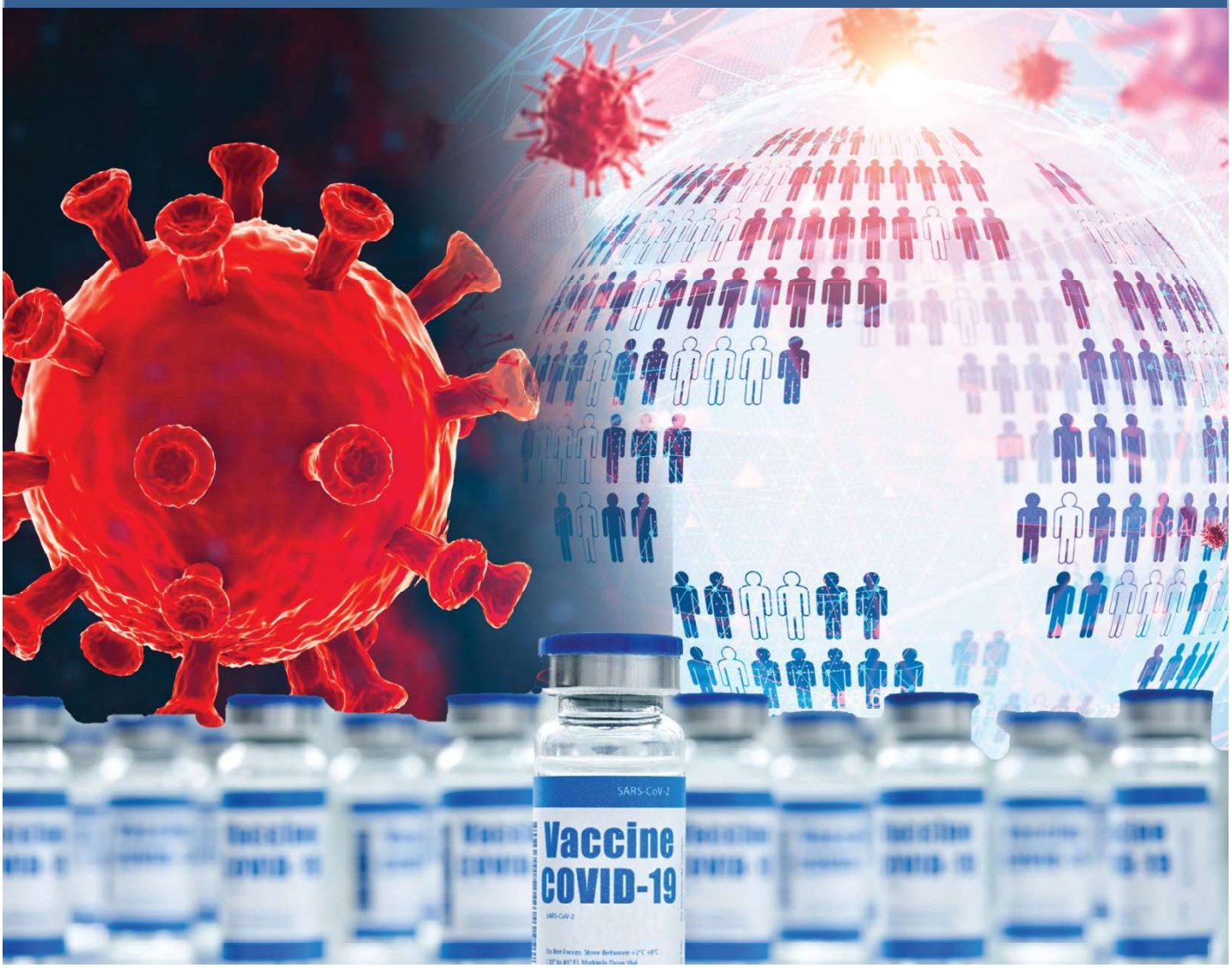
Review of COVID-19 Vaccine and Treatment Purchasing and Procurement



The Hon Mark Butler
Minister for Health and Aged Care
Parliament House
CANBERRA ACT 2600

Dear Minister

On 30 June 2022 you commissioned an independent review of the purchasing and procurement of COVID-19 vaccine and treatments to inform the next 12-24 months. This report provides the conclusions and recommendations of the review.

The review team engaged with a number of key stakeholders involved in Australia's response to the COVID-19 pandemic and rollout of vaccines and treatments. This included epidemiological experts both nationally and internationally, Commonwealth, state and territory Health departments and bodies, health sector organisations, as well as manufacturers of the vaccines and treatments procured within Australia.

As principal reviewer I was assisted by Professor Peter Collignon AM who provided expert medical advice. I would also like to acknowledge the work of the review project team led by Georgie Fairhall, Department of Health and Aged Care.

Early procurement of vaccines and treatments occurred in a highly competitive global market. In this context Australia secured a portfolio of effective COVID-19 vaccines and treatments enabling high rates of primary course vaccination preventing serious illness and death relative to global peers.

However, Australia and the world are not yet 'COVID-stable', and we are unable to confidently predict the timing or impact of new waves and variants. This uncertainty presents particular challenges. The availability of efficacious vaccines and treatments will continue to play a key role in ensuring ongoing protection for lives and livelihoods

The next two years are critical to supporting our economy, health and education systems to recover. Australia's approach to the procurement of vaccines and treatments needs to be responsive to the changing environment and should be guided by clear policy and understanding of risk appetite.

Consideration should be given to the decision-making structures and advice required, and whether new and existing pathways for procurement and distribution of vaccines and treatments should be retained or adapted. Finally, it is critical that Australia maintains surge capacity in the event of a serious new variant or another infectious disease.

Yours sincerely

Hon. Professor Jane Halton AO PSM
19 September 2022

1. Executive Summary

On 30 June 2022, the Minister for Health commissioned a rapid review of the procurement and distribution of COVID-19 vaccines and relevant therapeutic goods to ensure that Australia has sufficient supplies to meet immediate and prospective needs including for the next 12 – 18 months. See Terms of reference at Attachment 1.

Like many other countries, Australia is at an important point in the evolution of the SARS-CoV-2 pandemic. Management of the health and economic effects of continuing waves of infection has shifted to more permissive settings largely enabled by widespread vaccination and natural immunity from infection. Previous emergency settings have been replaced by individual responsibility for isolation in the event of infection. These more liberal settings have been widely welcomed by the community.

Unlike the early phases of the pandemic a range of treatments is also now available.

This new phase of the pandemic brings new challenges. We are not yet 'COVID-stable' and cannot reliably predict when new waves or variants might emerge. The ability to rapidly deliver effective vaccines and therapies to large numbers of people will remain relevant to planning and procurement for some time to come. There will continue to be a need for supply agreements and delivery arrangements that are effective and have the capacity to scale for spikes in demand.

In the medium term, hopefully, there is more stability/predictability in respect of SARS-CoV-2 allowing this virus to be managed much like other respiratory viruses (such as influenza). This will require a review of those systems to ensure that they are fit for purpose including ensuring ordering and delivery arrangements are responsive to demand and the specific needs of COVID-19 vaccines and treatments.

In the event a new and significantly different variant with severe health outcomes emerges, the capacity to respond rapidly and at scale should remain a policy and delivery priority.

This report outlines findings and recommendations in respect of current and future vaccine and therapeutic availability, the development pipeline, and priorities for procurement. This will ensure that Australians can access effective vaccines and therapies if/when needed to protect against infection and help prevent severe disease and death at a time of continued widespread COVID infection with new SARS-CoV-2 variants.

These observations and conclusions should inform current negotiations for immediate and future purchases of both vaccines and therapies. Current and potential distribution mechanisms together with advisory mechanisms are also considered.

Prior purchases are considered only to the extent these are relevant to existing and future supply and the lessons that can be learned in respect of fit for purpose supply and procurement arrangements going forward.

1.1 Conclusions

COVID-19 Pandemic

- It is not possible to accurately predict the further evolution of the virus and Australia is likely to continue to be challenged, at least in the short term, by emerging variants and new waves of disease.

Australia in context

- Australia has been successful at achieving high rates of primary course vaccination and maintaining a low death rate, but relative performance is beginning to wane.

Regulation of vaccines and treatments

- Where appropriate, Australia should continue to look for opportunities to ensure consistency with global regulators. Consideration should be given to permanent implementation of changes made during the pandemic which ease regulatory burden and do not impact public safety.
- Funding available to the TGA should enable it to continue its important work regarding pharmacovigilance and consumer safety.

Policies, decision-making and advisory mechanisms

- The need to mitigate the effects of COVID-19 is likely to remain. However, policy settings have not been updated to take account of already widespread COVID-19 infections and associated high levels of hybrid immunity, the possibility of future waves and variants, and developments in vaccine and therapeutic science and manufacturing. A portfolio approach and potentially redundancy will be needed to ensure access.
- This context continues to present real challenges in decision-making in respect of procurement of, eligibility for, and distribution of both vaccines and treatments. Supply chain issues remain with potential shocks or spikes in demand hard to estimate.
- Pre-pandemic structures and processes were not fit for purpose in an emergency context. With the likelihood of continuing waves of COVID-19 and the need for ongoing, integrated advice, new advisory structures and mandates will be required. It is timely to consider the role and nature of existing structures and processes. The *ad hoc* arrangements put in place at the beginning of pandemic require updating.

COVID-19 Vaccines

- Australia's procurement activities were consistent with other high-income countries. A portfolio and redundancy approach was adopted to mitigate risks and ensure adequate supply.
- Early procurement of vaccines and treatments occurred in the context of uncertainty and a global vaccine shortage – a “sellers' market”. Agreement to conditions not usually included in ordinary procurement contracts was necessary to secure commitments to supply.
- A portfolio approach will continue to be needed to mitigate the risk of supply shortage, delays, lack of success in clinical trials, manufacturing or regulatory failure.
- Delivery requirements for consumables are much less onerous than for vaccines. Current delivery arrangements should be reviewed to ensure value for money.
- In order to maximise coverage and reduce confusion it is important to:
    - clarify who the key decision-maker on vaccine eligibility is and which bodies act in an advisory capacity;

    - avoid complexity in eligibility criteria where there is no significant clinical difference between cohorts to ensure high levels of public awareness and vaccine uptake; and
    - align key public messaging, public health goals, and high-level COVID-19 vaccine policy.
- The proportion of vaccines administered by state and territory hubs has decreased over time with general practice and pharmacy now administering most vaccines. The ability to quickly stand-up mass vaccination clinics should be retained in the event of an emergency or period of high demand.
- Wastage is expected in an oversupply environment. Eligibility and priority use recommendations can affect wastage.
- New variant specific, bivalent, and more broadly protective vaccines are being researched and developed.
- Initial trial data, based mainly on antibody responses, show that variant specific vaccines may be more effective than the original wildtype vaccines against Omicron variants.

COVID-19 Treatments

- Australia has procured a range of treatments which are available through state hospitals and community pharmacy. It is important to continue to monitor the ongoing efficacy of COVID-19 treatments against the current dominant strains and latest clinical research.
- A systems approach to distribution and clear communication to patients about eligibility and access is needed to ensure available treatments are utilised to mitigate the impact of COVID-19.
- With considerable disruption to work and education still being experienced, the potential benefit of wider use of efficacious treatments (particularly where there are sunk costs) should be considered.
- Some wastage of therapeutics is to be expected as stock begins to expire due to slower than anticipated utilisation and treatments losing efficacy against current variants.
- Ongoing monitoring of COVID-19 mutations and variants, including impacts on treatment efficacy, will be required.
- Significant stocks of treatments are available. These should provide adequate cover for the next 12 months however mechanisms to scale up supply in the event of high or emergency demand are needed.

Transitional arrangements

- Policies, procurement, and delivery over the next two years should:
    - Encourage ongoing high levels of vaccination across the community for those that will benefit;
    - Enable the Health Minister to operate in the transition period (before 'COVID-stable' is achieved) to manage the downside risk associated with the emergence of a serious new variant;
    - Ensure that there is adequate and speedy access to vaccines and treatments by patients, if and when they are required;
    - Provide maximum possible protection through vaccinations and treatments over the short to medium term to protect the vulnerable, limit hospitalisation and death, and allow the economy and health system to recover;
    - Adopt a portfolio and redundancy approach to the procurement of vaccines and treatments, with acceptance of associated higher levels of wastage;

- Encourage a partnership approach with industry and sponsors ensuring transparency and optimal outcomes for Australian patients;
- Utilise existing and established distribution channels (primary care including general practice and pharmacies, and states and territories) and maintain capacity to ensure distribution of vaccines can be scaled up rapidly in the event of a need for high levels of vaccination for a new more virulent variant; and
- Facilitate decision-making which considers the ongoing public health management of the pandemic rather than the point in time relative risk (e.g. absolute risk of side effects as determined by TGA/medical analysis). Unless there are significant clinical differences, approaches should be simplified as much as possible to streamline and encourage public uptake.

Vaccines

- Forecasting required numbers of vaccines is an inexact science. Clear policy positions, risk frameworks, and understanding of the development pipeline, production issues, demand and delivery arrangements is needed to inform judgement and guide decision-making.
- On-demand ordering arrangement would significantly reduce the wastage of vaccine products in low and medium demand scenarios, and therefore reduce the total amount of vaccines required to meet demand in 2023 and 2024.
- Australia will likely have an over-supply of Novavax in 2023. Australia could implement more permissive eligibility settings for Novavax to increase uptake and reduce the need for additional mRNA vaccines; and/or work with the manufacturer to defer delivery of doses into 2024.
- Additional procurement of Moderna vaccines should be undertaken for 2023 to meet any anticipated shortfall in the number of mRNA vaccines required and to ensure access to vaccines for children under five years.
- Minimum endemic, 'COVID-stable', quantities of effective vaccines should form the foundation of 2024 vaccines orders. In the event 'COVID-stable' has not been achieved a prudent buffer should be based on medium demand options. Specific arrangements to scale up supply in the event of high or emergency demand should be designed and implemented.
- Global supply of any new effective variant specific and/or broadly protective vaccines will be constrained for some time once approved by regulators. Early purchases will continue to be made in a highly competitive market. Flexible APAs are required to navigate the procurement environment and ensure adequate supplies of vaccines in Australia. Existing APAs and supply agreements provide a starting point for negotiations.

Treatments

- Ongoing monitoring of new treatments and engagement with suppliers will be needed to ensure adequate supply of promising emerging treatments for Australia.

1.2 Recommendations

Recommendation 1: Public health campaigns designed to encourage sustained booster uptake for those that will benefit should be developed and delivered during 2023 and 2024 to improve coverage.

Recommendation 2: A clear, updated, policy framework including objectives for the management of COVID-19 should be developed to inform decision-making, purchasing, clinical decision-making and resource allocation. A statement of risk appetite should form a part of this framework.

Recommendation 3: Advisory structures should be streamlined, and advice should be integrated to enable decision-makers to undertake their role. The role of decision-makers and advisors should be clarified. Reasons for decisions should be evidenced including indicating where they are based on judgment. Care should be taken to prevent confusion at the clinical level about who is eligible to receive vaccines/treatments and recommendations for use including in respect of target populations.

Recommendation 4: Procurement decisions should be made in the context of agreed policy objectives, risk appetite (the acceptability of failure to supply), knowledge/predictions in respect of the evolution of the virus, and supply constraints including knowledge of market behaviour.

Recommendation 5: Vaccine distribution arrangements should be reviewed in order to test value for money and reduce wastage while ensuring timely access.

Recommendation 6: New mechanisms to manage stock held by the NMS for use in an ongoing pandemic or epidemic should be developed as a matter of urgency to enable greater transparency about and access to stock held.

Recommendation 7: The Department of Health and Aged Care should work with sponsors to ensure that adequate supplies of therapeutics are available to meet reasonably anticipated demand for the next two years. Mechanisms such as guarantees for minimum supply should be explored to ensure availability and access.

Recommendation 8: Steps should be taken, consistent with an agreed policy and risk appetite, to ensure adequate supplies of vaccines and treatments are available across 2023 and 2024 including in the event of spikes in demand. This should include additional Moderna vaccines in 2023 and, as a minimum and based on an assessment of 'COVID-19 stability', doses necessary to meet baseline demand in 2024.