Australian Government

Department of Health
Therapeutic Goods Administration

Dear Applicant,

Thank you for your communications with the Department of Health, of which the Therapeutic Goods Administration (**TGA**) is part of, in which you requested the **following** under the *Freedom of Information Act 1982* (**FOI Act**):

> *"Substantiated scientific evidence and data that proves through short term AND long term studies that the Covid 19 vaccines available in Australia are safe, effective, and necessary.*
>
> *Can you also provide substantiated scientific evidence and peer reviewed studies that proves making a vaccine mandatory for teachers decreases the risk of infection and transmission to staff and students in the workplace"*

We appreciate that there has been increased public interest in the COVID-19 vaccines in light of the recent announcement by the Victorian Government that all staff at schools and childcare services be fully vaccinated by 29 November 2021. We thank you for your query and would like to assure you that the TGA is committed to transparency and accountability through the FOI framework.

We have considered your query and determined that it is not a valid request under the FOI Act. This is because the information you have requested is either already publicly available, or not held by the TGA. The purpose of the FOI Act is to provide access to documents held by the TGA, not to refer you to publicly available information or to answer specific questions.

Nevertheless, we understand that your query is made in the interest of public health. Therefore, in order to assist you further, we wish to provide you with background information and links to publicly available resources that are relevant to your query. This information has been prepared in consultation with technical experts at the TGA to ensure that it is current and accurate.

Although we have provided general information about the safety, quality and efficacy of COVID-19 vaccines below, vaccine workplace requirements are beyond the remit of the TGA. In particular, specific questions about vaccine requirements in educational settings should be referred to the relevant State or Territory education and/or health department.

Please also note that while we have provided links and resources as a guide, they are not intended to be an exhaustive list and the TGA does not take responsibility for errors or omissions in third party publications.

The regulatory status of COVID-19 vaccines in Australia

Three COVID-19 vaccines are currently available as part of Australia's national vaccination program:

- the COVID-19 Pfizer (Comirnaty) vaccine (**'Pfizer vaccine'**),
- the COVID-19 AstraZeneca (Vaxzevria) vaccine (**'AstraZeneca vaccine'**), and
- the COVID-19 Moderna (SpikeVax) vaccine (**'Moderna vaccine'**).

These vaccines have all been provisionally approved by the TGA. The provisional approval pathway balances the benefits of early access with the uncertainties inherent to the fact that additional data

are required. This pathway is available for other prescription medicines, not just vaccines. Further details of the provisional approval pathway are available at: www.tga.gov.au/provisional-approval-pathway-prescription-medicines

Before a COVID-19 vaccine can be provisionally approved in Australia, the TGA must establish the acceptable safety, quality and efficacy of the vaccine based on a comprehensive evaluation of a wide range of information. This includes clinical studies, non-clinical and toxicological studies, chemistry, risk management and manufacturing information.

A large team of clinical and scientific experts at the TGA carefully review this data and seek advice from the Advisory Committee on Vaccines (**ACV**), an independent clinical expert committee, prior to a senior medical officer making a regulatory decision. Even though this is an expedited process, no element of the evaluation is rushed, and no data are overlooked. A vaccine is only provisionally approved by the TGA if this rigorous process is completed and the benefits are considered to be much greater than any potential risks. As part of the provisional approval, sponsors are also required to continue to submit evidence of longer-term safety and efficacy to the TGA.

Provisional approval is initially limited to a period of two years. The sponsor can apply for two extensions, up to a maximum of six years. Data from ongoing clinical trials will be key to providing robust evidence of the longer-term effectiveness including duration of protection against COVID-19, the potential need for boosters and to support a sponsor's application to transition their COVID-19 vaccine to full registration status if they choose to do so. Final results from ongoing clinical trials for these vaccines are expected to be available between 2021 – 2024, depending on the trial.

The TGA has published a range of regulatory documents relating to the provisional approval of each COVID-19 vaccine, which provides detailed information regarding the evaluation process and the data that were considered. These include the Australian Public Assessment Report (**AusPAR**), the Product Information (**PI**) and the Consumer Medicine Information (**CMI**), and they are available at: www.tga.gov.au/covid-19-vaccines.

Scientific evidence for the safety and effectiveness of COVID-19 vaccines

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.

The pivotal clinical trials supporting the safety and effectiveness of vaccines in the provisionally approved age groups have been peer-reviewed, published in reputable medical journals and are publicly available.

- With respect to the AstraZeneca vaccine, the following articles are published in the Lancet medical journal:
    - "*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*"
      Accessible at: https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)32661-1/fulltext

    - "*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*"
      Accessible at: https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)00432-3/fulltext

  - "*Global Statistical Analysis Plan for the combined integrated analysis of studies of ChAdOx1 nCoV-19 (AZD1222) vaccine*"
    Accessible at:https://ars.els-cdn.com/content/image/1-s2.0-S0140673620326611-mmc2.pdf

- With respect to the Pfizer vaccine, the following articles are published in the New England Journal of Medicine:
  - "*Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine"*
    Accessible at: https://www.nejm.org/doi/full/10.1056/NEJMoa2034577

  - "*Safety, Immunogenicity, and Efficacy of the BNT162b2 Covid-19 Vaccine in Adolescents*"
    Accessible at:
    https://www.nejm.org/doi/full/10.1056/NEJMoa2107456?query=featured_coronavirus

- With respect to the Moderna vaccine, the following articles are published in the New England Journal of Medicine:
  - *"Efficacy and Safety of the mRNA-1273 SARS-CoV-2 Vaccine"*
    Accessible at: https://www.nejm.org/doi/full/10.1056/NEJMoa2035389

  - *"Evaluation of mRNA-1273 SARS-CoV-2 Vaccine in Adolescents"*
    Accessible at: https://www.nejm.org/doi/10.1056/NEJMoa2109522?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%200pubmed#article_Abstract

Ongoing research continues to demonstrate the effectiveness of the COVID-19 vaccines in reducing disease severity and transmission. Large studies conducted in real-life situations have shown a marked reduction on the transmission following vaccination. For example, Public Health England (**PHE**) reported the results of a large study of household transmission using a linked data set:

- "*Effect of Vaccination on Household Transmission of SARS-CoV-2 in England*
  Accessible at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8262621/

Furthermore, emerging international evidence demonstrates that the COVID-19 vaccines generate durable protection against hospitalisation due to severe COVID-19. For example:

- "*Duration of protection of COVID-19 vaccines against clinical disease*" published on 9 September 2021 by Public Health England:
  Accessible at:
  https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1017309/S1362_PHE_duration_of_protection_of_COVID-19_vaccines_against_clinical_disease.pdf

- "*Comparative Effectiveness of Moderna, Pfizer-BioNTech, and Janssen (Johnson & Johnson) Vaccines in Preventing COVID-19 Hospitalizations Among Adults Without Immunocompromising Conditions — United States, March–August 2021*" published 24 September 2021 by the US Department of Health and Human Services/Centers for Disease Control and Prevention:
  Accessible at: https://www.cdc.gov/mmwr/volumes/70/wr/pdfs/mm7038e1-H.pdf

- "*Six-Month Effectiveness of BNT162B2 mRNA COVID-19 Vaccine in a Large US Integrated Health System: A Retrospective Cohort Study*" pre-print published 23 August 2021 by the Lancet
  Accessible at: https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3909743

FOI Disclosure Log

The TGA has also published several documents in response to previous FOI requests.

These documents offer 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 COVID-19 vaccines.

For documents that have already been released regarding the Pfizer vaccine, please see the TGA's Disclosure Log at www.tga.gov.au/foi-disclosure-log for documents released in response to FOI 2389 (FOI documents 1 – 7).

For documents released regarding the AstraZeneca vaccine please see the Disclosure Log for documents released in response to FOI 2494 (FOI documents 1 – 7). Please note, some commercially confidential information and personal information has been redacted from these documents.

Monitoring the safety of the COVID-19 vaccines

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: https://www.tga.gov.au/medicines-safety.

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.

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.

Each week, the TGA publishes the outcomes of our ongoing monitoring and safety investigations of the COVID-19 vaccines available at: www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report.

All adverse event reports submitted to the TGA are evaluated, duplicate reports are rejected, and the information in those reports is uploaded to the Database of Adverse Event Notifications (**DAEN**). The DAEN contains information on all 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.

As at 19 August 2021, the TGA has reduced the time between adverse event reports being accepted into our database and published on the DAEN from 90 days to 14 days. This decision was made in response to the strong public interest in adverse event reports relating to COVID-19 vaccinations and allows reports for vaccines publicly available more quickly.

In addition to the vaccine safety monitoring conducted by the TGA, AusVaxSafety, which is led by the 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.

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.

As at 26 September 2021, AusVaxSafety reported that less than half of Australians (43.8%) reported at least one adverse event following vaccination, and only 0.8% of Australians reported visiting a GP or ED following vaccination.

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: https://www.tga.gov.au/covid-19-vaccine-provisional-registrations.

Vaccine ingredients

The full lists of ingredients for each COVID-19 vaccines are publicly available on the TGA website at: https://www.tga.gov.au/covid-19-vaccine-information-consumers-and-health-professionals.

As part of the provisional approval process, the TGA requires that a comprehensive PI document and CMI leaflet be made publicly available for healthcare professionals and consumers. These documents also contain a full list of the ingredients found in each vaccine:

- The PI/CMI for the Pfizer vaccine is available at: https://www.tga.gov.au/covid-19-vaccine-pfizer-australia-comirnaty-bnt162b2-mrna-approved-use-individuals-12-years-and-older
- The PI/CMI for the AstraZeneca vaccine is available at: https://www.tga.gov.au/covid-19-vaccine-astrazeneca-chadox1-s
- The PI/CMI for the Moderna vaccine is available at: https://www.tga.gov.au/covid-19-vaccine-spikevax-elasomeran

Batch Assessment

The TGA also ensures there is an independent quality assessment of every batch of vaccine supplied in Australia through vaccine batch release assessment. For all COVID vaccines supplied through the government's vaccination program, a batch release assessment includes a review of documents

supplied by the sponsor which describes the manufacturing process; TGA laboratory testing (and/or review of testing results from an overseas regulatory laboratory that has been recognised by the TGA).

The results of this assessment are publicly available here: https://www.tga.gov.au/batch-release-assessment-covid-19-vaccines. This link provides 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.

Tests are performed on a variety of the vaccine's properties, including the ingredients in the product (composition, strength, and identity) and the absence of impurities (purity, integrity, and endotoxin). The testing results, along with the review of the manufacturing documentation for each batch, provides assurance that the vaccine being supplied is in line with registered products on the Australian Register of Therapeutic Goods (**ARTG**).

If you are interested in accessing general information on how ingredients are recorded for medicines, we refer you to:

- https://www.tga.gov.au/ingredients-therapeutic-goods and
- https://www.tga.gov.au/what-ingredients-are-my-medicine.

The risk of COVID-19 for young people and in educational settings

The Delta variant of the SARS-CoV-2 virus, which is circulating within Australia, is highly transmissible, including among young Australians. Since the emergence of the Delta variant, COVID-19 infections in children and young adults have increased globally, raising concerns about increased transmission potential within educational settings.

On 8 September 2021, the National Centre for Immunisation Research and Surveillance (**NCIRS**), which is the leading research organisation in Australia that provides expert advice on immunisation, prepared a report on SARS-CoV-2 transmission in all schools and early childhood education and care (**ECEC**) services and associated households in New South Wales (**NSW**) between 16 June 2021 and 31 July 2021, with contact tracing and test follow-up data to 19 August 2021. The report showed that transmission rates in schools, ECEC services and households seen during the current SARS-CoV-2 Delta variant outbreak in NSW are 5.2 times higher than those seen throughout 2020.

The report concluded that "*Higher population-level rates of Covid-19 vaccination, including vaccination of school/ECEC staff, are critical to reduce the risk of transmission in the community and in educational settings. In addition, vaccination of adolescents […] in higher risk LGAs, which is currently occurring as part of the outbreak response, is an important step towards returning students into the classroom."*

The full NCIRS report on SARS-CoV-2 transmission in NSW schools and ECEC services, can be found at: https://www.ncirs.org.au/sites/default/files/2021-09/NCIRS%20NSW%20Schools%20COVID_Summary_8%20September%2021_Final.pdf.

Additional information published by the NCIRS on COVID-19 in educational settings is available at: https://www.ncirs.org.au/covid-19-in-schools.

The Australian Technical Advisory Group on Immunisation (ATAGI) has also published detailed recommendations on the use of vaccines in adolescents 12 years of age and over: https://www.health.gov.au/news/atagi-recommendations-on-the-use-of-covid-19-vaccines-in-all-young-adolescents-in-australia

Conclusion

We hope the information we have provided above is helpful to you.

As the information you have requested is publicly available, or otherwise not held by the TGA, your FOI request is considered to be withdrawn.

Regards

Freedom of Information

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