Australian Government

BE COVIDSAFE

AUSTRALIAN COVID-19 VACCINATION POLICY



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Executive Summary

Making safe and effective COVID-19 vaccines available to all Australians is a key priority of the Australian, State and Territory governments. This Australian COVID-19 Vaccination Policy (Policy) outlines the approach to providing COVID-19 vaccines in Australia.

It sets out key principles, such as that COVID-19 vaccines will be made available for free to all Australian citizens, permanent residents, and most visa-holders. Further, it outlines how COVID-19 vaccines will be accessible on a rolling basis, dependent on vaccine delivery schedules and the identification of groups for most urgent vaccination.

This Policy also describes the shared and separate responsibilities of the Australian, State and Territory governments, as well as other key stakeholders. Each jurisdiction, including the Australian Government, will develop supporting Implementation Plans, which will articulate how it will give effect to its responsibilities under this Policy.

Key responsibilities of the Australian Government will include the regulation of vaccines, their acceptance from manufacturers, storage and transport to specified sites within States and Territories, setting funding policy, ensuring that appropriate data collection and monitoring systems are in place, and the national communications and information effort.

States and Territories' responsibilities include ensuring appropriately qualified and trained workforce for vaccines delivered at their vaccination sites, providing sites where vaccinations can safely take place, and ensuring that immunisation providers at state and territory vaccination sites remain compliant at all times with their safety, ethical, and reporting obligations.

1. Introduction

COVID-19 has created twin crises – a public health emergency and a profound global economic shock, both of which are having a significant impact on the wellbeing of Australians. In 2020, the Australian economy is expected to endure its largest annual fall in economic activity on official record.

A safe and effective vaccine, available globally, will dramatically improve health outcomes and societal wellbeing and facilitate economic recovery. Making safe and effective COVID-19 vaccines available to all Australians is a key priority of the Australian, State and Territory governments.

Purpose

This document outlines the key policy parameters and approach to providing COVID-19 vaccines in Australia, including:

- The Australian immunisation context;
- Roles and responsibilities of governments and other key stakeholders in a COVID-19 pandemic vaccination program;
- Information on the vaccines purchased by the Australian Government;
- Key features of the vaccination program, including how doses will be made available to those identified by medical experts as most in need and where and how vaccination will take place;
- How vaccine safety will be monitored;
- How data will be collected and reported to support public health outcomes, including the digital solutions that will be used to support consumers and clinicians through the vaccination process; and
- How accurate, timely information on COVID-19 vaccines and vaccination will be made available to consumers and clinicians.

The Policy is intended to provide a framework for the development of a related set of implementation plans managed by the Australian Government and State and Territory Governments. All implementation plans, and updates to those plans, will require endorsement by the Australian Government.

Australia's COVID-19 Vaccine and Treatment Strategy.

This documents outlines the way forward for the **fifth element** of Australia's COVID-19 Vaccine and Treatment Strategy. Released in August 2020, the Strategy supports early access to, and delivery of, safe and effective COVID-19 vaccines and treatments, as soon as they become available.

To do this, the Strategy focuses on five key areas.



Research and development

Identify and support world-leading research activities to speed up the development and manufacture of promising COVID-19 vaccines and treatments.



Purchase and manufacturing

Build a diverse global portfolio of investments to seek to secure early access to promising vaccines and treatments, using local manufacturing wherever possible.



International partnerships

Work with organisations and countries around the world to accelerate development of a safe and effective vaccine and treatments for COVID-19 and ensure access is available and affordable to all people.



Regulation and safety

Use the rigorous regulatory pathways managed by internationally best practice Therapeutic Goods Administration (TGA) to enable early access to COVID-19 vaccines and treatments. The TGA will work with international counterparts, sharing information on vaccine clinical trials, manufacturing and safety. This will ensure a safe and fast regulatory process for Australia and our region.



Immunisation administration and monitoring

Provide Australians with safe and effective vaccines under a targeted and responsive national COVID-19 vaccination policy and immunisation program. Policies and programs will be based on up-to-date health advice.

2. Immunisation policy, regulation and governance in Australia

Immunisation is one of the most successful public health interventions of the past 200 years. The low incidence of vaccine-preventable diseases in Australia attests to the effectiveness of our immunisation services, programs and policies. Since the introduction of routine immunisations in Australia in the 1950s, death or disability from vaccine-preventable diseases has reduced dramatically.

Australia's high-quality immunisation system is internationally recognised. Routine immunisation of infants in Australia began in the 1950s, and the first nationally funded infant program for diphtheria, tetanus and polio started in 1975. The immunisation program has since expanded to include a new vaccines for an expanding range of diseases and is a major public program funded by the State, Territory and Australian governments.

The National Immunisation Program (NIP)

Many immunisations in Australia are provided through the NIP. The NIP was set up by the Australian and state and territory governments in 1997. It aims to increase national immunisation coverage to reduce the number of cases of diseases that are preventable by vaccination in Australia. The NIP is a collaborative initiative involving all levels of government (Australian, state and territory, and local), healthcare providers, administrators and researchers. The program positively affects the health of all Australians at some point in their lives – either directly through vaccination or indirectly through reduced transmission of infectious diseases (community immunity).

The Australian Technical Advisory Group on Immunisation (ATAGI)

ATAGI is a ministerially appointed committee established to advise both the Australian Minister for Health as well as the Department of Health. It comprises medical and scientific experts on immunisation from around the nation and consumer representation. It provides advice on the medical administration of vaccines for the NIP as well as vaccine policy generally, including through the development of the comprehensive Australian Immunisation Handbook. ATAGI is playing a key role in providing evidence-based advice to the Department of Health on COVID-19 vaccination in Australia.

The Therapeutic Goods Administration (TGA)

The TGA rigorously assesses vaccines for safety, quality and efficacy before they can be used in Australia. Vaccines receive the same high level of scrutiny as other prescription medicines and related therapeutic goods.

The TGA regulates therapeutic goods through:

- pre-market assessment;
- post-market monitoring and enforcement of standards; and
- licensing of Australian manufacturers and verifying overseas manufacturers' compliance with the same standards as their Australian counterparts.

Therapeutic goods are divided broadly into two classes: medicines and medical devices. Vaccines are categorised as medicines. Medicines must be entered as either 'registered' or 'listed' medicines on the Australian Register of Therapeutic Goods (ARTG) before they may be supplied in or exported from Australia.

The TGA's decision to register a vaccine for use in Australia is informed by the advice of the Advisory Committee on Vaccines (ACV). The ACV is an independent committee appointed by the Australian Government Minister for Health. It is composed of members with expertise in science, medicine and public health, together with a consumer representative. The ACV complements expertise in the TGA, ensuring that assessments of vaccines are as robust as possible.

The TGA uses the best available scientific evidence to assess the risks and benefits of each vaccine. Evidence requirements are based on international guidelines developed by the European Medicines Agency.

Clinical trials are a key part of the scientific evidence reviewed during the TGA's assessment of a new vaccine. A clinical trial is a scientific study where a promising new medicine is given to a group of people to assess its risks and benefits.

The TGA carefully assess the results of clinical trials and the way in which the trials were conducted. It requires well-designed trials of a sufficient length with a sufficient number of people who represent the people for whom the vaccine is intended. The results must demonstrate that the benefits of the vaccine greatly outweigh the risks.

The TGA also requires vaccine manufacturers to meet manufacturing quality standards. As a further check, TGA laboratories assess the quality of every batch of a vaccine before it can be supplied in Australia.

The Office of the Gene Technology Regulator (OGTR)

The OGTR is responsible for the regulation of genetically modified organisms (GMOs) in accordance with the *Gene Technology Act 2001*. The objective of the Act is to protect the health and safety of people, and to protect the environment, by identifying risks posed by or as a result of gene technology, and by managing those risks through regulating certain dealings with GMOs.

The OGTR will be required to approve and license any COVID-19 vaccines being administered in Australia that use GMOs. These include all the adenovirus vaccines and some of the mRNA vaccines. Protein subunit vaccines will not generally require OGTR approval.

Commercial vaccines require a Dealings Involving Intentional Release (DIR) licence. Obtaining this licence involves two rounds of consultation, publication of risk assessment and publication of application (if requested).

Immunisation Coverage

Immunisation coverage in Australia is monitored through the use of the Australian Immunisation Register (AIR). The AIR is a whole of life, national immunisation register which captures all vaccines administered to those living in Australia. The AIR includes vaccines given under the NIP, through schools based programs and privately such as for seasonal influenza or travel. The AIR is administered by Services Australia under the *Australian Immunisation Register Act 2015*.

AIR data is used:

- to monitor the effectiveness of vaccines and vaccination programs, including adverse events;
- to identify any parts of Australia at risk during disease outbreaks;
- to inform immunisation policy and research;
- as proof of vaccination for entry to child care and school, and for employment purposes;
- to monitor vaccination coverage across Australia; and
- for eligibility for Family Tax Benefit and Child Care Subsidy payments.

The AIR Immunisation History Statement (IHS) displays all immunisations that an individual has had that are recorded on the AIR. The IHS can be viewed and printed via Medicare Online, myGov or the Express Plus Medicare mobile app. Vaccination providers can print an IHS on behalf of their patient. Immunisation information on My Health Record is updated via a daily feed from AIR data.

Monitoring immunisation coverage and administration will be key to ensuring vaccination course completion as well as assisting with any adverse event reporting.

3. The approach to COVID-19 vaccination during this pandemic

Robust, vaccine-specific programs supporting free access

The initial roll-out of COVID-19 vaccination during the pandemic will not fall under the NIP. It must draw from the strengths of the NIP – including the reliance on robust regulatory pathways, timely application of expert scientific and medical advice, and effective cross-jurisdictional coordination and delivery mechanisms – while adopting sufficient flexibility to ensure the **safe, efficient, effective and transparent** delivery of a pandemic-context vaccination program over an acceptable time period**.**

The TGA and the OGTR will continue to independently discharge their regulatory duties. It is expected that initial regulatory approval for use of COVID-19 vaccines is likely to occur through the TGA's provisional determination and registration pathway. The vaccines will be provisionally registered in the Australian Register of Therapeutic Goods on the basis of clinical data, with subsequent rolling review of additional clinical data as they become available with the aim to achieve full registration as soon as possible. The TGA will actively and comprehensively monitor any COVID-19 vaccines for safety after they are supplied in Australia, in accordance with its legislation.

The COVID-19 vaccination will be **free** for all Medicare-eligible Australians and all visa-holders, excluding visa sub-classes 771 (Transit), 600 (Tourist stream), 651 (eVisitor) and 601 (Electronic Travel Authority).

While the Australian Government strongly supports immunisation and will run a strong campaign to encourage vaccination, it is not mandatory and individuals may choose not to vaccinate. There may however, be circumstances where the Australian Government and other governments may introduce border entry or re-entry requirements that are conditional on proof of vaccination.

Clear lines of responsibility across governments

Australian, State and Territory governments are committed to successful immunisation of Australians with a safe and effective COVID-19 vaccine.

Clear lines of responsibility are required to ensure that this complex process is well managed, and it is clear who is accountable at each stage of the process. The sections on vaccine roll-out in this document indicate responsibilities for specific actions. Broadly:

The **Australian Government** is responsible for:

- selecting and purchasing vaccines;
- formally accepting vaccines from suppliers and ensuring that they meet the required standards;
- safely transporting vaccine doses to storage and administration sites within each State and Territory, and between these sites and vaccination locations where it determines necessary;
- specifying priority populations, drawing from advice from ATAGI;
- establishing overarching principles for immunisation scheduling;
- specifying minimum training requirements for the immunisation workforce and providing guidance on appropriate workforces for the various phases of the immunisation program;
- specifying types of and minimum requirements for vaccination locations;
- clinical governance of vaccine administration;
- developing and delivering the national communications campaign; and
- setting data collection and reporting requirements and adverse event monitoring via the TGA.

How these actions will be undertaken will be outlined in an **Australian Government COVID-19 Implementation Plan**, which will be developed in close partnership with ATAGI and the heads of the State and Territory health departments.

The Australian Government COVID-19 Implementation Plan will also include particular requirements for vaccination in residential aged care and residential disability settings; Aboriginal and Torres Strait Islander peoples; culturally and linguistically diverse communities; and vulnerable groups.

State and Territory Governments are each responsible for:

- ensuring appropriately qualified and trained workforce to support delivery of its jurisdictional implementation plan, in collaboration with relevant peak bodies and training providers;
- authorising, under State and Territory legislation, the selected workforce identified in the Commonwealth and State and Territory implementation plans to possess and administer COVID-19 vaccines;
- identifying specific vaccination sites (including in external territories) in accordance with the Policy and in line with the Commonwealth implementation plan that meet or exceed the minimum requirements; and
- ensuring that immunisation providers remain compliant at all times with their safety, ethical, and reporting obligations.

State and Territory Governments will each be responsible for developing **jurisdictional implementation plans** that give effect to the agreed national policy settings and legislative requirements.

Jurisdictional implementation plans will be required to demonstrate how identified priority groups for vaccination will be reached, and how this approach will ensure the needs of vulnerable groups are met. While each jurisdiction will have different considerations, such as varying requirements for rural and remote delivery, there should be a broad level of consistency across these plans as a whole.

In addition, the Australian, State and Territory governments will work together to ensure that the needs of the following groups are met: residential aged care and residential disability settings; Aboriginal and Torres Strait Islander peoples; culturally and linguistically diverse communities; and vulnerable groups. This will be done in consultation with relevant stakeholders including the Aboriginal and Torres Strait Islander Community Controlled Health Organisations (ACCHOs).

The Australian, State and Territory governments will also work together to ensure doses of vaccine are distributed to where they are most needed, based on live information on need and uptake at vaccination locations.

4. COVID-19 vaccines purchased for Australia

Unprecedented resources are being expended globally with the aim of rapidly developing safe and effective vaccines against COVID-19. As of November 2020 there are over 200 candidate vaccines, many based on newer unlicensed but promising vaccine platform technologies. They are in various stages of development, with over 40 vaccine candidates in human clinical trials. No vaccines have yet been licensed for COVID-19 in Australia.

The Australian Government has secured agreements for the supply of four promising COVID-19 vaccines, provided they prove to be safe and effective.

Due to the different platforms, characteristics and requirements for each vaccine, each will have specific planning and programmatic requirements. Information on the vaccines purchased to date is below.

The University of Oxford/ AstraZeneca vaccine

The University of Oxford/AstraZeneca (Oxford) vaccine is one of the most progressed vaccines in development globally for COVID-19. Doses will be onshore from early 2021, but available to Australians only once proven to be safe and effective and approved for use by the TGA.

In Australia, the vaccine will be manufactured by Australian-headquartered multinational biopharmaceutical company CSL in partnership with the developer, international pharmaceutical company AstraZeneca. The Oxford vaccine is one of nine vaccines supported by the Coalition for Epidemic Preparedness Innovations (CEPI), a global partnership to accelerate vaccine development.

Vaccine development process

- All vaccines must pass different stages of research trials to prove they are safe and effective.
- The CSIRO partnered with the CEPI to test the Oxford vaccine in pre-clinical (animal) trials in Australia.
- The Oxford vaccine has completed combined Phase 1 and 2 clinical trials, where it was tested in a small number of volunteers to show that it is safe. Trial results have been peer reviewed and published.
- As of October 2020, larger combined Phase 2 and 3 clinical trials are underway in the United Kingdom, United States, Brazil and South Africa, with the clinical trials expected to enrol a total of 50,000 people. The Phase 3 clinical trial in the US includes approximately 30,000 adult participants, of whom at least 25% of will be 65 years of age or older.

Doses for Australia

Before the Oxford COVID-19 vaccine is approved for use in Australia it must pass the Therapeutic Goods Administration's (TGA) rigorous assessment and approval processes. This includes assessment of its safety, quality and effectiveness. The TGA is actively monitoring COVID-19 vaccine development that is occurring both in Australia and around the world. In October 2020, the TGA granted a provisional determination to AstraZeneza for this vaccine candidate. This means that it is now eligible to apply for provisional registration on the Australian Register of Therapeutic Goods. If the Oxford vaccine is successful:

- Australia has secured 53.8 million doses of this vaccine
- 3.8 million doses will be delivered to Australia in early 2021
- 50 million doses will be manufactured in Australia in monthly batches. CSL will manufacture these doses on behalf of AstraZeneca.

Novavax vaccine

Novavax is developing a vaccine for COVID-19. If the vaccine is proven to be safe and effective and is approved for use, it will be available in Australia as early as the first half of 2021.

It is expected that 51 million doses will be made available in Australia during 2021, which will supply enough doses to cover Australia's whole population. Doses for Australia will be manufactured in several locations across Europe. The Novavax vaccine is one of nine vaccines supported by the Coalition for Epidemic Preparedness Innovations, a global partnership to accelerate vaccine development.

Vaccine development process

- All vaccines must pass different stages of research trials to prove they are safe and effective.
- The results of the Phase 1 clinical trials, published in the New England Journal of Medicine in September 2020, showed the vaccine generated a strong immune response and had a favourable safety profile in its limited trial participants. Phase 1/2 clinical trials are currently being conducted in Australia and the United States. Large-scale Phase 3 clinical trials are currently underway in the United Kingdom (UK) involving up to 15,000 volunteers.
- More large-scale clinical trials are planned for other countries in late 2020 and early 2021. The vaccine is being tested in adults 18-84 years of age in different populations, people living with HIV, and those with other chronic conditions.

Doses for Australia

Before the Novavax COVID-19 vaccine is approved for use in Australia, it must pass the Therapeutic Goods Administration's (TGA) rigorous assessment and approval processes. This includes assessment of its safety, quality and effectiveness. The TGA is actively monitoring COVID-19 vaccine development that is occurring both in Australia and around the world. If the Novavax vaccine is successful it is expected:

- 51 million doses will be made available in Australia during 2021

Pfizer and BioNTech Vaccine

Pfizer and BioNTech are jointly developing a vaccine candidate for COVID-19. If the vaccine is proven to be safe and effective, and is approved for use, it will be available in Australia from early 2021.

The vaccine doses purchased by the Australian Government will be manufactured in the United States, Belgium and Germany. The Pfizer/BioNTech vaccine is one of nine vaccines supported by the Coalition for Epidemic Preparedness Innovations, a global partnership to accelerate vaccine development.

Vaccine development process

- All vaccines must pass different stages of research trials to prove they are safe and effective.
- Preclinical results in animal studies announced by Pfizer and BioNTech showed immunisation prevented infection with COVID-19 in the lungs and nose. These findings will be submitted to a research journal for peer review.
- Preliminary results of the Phase 1 clinical trial, published in the New England Journal of Medicine in October 2020, showed the vaccine generated a strong immune response.

- Early (Phase 1/2) human clinical trials are being completed in the United States, Germany and Japan.
- Large-scale human clinical trials (Phase 2/3), involving 44,000 participants, are underway in the United States, Germany, Argentina, Brazil and South Africa. The vaccine is being tested in adults 18-54 years of age, 55-85 years of age and adolescents 12-18 years of age. The Pfizer/BioNTech vaccine is the first COVID-19 vaccine to be tested in adolescents.

Doses for Australia

- If the Pfizer/BioNTech vaccine is successful:
  - 10 million doses will be delivered to Australia from overseas, the first supply is expected to arrive in the first half of 2021.
  - It is expected that each person will require two doses, about a month apart, for vaccination to be complete.
  - Therefore, the Pfizer/BioNTech vaccine has the potential to vaccinate up to 5 million people.
- Pending further understanding of safety and efficacy in different population groups, it is likely that the first doses will be given to priority populations (see 'prioritisation').
  - The vaccine is being tested in adults 18-55 years of age, 65-85 years of age and adolescents 12-18 years of age.

COVAX

In addition to the advance purchase supply agreements for the AstraZeneca, Novavax and Pfizer/BioNTech vaccines, Australia has also signed up to COVAX, one of the three pillars of the World Health Organization Access to COVID-19 Tools accelerator. COVAX is led by Gavi, the Vaccine Alliance. COVAX has a broad portfolio of potential vaccines candidates and aims initially to have 2 billion doses of an effective vaccine available globally by the end of 2021. Australia's commitment to COVAX will allow purchase of sufficient vaccine to cover 50% of the population, with an initial focus on high risk workforce.

Other agreements

The Australian Government supported the University of Queensland's research into a possible COVID-19 vaccine. This vaccine has undergone phase one clinical trials, however will not be proceeding to phase three.

Other potential Advance Purchase Agreements for specific vaccines

The Australian Government continues to monitor the emerging evidence and is actively engaging with the developers of other potential vaccine candidates. There is the potential for the Australian Government to enter into further APAs, subject to the advice of the COVID-19 Vaccines and Treatments – Science and Industry Technical Advisory Group.

5. Roll-out of the COVID-19 pandemic vaccination program

This vaccination program is significant in scale and complexity. Planning is being undertaken while vaccines are still being developed. Not all vaccines Australia invests in are guaranteed to be successful, and access to safe and effective vaccines will likely come in tranches. Each vaccine may have a safety and efficacy profile suited to different groups within the population. Each vaccine will have its own storage, handling and administration requirements. The Australian, State and Territory governments all share the goal of getting safe and effective vaccines to the people who most need it as quickly as possible, to support the physical, mental and economic wellbeing of the nation. Planning for rapid roll-out must take place while significant uncertainties remain, including what the COVID-19 active case load in jurisdictions might be at the time vaccines become available.

Prioritisation

When vaccines are available, supplies will initially be limited and directed towards priority groups for vaccination. Deciding upon which groups to prioritise is difficult and contentious. Different candidate vaccines will vary in their efficacy to prevent or modify clinical endpoint outcomes, their safety profile, and their suitability for different age groups or people with underlying medical conditions.

ATAGI, following a request from the Australian Government Department of Health, has developed preliminary advice on priority population groups to facilitate planning for the deployment of any safe and effective vaccine(s) as soon as authorisation is obtained for use in Australia. The underlying principle of this advice is that the vaccination program should contribute significantly to the equitable protection from COVID-19 of all people living in Australia.

This preliminary advice has been developed based on a review of Australian epidemiological data on the impact of the COVID-19 pandemic so far and anticipated risks. No data is yet available on the efficacy and safety of COVID-19 vaccines.

Prioritisation takes account of the following considerations:

- disease epidemiology and clinical impact;
- safety characteristics of available vaccines;
- efficacy and mechanism of action of available vaccines (i.e. ability to prevent acquisition, reduce viral shedding and transmission, and/or reduce severe clinical outcomes of infection);
- regulatory, programmatic and operational considerations (e.g. vaccine supply, storage and delivery);
- public confidence and acceptability;
- social and economic impact; and
- relevant ethical considerations.

Preliminary priority population groups

The three priority groups identified by ATAGI are:

- Those who are at **increased risk of exposure** and hence being infected with and transmitting SARS-CoV-2 to others at risk of severe disease or are in a setting with high transmission potential. This includes health and aged care workers; other care workers, including disability support workers; and people in other settings where the risk of virus transmission is increased, which may include quarantine workers.
- Those who have an **increased risk, relative to others, of developing severe disease or outcomes** from COVID-19 including Aboriginal and Torres Strait Islander people, older people and people with underlying select medical conditions.
- Those **working in services critical to societal functioning** including select essential services personnel and other key occupations required for societal functioning.

ATAGI, in consultation with the Science and Industry Technical Advisory Group, will finalise the population prioritisation prior to the implementation plans being finalised and agreed by the Commonwealth. The prioritisation will consider the health risk to and the transmission risk of the particular population groups including those working in services critical to societal functioning.

Allocation of doses across jurisdictions

Oversight of dose stock levels, dose allocation, and coordination of movement and tracking of doses will be managed by the Australian Government in close collaboration with State and Territories, through departments of health.

It is expected that for States and Territories where the entire jurisdiction is as operating in a "COVID-19 normal" environment, with manageable case numbers and minimal community transmission, the Australian Government will allocate vaccine doses in line with the prioritisation policy outlined above and calculated on the basis of data on numbers of residents in those jurisdictions who are in the relevant priority groups.

Where a State or Territory has a region or regions where significant COVID-19 community transmission is taking place, additional doses may be allocated to support ring-fencing, where this is supported by the epidemiological data. The Australian Government will take the advice of the AHPPC and ATAGI into account when considering this, as well as assessing whether vaccine stock levels are sufficient to support the request.

Logistics and distribution

The physical roll-out of potentially a number of different vaccines with specific storage, transportation, security and administration requirements will be complex and atypical. The Australian Government will be responsible for safely transporting vaccine doses to storage and administration sites within each State and Territory, and between these sites and vaccination locations where it determines necessary. It will ensure relevant logistics and storage chains are in place for each vaccine type, and will establish a mechanism to track and trace all doses of vaccine as they move through the system.

Once vaccine doses are delivered to a State or Territory vaccination site, States and Territories will take responsibility for the physical safety and appropriate storage and handling of those doses. States and Territories will need to ensure that their providers report on stock levels, doses administered, and any wastage in accordance with the data and reporting requirements of the Australian Government.

Vaccination locations

Vaccination sites will be agreed by the Australian Government and the States and Territories through their jurisdictional implementation plans.

There are a number of likely vaccination locations. All vaccines must be administered in accordance with the relevant legislation, best practice, and the guidelines and recommendations the Australian Immunisation Handbook. Vaccination locations must facilitate the safety of vaccines, staff, and consumers; be adequately staffed with appropriately trained personnel; have the facilities and protocols in place to ensure data is reported in an accurate and timely way; and be able to manage high volumes of vaccinations.

Locations may, over time, include:

- **General practice clinics**. These are currently the major site of immunisation in Australia and have well established protocols for vaccination.
- **GP Respiratory Clinics** (established for COVID-19 assessment and testing). With some additional training of the workforce, these could be repurposed to provide dedicated vaccination sites.
- **Dedicated vaccination clinics,** established by State and Territory health services (including local councils). These would need to be in a facility where appropriate post vaccination monitoring and after care can be provided (i.e. not drive through locations).
- **Workplace vaccinations**. Some larger corporations and high risk workplaces may establish workplace vaccination clinics in partnership with State and Territory health services or private providers.

- **In-reach vaccination** teams. A dedicated nurse vaccinator workforce will need to be trained up to progressively visit aged care facilities, and other in-reach services may be provided to vulnerable people or targeted populations who cannot access another vaccination location.
- Appropriate locations identified by the **Aboriginal and Torres Strait Islander Community Controlled Health sector**.
- **Pharmacies**. Pharmacists are licensed to varying degrees in each State and Territory to administer vaccines. They are likely to play a role in COVID-19 vaccination for some part of the population (e.g. healthy adults) at some stage, depending on the safety profile of the vaccines.
- If vaccines are licensed for children, the State and Territory **school based** vaccination programs could be used to achieve wide coverage of school aged children.

To achieve wide population coverage it is likely that all or most of the above will need to be utilised over several months. To minimise wastage, noting the use of multi-dose vials, sites where dozens of people could be vaccinated per day will be necessary. Further, given that these are new vaccines, locations that have medical practitioners on-site are preferable for the first three to six months of the roll-out of any COVID-19 vaccine in case of adverse events.

Workforce

States and Territories will be responsible for ensuring an appropriately qualified and trained workforce can support delivery of its jurisdictional implementation plan, in collaboration with relevant peak bodies and training providers. Jurisdictions must ensure that their immunisation workforce has the legal authority to administer COVID-19 vaccines under State and Territory legislation, including having the necessary qualifications and meeting any relevant conditions. Jurisdictions must also ensure that their COVID-19 immunisation workforce has undertaken any bespoke training identified at a national level, which is expected to include handling and administration training related to particular COVID-19 vaccines as well as in relation to use of multi-dose vials.

Safety monitoring

The TGA monitors vaccines for safety after they are supplied in Australia.

The TGA receives adverse event reports from consumers, health professionals, the companies who supply vaccines, and state and territory health departments. The reports are published in the publically available Database of Adverse Event Notifications (DAEN). Reporting serious adverse events is mandatory for the companies who supply vaccines in Australia. These companies must also develop and implement risk management plans for their vaccines.

The TGA has developed a COVID-19 Vaccine Pharmacovigilance Plan that builds on its already well-established Adverse Events Monitoring System (AEMS) by improving capacity and capability for adverse event reporting to the TGA by state and territory health departments, expanding active surveillance systems for COVID-19 vaccines and enhancing existing processes for safety signal detection and investigation, public communications and implementation of regulatory and programmatic responses. International collaboration and building on existing partnerships with organisations in Australia that have high-level technical expertise in vaccine safety are also core elements of the plan.

TGA laboratories also help monitor vaccine safety. Alongside assessing the quality of all vaccine batches before they are supplied in Australia, the laboratories may also test the quality of selected vaccine batches after they are supplied in Australia. Laboratory testing results are published on the TGA website.

If the TGA suspects there is a problem with a vaccine, it will launch an investigation. In some cases, this could mean suspending the use of a vaccine during the investigation. The community is notified of safety concerns through the publication of alerts on the TGA website.

In addition to the TGA safety monitoring, the Australian Government funds an active safety, surveillance and monitoring system called AusVaxSafety. The current contract for this is held by a consortium led by the National Centre for Immunisation Research and Surveillance (NCIRS). This system links and captures data from a range of systems including “Adverse Events Following Immunisation-Clinical Assessment Network (AEFI-CAN)”.

Active surveillance (proactively seeking evidence of adverse effects) will be required for the COVID-19 vaccine programs.

Funding

Charges should not be levied to consumers for COVID-19 immunisation.

Consistent with the shared funding responsibility for immunisation, the Australian Government and State and Territory Governments will determine the approach to funding of the COVID-19 vaccination program. Possible options include amending the existing *National Partnership Agreement on COVID-19 Response and/or the National Partnership on Essential Vaccines.* Any activity-based payments should be designed to incentivise the administration of second doses required for COVID-19 immunisation.

The Australian Government may also establish direct funding relationships, if needed, to support vaccination across particular populations.

6. Data and reporting

Managing the most effective and efficient roll-out of COVID-19 vaccine(s) will require significant coordinated data and reporting mechanisms. A consumer- and clinician-centred approach to designing digital, data and reporting systems will help to manage public demand, minimise reporting overhead, and improve efficacy of the rollout. This Australian Government has commenced work on this approach and is identifying key system capabilities and gaps.

Australian Immunisation Register (AIR)

For the COVID-19 vaccine, the AIR will be used to, among other things:

- monitor immunisation coverage levels and service delivery, which can help to identify regions at risk during disease outbreaks;
- measure vaccination coverage at a local, state and national level.
- determine an individual's immunisation status, regardless of who immunised them
- provide an Immunisation History Statement to prove their immunisation status for child care, school, employment or travel purposes

It is highly likely that two doses of a COVID-19 vaccine will be required for immunisation. Further, each patient will need to have **two doses of the same vaccine**, i.e. two doses of the Oxford vaccine or two doses of the Pfizer vaccine.

The AIR will be the unifying national system to monitor both overall immunisation levels and individual immunisation status. It will be mandatory for vaccination providers to make timely recordings of any COVID-19 vaccinations into AIR.

Medical practitioners, midwives and nurse practitioners with a Medicare provider number are:

- automatically recognised as vaccination providers by the AIR.
- authorised to record or get immunisation data from the AIR.

Other eligible health professionals and organisations can apply to become recognised vaccination providers and access the AIR using Services Australia's Health Professionals Online Service (HPOS).

The Australian Government is undertaking a review of AIR functionality to support this role, including an anticipated large number of new registrants and new providers, to ensure technical capacity to fulfil the key monitoring role.

Digital Health

My Health Record (MHR) will play a key role for Australians as an authoritative record of their vaccinations. MHR is already connected to the AIR and it supports mobile app connectivity to potentially enable the generation of immunisation certificates.

Importantly, MHR is already integrated into public and private health care settings (such as public hospitals and general practice). It is integrated with myGov, giving Australians easy access to their health information. Using MHR for direct engagement with clinicians and consumers can help ensure successful rollout – for instance, by delivering personalised messages to consumers reminding them to have their second dose of a vaccine.

Pharmacovigilance

Pharmacovigilance is defined by the World Health Organization as the science and activity related to detecting, assessing, understanding and preventing adverse effects and other medicine-related problems. Monitoring for adverse events following the COVID-19 will be important for clinician and consumer safety and confidence in the vaccination program. The TGA collects and evaluates information related to the benefit-risk balance of medicines in Australia to monitor their safety and, where necessary, take appropriate action. Currently, a National Adverse Events Following Immunisation (AEFI) reporting form is used to report adverse reactions to vaccination to the TGA, in addition to reporting to State and

Territory departments of health. The TGA is improving mechanisms for consumer feedback for ease of post-administration monitoring and feedback.

All sponsors who have medicines registered or listed on the ARTG are subject to mandatory pharmacovigilance requirements and must also develop and implement risk management plans for their vaccines. These will be enhanced by active surveillance programs managed by the Australian Government, likely operated by AusVaxSafety.

Sponsors of medicines approved for supply in Australia, are legally responsible for meeting pharmacovigilance reporting requirements for their medicine. Sponsors must, among other things:

- let TGA know who the Australian pharmacovigilance contact person is
- submit any serious adverse reaction reports to the TGA
- notify the TGA of any significant safety issues they identify
- keep records pertaining to the reporting requirements and safety for their medicine

The TGA expects sponsors to have an effective pharmacovigilance system in place in order to:

- monitor and take responsibility for the safety of their medicine
- meet legislative requirements for reporting serious adverse reactions and significant safety issues
- identify any changes to the benefit–risk balance of their medicine
- take appropriate action in a timely manner when necessary
- update product labels and product information with new safety information in a timely way.

7. Communications strategy

A comprehensive communications strategy is being implemented by the Australian Government to support this Policy. The communication strategy will provide timely, transparent and credible information to inform and educate the Australian public, and health providers, about COVID-19 vaccines and vaccination. This will build confidence in the regulatory processes for COVID-19 vaccines and treatments, keep Australian's up to date on progress of and vaccine candidates, including international developments and local investment in research and ensure implementation plans for a national vaccination program are clearly communicated to support high uptake.

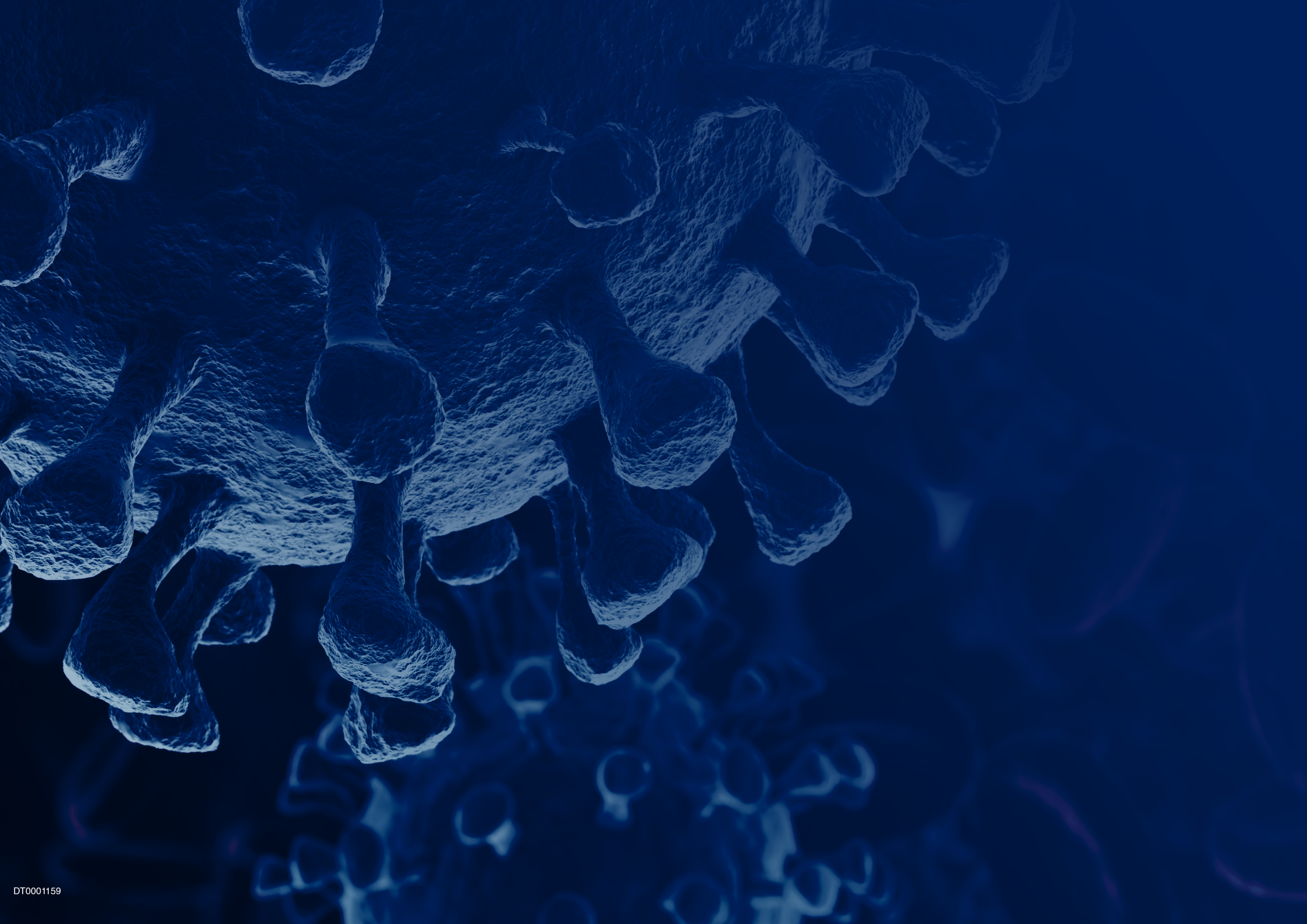
The immediate approach focuses on regular, transparent communication through Australian Government channels, media and credible spokespeople. As more becomes certain, dedicated market research will underpin a national communication plan to achieve the reach necessary to achieve broad uptake.

Key messages have been prepared in the following categories: Community benefit; Effectiveness; Science and safety; Government response and oversight; Availability, cost and administration; Information and consent; and Processes for the health sector. Key messages include:

- A COVID-19 vaccine is the best way to protect the Australian community
- Our goal is early access to, and delivery, of safe and effective COVID-19 vaccines and treatments for all Australians
- We continue to follow our rigorous regulatory procedures in Australia to ensure that vaccine candidates are effective and safe for use
- As doses become available they will be provided to high-risk groups first
- Which groups are eligible for the first doses of a vaccine will depend on the nature of the vaccine and its testing results, and any current outbreaks.
- As more doses become available, as many Australians as possible will be encouraged to vaccinate
- Australians are encouraged to rely on reputable and authoritative sources of information to help them make informed choices and stay up to date

The two categories of key stakeholders are:

- Health sector - health professionals; peak bodies; General Practitioners; public health networks; pharmacists; disability support workers; Aboriginal mental health services; aged care providers.
- Consumers - all Australians, including the following segments: enthusiastic sentiment; hesitant sentiment; adverse sentiment; priority populations; parents; CALD; Aboriginal and Torres Strait Islander peoples; and people with disabilities.



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