COVID-19 Vaccines

- The Australian Government is working to ensure that a safe and effective COVID 19 vaccine will be available to Australians, as soon one becomes available.
- The Australian Government's COVID 19 Vaccine and Treatment Strategy (Strategy) was announced by the Prime Minister on 19 August 2020. The Strategy identifies action in relation to:
    - research and development;
    - purchase and manufacturing;
    - international partnerships;
    - regulation and safety; and
    - immunisation administration and monitoring.
- Over $3.8 billion has been allocated to support activities aligned with the Strategy. This includes actions across a number of areas:
    - Advance purchase agreements to secure direct purchase of vaccine or treatment doses.
    - Manufacturing agreements to establish arrangements to utilise and expand Australia's manufacturing capability and capacity.
    - International and multilateral agreements to support and facilitate access for Australia and its region.
    - Procurement contracts to facilitate the purchase of goods, materials or services necessary for the distribution or deployment of vaccines and treatments.
    - Research and development of vaccines, therapeutics and health research infrastructure.
- On Monday 7 September 2020 the Prime Minister announced production and supply agreements worth $1.7 billion to secure early access to approximately 84.8 million vaccine doses in 2020 21 and 2021-22, with 95% of the doses to be manufactured onshore. These agreements are for the University of Oxford/AstraZeneca (Oxford) and the University of Queensland/CSL (UQ) COVID-19 vaccines.
    - The agreement in relation to the Oxford vaccine follows on from the signing of a letter of intent with AstraZeneca, announced by the Prime Minister on 19 August 2020.
- On Thursday 5 November 2020 the Prime Minister announced $1.5 billion for two new COVID-19 vaccine agreements between the Australian Government and Novavax Inc and Pfizer/BioNTech. These new agreements have secured an additional 50 million vaccine doses, if proven safe and effective.
- Should these vaccines prove to be successful and safe and meet the Therapeutic Goods Administration's stringent assessment requirements and approval processes, Australians will have access to a total of 134 million doses, including:
    - 33.8 million doses of the Oxford vaccine, with delivery expected to commence at the beginning of 2021.
    - 51 million doses of the UQ vaccine, with doses expected to be available from mid-2021.
    - 40 million doses of the Novavax vaccine, available from the first half of 2021; and
    - 10 million doses of the Pfizer/BioNTech vaccine, available in the first half of 2021.
- All four vaccines are likely to require two doses per person.
- Australia has signed an agreement with Gavi, the Vaccine Alliance to formally join the COVAX Facility. The agreement provides the option to purchase successful COVID 19 vaccines from a broad portfolio of candidates to cover up to 50 per cent of Australia's population. The Facility is an important

component of Australia's COVID-19 Vaccine and Treatment Strategy and serves as insurance for our Advanced Purchase Agreements in the event they do not meet our domestic needs. A total of 156 countries have committed or are eligible to receive vaccines through the Facility, which represents the best multilateral effort to end the acute phase of the pandemic in both developed and developing countries.

    - The joining of the COVAX Facility is in addition to the $80 million investment to secure COVID-19 vaccines for developing countries through the Advance Market Commitment component of the Gavi Facility.

- The Australian Government has an agreement in place, worth $24.7 million, to purchase needles, syringes and sharps containers from company Becton Dickinson to support the delivery of vaccines once available.
- To support decision-making in relation to purchasing and manufacturing arrangements the Commonwealth Government has established a *COVID-19 Vaccines and Treatments for Australia – Science and Industry Technical Advisory Group*. This group, chaired by Dr Brendan Murphy, brings together science, technology and pharmaceutical experts from across the country. Membership is at Attachment A.
- On 13 November 2020 National Cabinet endorsed Australia's COVID Vaccination Policy (Vaccination Policy). The Vaccination Policy sets out the roles and responsibilities of the Australian Government and state and territory governments in relation to the implementation of a COVID-19 vaccination program in Australia from early 2021.
- The Australian Government is working with the States and Territories on the development of COIVD-19 vaccination program implementation plans, and consulting with medical and technical experts and peak bodies.
- Australian Technical Advisory Group on Immunisation (ATAGI) is advising the Department of Health to determine priority groups. ATAGI has provided preliminary advice on the priority groups for the first doses of a COVID-19 vaccination to the Australian Government.
- The three priority groups initially 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.
    - Those who have an increased risk, relative to others, of developing severe disease or outcomes from COVID-19.
    - Those working in services critical to societal functioning.
- This preliminary advice is consistent with guidance from the World Health Organisation. As further clinical trial data becomes available, this advice will be updated to develop priority groups for each vaccine.
- While there are currently more than 212 vaccine candidates in development, including 48 in human clinical trials (as at 12 November 2020), there is no guarantee that a safe and effective vaccine will be found.
- Ten candidates have entered Phase 3 trials, including candidates from The University of Oxford/AstraZeneca, Pfizer/BioNTech, Moderna, Janssen and Novavax.
- Within Australia, four vaccine candidates have commenced clinical trials: the UQ/CSL COVID-19 candidate, one developed by Flinders University and Vaxine, and two being developed by international companies (Novavax and Clover Biopharmaceuticals, both with support from CEPI).

COVID-19 Research: Medical Research Future Fund (MRFF) and other

- The Australian Government has invested $367 million (including the below MRFF funding) on research investment for diagnostics, vaccine development, antiviral development, clinical trials, digital health research infrastructure and research into the human immune response to COVID-19 infection.
- As at 6 October 2020, the Australian Government has announced over $96 million in funding for research into COVID-19 from the MRFF.
  - Vaccine development
    - $5 million in vaccine research and clinical trials being progressed at the University of Queensland, in partnership with the Queensland Government and Ramsay Healthcare.
    - $3 million to the University of Melbourne to progress two vaccine candidates under development.
    - $3 million the University of Sydney to evaluate their vaccine candidate in early stage clinical trials.
    - $7.7 million for vaccine candidate research through a competitive grant opportunity that is accepting expressions of interest from promising projects over three rounds (Round 2 is currently open and closed on 11 November 2020).
  - Up to $1 million to Vaxine Pty Ltd to progress COVAX-19 through the Biomedical Translation Bridge program [more information below with other grantee].
  - Antivirals
    - $0.35 million for the University of Queensland for a clinical trial (ASCOT trial) assessing whether hydroxychloroquine and an HIV drug (lopinavir-ritonavir) used either in combination or on their own can reduce severity and length of COVID-19 if given to patients with the virus early after diagnosis.
    - $7.3 million to nine research teams to support the development of promising antiviral therapies for COVID-19.
      - The most successful of the projects will have an opportunity to seek additional funding of up to $10 million to accelerate their therapy to clinical practice, including for human trials.
    - $3 million for the Walter and Eliza Hall project assessing the effectiveness of hydroxychloroquine for prevention of COVID-19 infection amongst health care workers.
    - $2 million for an innovative project using stem cell-derived tissues to rapidly test drugs already approved for use in humans for activity against COVID-19.
      - The project commenced in 2019-20 through The Peter Doherty Institute for Infection and Immunity and The Queensland Institute of Medical Research Berghofer.
      - Other labs are expected to join the project in 2020-21.
  - Respiratory medicine research
    - $6.8 million for seven clinical trials investigating treatments for the severe respiratory symptoms of COVID-19.
  - Diagnostics
    - $2.6 million for the Peter Doherty Institute for Immunity and Infection to increase Australia's ability to conduct widespread testing for the diagnosis and clearance of COVID-19.

- $1 million to the University of Sydney for a project using artificial intelligence to support frontline health workers using CT scans to quickly and more accurately diagnose the severity of coronavirus in patients who are having difficulty breathing.

- Public health
  - $1.5 million for 'living guidelines' on the clinical management of patients with suspected or confirmed COVID-19 infection across primary, acute and critical care settings.
  - $3.1 million for six rapid research projects to improve the national mental health system response to the impacts of the COVID-19 pandemic.
- Cross-cutting
  - $25 million for clinical trials to investigate effective mechanisms for the prevention or treatment of COVID-19 or its symptoms. The open competitive Grant Opportunity was announced on 20 August 2020 and closed on 23 September 2020.
  - $3.3 million to the University of New South Wales for genomics research into the behaviour, spread and evolution of the SARS-CoV-2 virus.
  - $4 million for digital health research infrastructure research to help health systems respond faster to high-need emerging challenges (competitive grant opportunity closed 14 July 2020).
  - $3 million for three projects researching the human immune response to COVID-19 infection, particularly in at-risk people (competitive grant opportunity closed 9 July 2020).
  - $600,000 for research to understand the community's information needs and behavioral drivers during outbreaks, and strategies to address these (competitive grant opportunity closed 14 July 2020).
  - $4.1 million for five COVID-19 research projects (announced 3 September 2020) through the $22.3 million Biomedical Translation Bridge (BTB) Program (Medical Research Commercialisation Initiative), including:
    - a new treatment for respiratory complications as a result of COVID-19 (Dimerix Bioscience Pty Ltd)
    - an intranasal spray, utilising an already-marketed, broad-spectrum antiviral dendrimer for COVID-19 (Starpharma Pty Ltd)
    - a rapid-response COVID-19 assay (SpeeDx Pty Ltd)
    - a novel ventilated hood for patient isolation to provide better patient respiratory treatment and protect hospital staff from COVID-19 (University of Melbourne)
    - an Australian COVID-19 vaccine, COVAX-19® (Vaxine Pty Ltd) [mentioned also under 'vaccine development']

- The Government has also announced:
  - $2 million to APPRISE (the Australian Partnership for Preparedness Research on Infectious Disease Emergencies) from the National Health and Medical Research Council for COVID-19 research for fast tracked clinical and public health studies that will inform the national health response to coronavirus and to rapidly develop responses to address coronavirus in key populations, including Aboriginal and Torres Strait Islander peoples and people in aged care.

- Funding for CSIRO:

- $220 million to upgrade the Australian Centre for Disease Preparedness, Australia's high containment biosecurity research facility in Geelong (formerly the Australian Animal Health Laboratory).
- Up to $10 million to support COVID-19 vaccine development work.

  - alongside Brandon Capital Partners, $11.7 million from the Biomedical Translation Fund (BTF) to test an innovative nasal treatment to fight COVID-19, common colds and influenza. INNA-051 is being developed by Australian biotech company Ena Respiratory.

- The Prime Minister pledged $352 million at the EU COVID Vaccine Pledging (virtual) Conference on 4 May 2020 including:

  - $15 million from the overseas development assistance budget to the Coalition of Epidemic Preparedness Innovations (CEPI) and the Foundation for Innovative New Diagnostics (FIND) – *this was new money in 2020-21*
  - $337 million of investment in research and development work on vaccines, diagnostics, therapeutics and respiratory medicine – *this was a sum of existing Commonwealth and state investments at that time*.

Questions on Notice (QoNs)

PDR No	**Subject**
IQ20-000038	Evidence timeline for vaccine
IQ20-000275	Funding the Medical Research Future Fund
QB20-00327	COVID19 Research Response

Attachment A

COVID-19 Vaccines and Treatments for Australia – Science and Industry Technical Advisory Group Membership

Name	**Organisation**
Dr Brendan Murphy (Chair)	Secretary, Department of Health
Prof Paul Kelly (Deputy Chair)	Acting Chief Medical Officer, Department of Health
Mr John Anderson	Independent Advisor
A/Prof Chris Blyth	Co-chair, Australian Technical Advisory Group on Immunisation
Prof Allen Cheng	Co-chair, Australian Technical Advisory Group on Immunisation
Dr Alan Finkel AO	Australia's Chief Scientist
Mr Rob Hetherington	Independent Adviser
Dr Larry Marshall	Chief Executive, CSIRO
Ms Sue MacLeman	Chair, MTP Connect
Ms Kirsten O'Doherty	Independent Adviser
Dr Felicia Pradera	Program Manager for Medical Countermeasures Development, DMTC
Mr Mark Sullivan	Managing Director, Medicines Development Ltd
Prof Andrew Wilson	Chair, Pharmaceutical Benefits Advisory Committee