Australian Government
Department of Health and Aged Care

Government Response to the Review of COVID-19 Vaccine and Treatment Purchasing and Procurement

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Title: Government Response to the Review of COVID-19 Vaccine and Treatment Purchasing and Procurement

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Introduction

The Independent Review of COVID-19 Vaccine and Treatment Purchasing and Procurement (the Review) was commissioned on 30 June 2022 by the Minister for Health and Aged Care and delivered to government on 23 September 2022. The Review examined the procurement and current supply arrangements for COVID-19 vaccines and treatments, with the overarching aim to ensure government remains ready and able to continue to meet current and future COVID-19 requirements for Australia.

The Review highlights a number of challenges and environmental factors that impacted on the procurement, supply and distribution and COVID-19 vaccines and treatments during the early phases of the pandemic. It also examines the opportunities afforded by a more stable and predictable COVID-19 environment including the capacity to review and update systems to ensure they are fit for purpose, effective, efficient and delivering value to government.

The Review includes eight recommendations for government including the need for public health campaigns to enhance booster uptake, an update to the COVID-19 policy framework, the streamlining of advisory structures, a review of vaccine distribution arrangements and the need to ensure adequate supplies of vaccines and treatments through to 2024.

Seven of the eight recommendations have been accepted by the Australian Government and will be implemented by the Department of Health and Aged Care (the Department). One recommendation, in relation to the National Medical Stockpile (NMS), has been partially accepted, noting that this recommendation was largely outside the terms of reference for the review.

The recommendations have been considered within the broader context of the Australian Government's National COVID-19 Health Management Plan for 2023 (the National Plan), which outlines the Australian Government health supports to manage COVID-19 during 2023.

This document outlines a range of activities aligned with the recommendations of the Review, designed to optimise the Australian Government's ongoing response to COVID-19 through 2023 and 2024.

The ongoing arrangements for the funding, purchasing and eligibility of vaccine and treatments are both commercially sensitive and the subject of Government consideration. The Review provides a basis for a way forward, however the evolving nature of both the virus epidemiology and public response to COVID-19 continue to change as should the response. The Review highlights opportunities for future arrangements which will be incorporated as noted in this response.

The Australian Government thanks Professor Jane Halton AO, who led this review, for her leadership and guidance.

Strategic Context

Since the World Health Organization (WHO) declared the novel coronavirus (COVID-19) a worldwide pandemic on 11 March 2020 we have experienced nearly three extraordinary years which have seen a 1-in-100-year pandemic impact economies, health services and supply chains across the globe. COVID-19 challenged Australia's economy and put incredible pressure on our health system. Globally, no one was prepared for a pandemic of this nature, the scale of which has not been seen since the 1918 influenza pandemic.

Australia's response to COVID-19 has been effective, with treatments and vaccines being a critical component of Australia's national response and ongoing management strategy to ensure our health system can effectively support COVID-19 patients and also continue to provide the necessary population health care.

Over 64 million total vaccine doses have been administered since the COVID-19 vaccination program began in February 2021.

Health system funding from the Australian Government in response to the COVID-19 pandemic has exceeded $50 billion, provided across the spectrum of sectors including public hospitals, aged care, primary care, vaccines and treatments, PPE, public health measures and pathology.

Australia has not yet entered a 'COVID stable' state. COVID-19 remains largely unpredictable with the potential for future waves of varying severity and new variants, and the risk profile will continue to change with the development and availability of new vaccines and treatments.

Australia is, however, through the 'emergency' phase of the pandemic which allows for a shift towards a more sustained and long-term approach to the management of COVID-19. There are significant lessons learnt from the emergency phase which are now informing approaches within usual government processes and programs.

The National COVID-19 Health Management Plan for 2023 released in December 2022 sets out a path of transition for COVID-19 measures away from emergency response phase to a more sustainable model, while retaining scalable supports to safeguard the health and aged care systems. The National Plan includes a suite of interconnected whole of system measures to guide Australia's transition of management of COVID-19 from high-intensity/high-cost, whole of population health supports to more proportionate, scalable and targeted arrangements.

The pace and scale of transition of COVID-19 measures to a more sustainable state needs to be carefully balanced against the risk of future waves and the need to ensure that the system has latent capacity to respond.

One key measure of the National Plan is the transition of the National COVID-19 Vaccine Program to a model similar to the National Immunisation Program (NIP), with storage and distribution arrangements aligned to those of the NIP.

The Australian Government, through the Department, currently delivers the National COVID-19 Vaccine Program and has responsibility for the procurement, storage, logistics, distribution, administration, compliance, reporting and funding for COVID-19 vaccines. The future vaccine program model will be established as a collaborative program involving the

Australian Government along with state and territory governments. An agreement will be entered into between the state, territory and Australian governments.

The Australian Government will continue to be responsible for COVID-19 vaccine policy and the purchase of vaccines covered by the program. The state and territory governments will progressively assume responsibility for coordination and oversight of immunisation service delivery and distribution of vaccines similar to the NIP.

An immediate transition to a NIP-like model is not possible as the characteristics of COVID-19 vaccines (such as the requirement for ultra-low temperature control and the transition to single dose vials) and established supply and distribution arrangements differ significantly from those established under the NIP. The Department will work closely with states and territories to enable a smooth and safe transition of vaccine storage and distribution over the next 12 months.

In addition to vaccines, the availability of effective treatments for COVID-19 has been crucial for preventing severe illness and death and safeguarding the health and aged care systems on which the population relies. Australia has invested in a diverse range of treatments which target different stages of COVID-19, procured by both the Australian Government and states and territories. The Department will continue working collaboratively with industry, states and territories and other stakeholders to monitor domestic and global supply and ensure Australia has ongoing access to a portfolio of treatments for COVID-19.

The Department will continue to review and assess COVID-19 support measures in line with the contextual risk environment to ensure they are fit for purpose as the epidemiological outlook changes over time.

Response to recommendations

Recommendation 1: Boosting uptake through public health campaigns

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

Government response:

The government **accepts** this recommendation.

Public health campaigns and whole of population communication strategies through the emergency phase of the pandemic have been critical to the success of Australia's COVID-19 vaccination efforts.

The Review notes that, following early success with managing the pandemic, the uptake of COVID-19 boosters has waned. Unsurprisingly, after living with the virus threat since early 2020, Australians are increasingly fatigued by COVID-19 and disengaged from related news and information. The challenge for communication is to cut through this fatigue and promote uptake of booster doses in an engaging way. Communication design will be based on vaccination data, consumer research and insights from advisory groups.

The Department will continue monitoring public discourse, social media and media commentary to understand and address barriers to booster uptake and target communications accordingly.

The winter season will provide an opportunity to further boost vaccination rates, with an increased awareness of the risk of respiratory illnesses during colder months.

The government will invest $41.8 million for communication activity in 2022-23 to ensure everyone in Australia, especially populations in vulnerable situations, continue to have the information and awareness to make decisions that help protect themselves and others from severe COVID-19 illness. This will include targeted communications for those most at risk of severe illness and where data has identified a relatively low uptake of preventive measures such as vaccines. In particular, additional and culturally appropriate communications plans will be designed for each group for which a booster is recommended with an emphasis on high-risk groups including older Australians, First Nations peoples, people with disability, people from particular culturally and linguistically diverse communities, people with complex underlying health conditions and the immunocompromised.

A range of communication channels will be used to reach and engage the different groups including online, community networks and targeted advertising. Information will be regularly provided to the media, health care professionals, and business and community organisations to support their COVID-19 communication efforts.

Recommendation 2: Policy framework for COVID-19 management

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 part of this framework.

Government response:

The government **accepts** this recommendation.

Rapid decision making was necessary during the early stages of the COVID-19 pandemic. In this context, decisions on the management of COVID-19 in Australia were based on the best available advice at the time, an approach necessary to ensure the rapid development and implementation of public health measures to protect against widespread deaths from COVID-19.

The Review notes these policy settings, developed at the start of the pandemic, require updating to reflect the current COVID-19 environment including the widespread availability of effective COVID-19 treatments which were not available during the initial stages of the pandemic.

The National COVID-19 Health Management Plan for 2023 published in December 2022 outlines clear objectives and a range of health supports for the management of COVID-19 over the next twelve months, developed to reflect the current COVID-19 environment in Australia and globally. It provides a framework to inform decisions and actions across the spectrum of health measures relating to COVID-19 management, including investment in vaccines and treatments.

The National COVID-19 Vaccine Program is underpinned by both the National Plan and the Australian COVID-19 Vaccination Policy. The latter was developed by the Australian Government in partnership with state and territory governments in late 2020, and sets out the key principles guiding the program and outlined the shared and separate roles and responsibilities of each jurisdiction and key stakeholders. The key goal of the policy has been to protect against severe disease and death, particularly in vulnerable populations.

While updated settings for the COVID-19 Vaccine Program are outlined in the National Plan, the government has committed to a further review of the policy framework guiding Australia's ongoing management of COVID-19 to re-align public health goals, vaccine policy and public health messaging. This review will take into account the changing COVID-19 environment, such as levels of hybrid immunity and vaccine efficacy against new COVID-19 variants, with the aim to provide a more simplified and streamlined approach to boosters and public health communications going forward.

The government will consider policy arrangements recommended in the Review, including (but not limited to):

- Ongoing access to COVID-19 vaccination based on clinical advice, including in the context of growing hybrid immunity
- Targeted strategies to reach populations with low vaccine uptake
- A continued focus on the goals of preventing severe disease and death
- Management of risk and capacity for surge and transition periods

- Clarification on the ongoing role and utilisation of treatments and vaccines as complementary clinical tools
- The continuation of a portfolio approach to vaccines and treatments
- Wastage minimisation strategies
- Effective utilisation of distribution channels, including during surge periods
- Strengthening partnerships with industry to deliver optimal outcomes for government and people in Australia
- Progressively aligning the COVID-19 vaccination program with the delivery of other government funded vaccines
- Funding arrangements for ongoing COVID-19 measures, using the strategic framework to support the transition of measures and policies to a sustainable COVID-19 steady state as agreed by National Cabinet on 9 December 2022.

Recommendation 3: Governance and advisory structures

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 judgement. 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.

Government response:

The government **accepts** this recommendation.

Since the commencement of the pandemic and government response, a range of temporary and ad-hoc governance and advisory arrangements were established which had impacts for decision making, lines of accountability and responsibility, duplication and complexity. There are currently several federally managed advisory bodies, cross-jurisdictional advisory bodies, committees and other structures with, at times, overlapping or no longer fit-for-purpose roles and responsibilities.

These actions were, during the emergency phase of the response, appropriate. The Review recommends, with the need for ongoing, integrated advice, new advisory structures and mandates will be required to replace ad hoc arrangements put in place at the start of the pandemic. A review of these arrangements is timely to ensure appropriate structures and frameworks are in place for the future of the National COVID-19 Vaccine Program.

The Government has commenced implementing this recommendation to integrate advisory structures through the 2023 National Plan. Funding will cease for the temporary National COVID-19 Cinical Evidence Taskforce after 31 December 2022. The Taskforce was established at the start of the pandemic given the lack of knowledge about care for people with COVID-19, to develop treatment advice and to update this frequently as new reseach emerged. Advice about clinical treatment for COVID-19 will now be managed under usual arrangements, including advice provided by the Therapeutic Goods Administration, and where applicable, the Pharmaceutical Benefits Advisory Committee. The Department will continue examining the operation of governance and advisory structures through a functional

review of these arrangements to inform ongoing structures relating to both COVID-19 vaccines and therapeutics. It is anticipated that this review will be completed by mid-2023.

As the National COVID-19 Vaccine Program transitions to its future state, it will be important that appropriate accountability and governance arrangements are built into the new approach to program delivery and that risks associated with the transition period itself are actively managed.

Recommendation 4: Decision framework for procurement

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.

Government response:

The government **accepts** this recommendation.

The Department has had significant learnings from undertaking procurement during the peak of the pandemic. Internationally competitive markets, relatively small international volume purchases and the level of urgency of supply resulted in a risk appetite different to normal procurement practices. The Department is committed to applying updated requirements to procurement practices given the shifts in the commercial and epidemiological environment that influence procurement activities. It should be noted that vaccines with provisional approval from the Therapeutic Goods Administration (TGA), rather than full registration, are not yet available on the open market and can only be procured by government.

As noted in the Review, in order to protect human health, early procurement decisions for vaccines were exempted from standard Commonwealth Procurement Rules in August 2020 due to the exceptional circumstances posed by the pandemic. By the end of 2020 this resulted in Australia being able to secure approximately 110 million doses of vaccines through Advance Purchase Agreements (APAs), later adjusted upwards to over 250 million doses. APAs were also used to procure treatment options for COVID-19 once these became available in mid-2021.

These procurement decisions were specifically made within the context of certain identified risks, such as the potential for supply chain disruption, failure of clinical trials, limited supply, and associated issues with regulatory approvals. As such, the volume of procured vaccines reflected the then government's policy of wanting to secure enough vaccines for the entirety of the Australian population, with additional doses reserved for boosters, and to contribute to international vaccination efforts through donations. As of 10 February 2022, 97.5% of Australian's population have received a first dose, with 96.1% having received two doses and 72.4% with three doses.

Despite these high rates of vaccination, Australia continues to have sufficient supply of vaccines to meet need based on moderate scenario modelling. The Australian Government continues to amend existing APAs where necessary to reflect the changing nature of the virus, for example by ensuring access to bivalent vaccines and other emerging treatments. As a result, Australia currently has enough vaccine stock to last throughout 2023, with the last deliveries under existing APAs scheduled for Q4 2023.

In line with Recommendation 4, and consistent with the Australian Government's portfolio approach to COVID-19 vaccines, the Moderna APA was amended in February 2023 to secure additional supply, ensuring ongoing availability of this vaccine into 2024.

The government accepts future APAs for both vaccines and treatments will need to be negotiated based on emerging conditions both in Australia and abroad. Ideally this will result in APAs that are more flexible and tailored to needs of the Australian population. This includes taking into account the Australian Government's commitment to establishing onshore manufacturing presence for mRNA vaccines and the expected increase of viable vaccines expected to enter the market. Procurement decisions will continue to be made in line with ongoing policies informed by subject matter experts, with a view to ensure Australians maintain optimal access to vaccines and treatments over time.

Recommendation 5: Logistics arrangements for COVID-19 vaccines

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

Government response:

The government **accepts** this recommendation.

Improving value and efficiency of the COVID-19 Vaccine Program

In May 2022 the Department commissioned an external review of the logistics arrangements and supply chain supporting the COVID-19 vaccine rollout. A number of operational changes to the COVID-19 vaccine rollout are being implemented, informed in part by this external review and the recommendation of the Halton Review. These changes are designed to improve value and cost efficiency by streamlining distribution logistics and optimising the use of existing distribution pathways including those of state and territory governments.

At the commencement of the COVID-19 vaccine rollout the Department had two contracts for the storage, logistics and distribution of vaccines. These arrangements reduced risked and provided greater capability on the east coast of Australia where there was the highest demand. Now that vaccine uptake has stabilised and there are established vaccine administration channels there is the opportunity to reduce expenditure.

One such change is the move from two logistics providers to one which will deliver significant distribution and cost efficiencies. Further efficiencies are anticipated when vaccine storage and logistics responsibility transitions to state and territory governments in late 2023.

As the National COVID-19 Vaccine Program evolves and transitions to a more sustainable arrangements, so will the digital and data capabilities required to support the program. This includes, where required, transitioning the enabling platforms and bespoke systems developed for the operational and reporting aspects of the COVID-19 vaccine rollout to support a more NIP like approach.

Transition of COVID-19 vaccine distribution arrangements

New vaccine distribution channels, outside of the usual NIP model and existing Department logistics arrangements, were established for the COVID-19 vaccine context to meet the

unique requirements around cold chain infrastructure, temperature monitoring, stock and wastage reporting, and scalability.

These arrangements differ from usual channels for vaccine administration in Australia. The existing arrangements are through the NIP. The NIP is underpinned by the National Partnership for Essential Vaccines (NPEV), a formalised agreement between the Australian Government and state and territory governments for the delivery of vaccine programs. This agreement stipulated the Australian Government is responsible for national immunisation policy and the purchase of vaccines, while state and territory governments are responsible for coordination and oversight of immunisation service delivery and distribution of vaccines.

Part of the transition of pandemic response measures to a more sustainable model is to shift the distribution and administration of COVID-19 vaccines to a model similar to the NIP arrangements. Under such a model, states and territories would assume responsibility for storage and logistics of COVID-19 vaccines, and assurance activities such as training, compliance and accreditation of sites as they do for NIP vaccines.

Two of the most significant challenges for this transition are the multidose vaccine vials and the complex storage and distribution of vaccines that require ultra-low temperature control. The capability and capacity (for the volumes required for the program) to manage a vaccine with these requirements is not currently available (nor is standard practice) for vaccines provided through the NIP.

Transition of vaccine storage and distribution from the Australian Government to states and territories requires careful planning to ensure that flexibility and capability to stand up intensive surge response is retained, should it be required. Care is being taken not to dismantle critical program delivery and support structures too early before there is full capability across all jurisdictions.

A pilot is currently underway to trial COVID-19 vaccines and storage logistics for a suite of vaccines using existing infrastructure in New South Wales. This pilot will identify key challenges and help to inform planning for the transition of COVID-19 vaccine program delivery to states and territories in 2023.

The Department will continue to provide the same level of support to vaccination sites until transition of the program is complete. The Vaccine Operations Centre (VOC) will continue to provide support to health professionals and manage incidents to ensure the safe handling and administration of COVID-19 vaccines.

Waste reduction strategies

Levels of wastage with the COVID-19 Vaccine Program remain within the acceptable levels indicated by the World Health Organization (WHO). The WHO estimated between 15% and 40% wastage for multi dose vials that need to be discarded post opening. As at 10 February 2022, Australia's wastage rate was 18.2%. The most common cause of wastage across all jurisdictions has been dose expiry, including thawed vaccine and batch expiry.

However, there is value in exploring all avenues to avoid wastage.

The Department carefully tracks, monitors, analyses and forecasts wastage as an ongoing component of the program. Based on this information, a number of strategies have been designed to minimise wastage and optimise vaccine usage, including:

- **International donations:** where practical, the Department works with the Department of Foreign Affairs and Trade to donate excess stock to regional neighbours depending on their needs and has donated 23.5 million doses from the Department's procured supply. Australia has also offered 16.8 million vaccine doses to the COVAX Facility for distribution to participating countries.
- **Vaccine product changes:** the Department has worked closely with suppliers to improve the way in which vaccine products are packaged and delivered, including shifting to single dose syringes which will reduce the need to dispose excess doses within a single multi dose vial. In partnership with the TGA, suppliers have also applied to extend the shelf life of some vaccines.
- **Optimising logistics and distribution**: wastage can be reduced through optimising storage, logistics and distribution of vaccines. A range of policies, procedures and protocols have been put in place to achieve this optimisation such as the amendment of delivery schedules, reduced allocations to prevent over-ordering, the implementation of stock transfers and reverse logistics, and a shift in the vaccine ordering process to an 'as needed' model.
- **Data and reporting on wastage:** data is used to monitor and predict vaccine wastage, support effective stock management, and to measure the impact of program changes and wastage control measures such as ordering protocols, allocation reductions and the availability of stock transfers and reverse logistics.
- **Site accountability**: the Department monitoring wastage rates at vaccination sites to identify locations with higher-than-normal wastage rates and put in place mechanisms to address wastage issues.
- **External vaccination providers:** As part of panel agreements, all external vaccine providers contracted by the government to deliver COVID-19 vaccines required clinical governance and processes around storage and management of the vaccines.

Future arrangements for the COVID-19 Vaccine Program will consider the impact of decisions on wastage and include further implementation of waste reduction strategies.

Recommendation 6: Stockpile management and access

New mechanisms to manage stock held by the National Medical Stockpile 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.

Government response:

The government **accepts** this recommendation in part, noting that certain information will not be released due to potential impacts that would compromise its security position.

The NMS has been a key pillar in Australia's COVID-19 pandemic response, expanding to include more products and more recipients than ever before including Personal Protective Equipment (PPE), Rapid Antigen Tests (RAT), COVID-19 treatments and other medical supplies. This expansion was crucial in the context of globally constrained supply chains, and while many of these challenges have now resolved it remains essential the NMS is poised to continue to provide support in emergency circumstances.

The NMS continues to provide support to the aged care, First Nations and the disability sectors and COVID-19 treatments to public hospitals through states and territories.

Work is underway to implement recommendations made by the Australian National Audit Office (ANAO) during recent audits conducted throughout the pandemic.

There is alignment between recommendation six of the Review and recommendation three of the ANAO audit of NMS planning and governance of COVID-19 procurements, published in December 2020, regarding the establishment of a mechanism for regular sharing of information between jurisdictions about stockpile inventories that will function in both business-as-usual and emergency conditions. The Department will continue efforts to implement this recommendation, including enhancements to NMS governance arrangements and the development of an end-to-end inventory management system.

The future of the NMS is also being considered as part of planning for the establishment of a new Australian Centre for Disease Control (CDC). The establishment of a CDC was a commitment made by government during the 2022 Federal Election campaign and is expected to improve pandemic preparedness including management of the NMS through analysing needs, procuring and managing stock, and distributing supplies as needed.

Full transparency of the holdings of the NMS would not be possible due to national security considerations.

Recommendation 7: Securing COVID-19 treatments

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.

Government response:

The government **accepts** this recommendation.

The Department has been and will continue to work closely with sponsors of treatments and clinical experts to ensure Australia remains well placed to manage the impacts of COVID-19 over the coming years. This includes monitoring and understanding the benefits of emerging therapies and changes in the efficacy of existing treatments. The Government is also transitioning appropriate COVID-19 treatments away from emergency purchase arrangements to normal procurement and Pharmaceutical Benefits Scheme subsidy arrangements where possible. This supports the move from the emergency phase of the pandemic to a more sustainable approach to the management of COVID-19, using well established access and distribution channels.

Procurement of therapeutic supplies

In 2021 the Department entered into Advanced Purchase Agreements (APAs) with a range of manufacturers to secure a diverse range of treatment options and ensure adequate supply to meet demand. These APAs have been varied as required, including in response to new variants or changes in supply and demand.

Oral antiviral therapies, which are suitable for prescribing, dispensing and use in the community, are now primarily distributed through the PBS arrangements, providing benefits in terms of using community pharmacy distribution mechanisms to deliver treatments to larger numbers of eligible people.

Health Technology Assessment

Access to rapid Health Technology Assessment (rHTA) for COVID-19 treatments has allowed for informed decisions on treatments to be made quickly to secure supply. This is a time limited pandemic response measure, however given the breadth of new variants and treatments on the horizon, the Government has extended support for these arrangements to 31 December 2023. Continued access to expert advice enables a rapid evidence-based response to changing circumstances, including the emergence of new variants.

In parallel, the Government is also working with sponsors to transition suitable treatments to normal HTA assessment processes, as more and higher quality clinical evidence becomes available.

While this allows for assessment by bodies like the Pharmaceutical Benefits Advisory Committee, not all treatments will be suitable for listing on the PBS, or meet PBS listing requirements, and to ensure a secure portfolio of treatments for Australia, as well as vaccines, further direct purchases of treatments will be considered by Government where necessary. This is expected to be targeted at treatments not able to be delivered through public hospitals and managed through normal hospital procurement arrangements, supported by national oversight to monitor supply and demand.

Monitoring demand for COVID-19 treatments

Meeting ‘reasonably anticipated demand’ for treatments requires matching of patient demand for COVID-19 therapeutics with available supply, and this work is continuing with state and territory governments. The addition of oral antivirals to the PBS has considerably improved data quality and availability for supply and demand of these medicines, which is closely tracked by the Department. The Department will explore mechanisms to optimise linkage of anticipated demand for these and other treatments supplied through hospitals across patient cohorts to ensure that sponsors, public hospitals and the NMS have necessary supplies, especially in high demand scenarios.

Recommendation 8: Securing adequate supplies to meet demand

Steps should be taken, consistent with an agreed policy approach to 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.

Government response:

The government **accepts** this recommendation.

Australia adopted a portfolio and redundancy approach for early procurement of COVID-19 vaccines and treatments, in the context of global supply challenges and the need for risk mitigation. As the COVID-19 environment evolves, so too should the government's approach to procurement of vaccines and treatments. The next phase of procurement, assessment and monitoring for vaccines and treatments will be informed by the policy framework guiding the ongoing management of COVID-19 in Australia and continue to be based on evidence and clinical advice.

The Australian Government entered into five separate agreements for the supply of COVID-19 vaccines. These included agreements with Pfizer, AstraZeneca, Novavax, Moderna and the COVAX Facility for over 250 million doses of vaccine. This diverse portfolio of vaccines and treatments provides Australian's flexibility of choice and enables the government to address variants of concern in the future.

The Australian Government has also entered into six separate agreements to secure a diverse range of treatment options which target different stages of COVID-19. This includes agreements with Gilead Sciences, GlaxoSmithKline (GSK), Roche, Merck Sharp and Dohme (MSD), Pfizer, and AstraZeneca.

The Australian Government has further entered into an agreement with Moderna to establish onshore manufacturing and guaranteed supply, with locally produced COVID-19 vaccines.

There are more than sufficient doses to complete future vaccine requirements in 2023 and, by managing a staged delivery and with extended shelf life, into 2024.

Any future procurement will be informed by modelling which includes low, medium and high-risk scenario planning, ongoing risk assessment based on epidemiology and the need to secure access to the most updated vaccines and treatments as soon as possible.

Current modelling indicates that a small supplementation in vaccines is required to ensure the full suite of current vaccines continue to be available consistent with the recommendations of this Review. In response, the Australian Government has agreed to purchase additional doses of Moderna vaccine to ensure ongoing availability of this vaccine.

The balance between supply and demand for both vaccines and treatments will continue to be closely monitored and additional procurement undertaken as needed (including ultimately via onshore manufacturing) to ensure Australians have ongoing access to a portfolio of treatments and vaccines. Vaccine procurement will be continually reviewed in line with administration, stock expiration, wastage and donation assessments before further consideration by Government.

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All information in this publication is correct as at February 2023