not hold any documents referred to in your request. This research and information is available in the public domain as described above.

As a consequence, relying on section 24A of the FOI Act, I cannot provide access to the documents you requested.

FOI review rights

If you are dissatisfied with my decision, you may apply for a review.

Internal review

Under section 54 of the FOI Act, you may apply for internal review of this decision. In accordance with section 54B of the FOI Act, an application for internal review must be made in writing within 30 days after the day you are notified of this decision (or such further period as the department allows). To assist in the internal review process, please provide reasons you consider the review of my decision is necessary.

The internal review will be carried out by another officer of this department within 30 days of receipt of your application.

An application for an internal review should be addressed to:

Email: FOI@health.gov.au
Mail: FOI Unit (MDP 516)
Department of Health
GPO Box 9848
CANBERRA ACT 2601

Information Commissioner review

Alternatively, under section 54L of the FOI Act, you may apply to the Office of the Australian Information Commissioner (OAIC) for review of my decision by the Information Commissioner (IC).

In accordance with subsection 54S(1) of the FOI Act, an IC review application in relation to a decision covered by subsection 54L(2) (access refusal decisions) must be made in writing within 60 days after the day you are notified of this decision (if you do not request an internal review).

More information about IC review is available on the OAIC website at:
https://www.oaic.gov.au/freedom-of-information/reviews/

The OAIC can be contacted by:

Phone: 1300 363 992
Email: enquiries@oaic.gov.au

Complaints

If you are dissatisfied with action taken by the department, you may also make a complaint.

Complaint to the department

Complaints to the department are covered by the department's privacy policy. A form for lodging a complaint directly to the department is available on the department's website:
https://www.health.gov.au/about-us/contact-us/complaints

Complaint to the IC

Information about making a complaint to the IC about action taken by the department is available on the OAIC website:
https://www.oaic.gov.au/freedom-of-information/reviews-and-complaints/make-an-foi-complaint/

Relevant provisions of the FOI Act

The FOI Act, including the provisions referred to in this letter, can be accessed from the Federal Register of Legislation website:
https://www.legislation.gov.au/Details/C2021C00382

Contacts

If you require clarification of any of the matters discussed in this letter you should contact the department's Freedom of Information Unit on (02) 6289 1666 or at FOI@health.gov.au.

Yours sincerely

Megan Lancaster
Assistant Secretary
Public Health and Surveillance Branch

22 November 2021