



The Hon Greg Hunt MP
Minister for Health and Aged Care

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Mr Ken O'Dowd MP
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Standing Committee on Petitions
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Dear Chair

I refer to your correspondence concerning petition EN3070 - Stop use of experimental COVID19 vaccines in young people/students.

The Australian Government wants everyone in Australia to have access to a safe, free, COVID-19 vaccine, if they choose to be vaccinated. Moreover, the safety of the population has always been the highest priority of the Government. For these reasons, decisions concerning COVID-19 vaccines have been guided by the expert medical advice of the Australian Technical Advisory Group on Immunisation.

The Therapeutic Goods Administration (TGA) formally assesses the safety, quality and efficacy of medicines, including vaccines, prior to their approval for use in Australia. All vaccines must pass the TGA's rigorous assessment and approval processes, after being tested in large clinical trials on thousands of people. Technical experts analyse the three phases of clinical trials test for safety at every phase, as well as how effective the vaccine is at protecting against infection and disease.

This involves comprehensive review of clinical trial data, non-clinical and toxicological studies, chemistry, manufacturing, quality, risk-management and other information by a large team of clinical and scientific experts. Advice is then sought from an independent expert committee before a regulatory decision is made.

All COVID-19 vaccines used in the rollout have been granted provisional approval following a complete assessment of all this available data. No part of the process has been rushed and the TGA does not have an 'Emergency Use Authorisation' pathway for COVID-19 vaccines.

The urgency of the global pandemic means that researchers, agencies such as the World Health Organization and governments all over the world are prioritising the development, assessment and rollout of COVID-19 vaccines.

There is a combination of reasons why safe and effective COVID-19 vaccines have been able to be designed, researched and made available sooner than previously seen. For example:

- unprecedented levels of funding—the pandemic is a global priority and governments around the world are investing in research and manufacturing facilities

- technology—the evolution of technology has allowed vaccines to be developed at a faster pace than in the past. New technologies have helped scientists understand the coronavirus and its make-up more easily, which has allowed them to start working on vaccine design more quickly
- combined clinical trials—in response to the pandemic, some pharmaceutical companies have combined clinical trial phases 1 and 2
- expedited review process by regulatory agencies—the TGA is engaging early with pharmaceutical companies about their vaccines and is accepting rolling data. This means that the TGA can accept, review and assess clinical trial data as it becomes available, rather than all at once at the end of the three clinical trial phases.

All vaccines must pass the TGA's rigorous assessment and approval processes including clinical trials. Technical experts analyse the three phases of clinical trials test for safety at every phase, as well as how effective the vaccine is at protecting against infection and disease.

The TGA requires robust scientific data before supporting a vaccine candidate and will only register and approve a COVID-19 vaccine if it is found to be safe and effective, following its complete assessment of data.

Participation in clinical trials is a voluntary process with terms and conditions to which participants agree. Importantly:

- The Australian Government is not involved in setting these terms and conditions
- This is a contractual matter between individuals and clinical trial sponsoring companies.

The Australian Immunisation Handbook (Handbook) has information about 'valid consent', including criteria for consent to be legally valid. The Handbook states that, in general, a parent or legal guardian of a child has the authority to consent to that child being vaccinated. Some Australian states and territories have legislation that addresses the issue of a child's consent to medical treatment.

The common law applies in the states and territories that do not have specific legislation relating to children's consent to medical treatment. This common-law position is often referred to as Mature Minor or Gillick competence.

For certain procedures, including vaccination, a child or adolescent may be determined to be mature enough to understand the proposed procedure, and the risks and benefits associated with it. These young people may have the capacity to consent under certain circumstances.

The TGA has provisionally approved the Pfizer and Moderna COVID-19 vaccines for use in people aged 12 years or older. In doing so, the TGA undertook an independent and rigorous assessment of the available data for the Pfizer and Moderna mRNA COVID-19 vaccines.

The data provided to the TGA was comprehensive and included pre-clinical and clinical studies, non-clinical and toxicology studies, chemistry, manufacturing, risk-management and other information. All data was carefully reviewed by a large team of TGA's technical and clinical experts before provisionally approving both vaccines.

The TGA is also part of a network of international regulators that meet regularly to discuss the development of COVID-19 vaccines. This information, together with the potential to use already established work-sharing arrangements and collaboration with other international regulators, is assisting the TGA to expedite the evaluation of any new vaccines without compromising on strict standards of safety, quality, and effectiveness.

The rollout and distribution of COVID-19 vaccines will occur in line with the Operation COVID Shield National COVID Vaccine Campaign Plan. For specific information on the COVID-19 vaccine rollout, please visit my Department's website at: www.health.gov.au/initiatives-and-programs/operation-covid-shield.

Thank you for writing on this matter.

Yours sincerely

Greg Hunt