A submission by **CO**VERSE on the audit criteria: Was the 2021-22 procurement of Moderna onshore mRNA vaccines effective?

About **CO**VERSE

We are the national peak body representing Australians who have been adversely impacted by the COVID-19 vaccines. Our science-led organisation is 100% controlled and operated by COVID-19 vaccine-injured Australians and is a charity registered with the Australian Charities and Not-for-profits Commission.[1] Full details of our organisation and activities can be found on our website at ***coverse.org.au***.

We have no conflicts of interests and have not accepted any funds from government, medical groups, or pharmaceutical corporations. As advocates for safety, transparency and accountability, we welcome this audit and are grateful for the opportunity to contribute.

Our submission is made in the context of the ANAO's focus on the **effectiveness** of the 2021–22 procurement of Moderna's onshore mRNA vaccine manufacturing capacity. Our comments focus on the administration and oversight of the Commonwealth Government's agreement with Moderna and the broader regulatory environment supporting this initiative.

Key Concerns

1. Exemption from PBAC and ATAGI Review Undermines Oversight and Administrative Consistency

Multiple independent sources[2] confirm that Moderna's mRNA vaccines, under a 10-year agreement with the Australian Government, were exempt from the standard review process by the Pharmaceutical Benefits Advisory Committee (PBAC) and the Australian Technical Advisory Group on Immunisation (ATAGI). These reviews are critical for ensuring cost-effectiveness, safety, and efficacy in Australia's National Immunisation Program (NIP).

By allowing Moderna to bypass this critical evaluation, the procurement process departed from standard, trusted mechanisms. This decision compromises the integrity of public administration and raises the following questions:

- Whether this exemption was part of the original agreement or added later;
- What governance and risk management processes were used to justify bypassing PBAC/ATAGI review;
- Whether appropriate compensating controls or safety checks have been implemented in lieu of PBAC/ATAGI scrutiny;

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[1] *www.acnc.gov.au/charity/charities/ef2b7613-c6d1-ed11-a7c7-00224893b304*

[2] *https://publichealthpolicyjournal.com/australia-inks-2-billion-deal-allowing-moderna-mrna-vaccines-to-bypass-key-step-in-safety-process/*
https://mednews.com.au/modernas-ex-nip-funding-deal-revealed/

- How this exemption aligns with the principles of consistent, transparent public sector administration.

For the vaccine-injured community, this exemption is particularly troubling; it suggests that public health protections can be suspended in commercial agreements.

2. Lack of Transparency in Contractual Terms

Despite the scale and duration of this agreement (reportedly up to $2 billion over 10 years), key financial and operational details of the Moderna agreement remain undisclosed; including total costs, unit pricing, dose quantities, and performance benchmarks.

This lack of transparency undermines the public's ability to assess whether the procurement represents value for money. Given that substantial public funds are involved, and the agreement has long-term implications for health system planning, this secrecy reduces trust in the integrity of government contracting and delivery.

3. Preferential Treatment May Have Distorted the Vaccine Market

Reports[3] also indicate that other domestic vaccine manufacturers (such as CSL Seqirus - Australia's largest vaccine manufacturer) raised concerns about the lack of a level playing field. Allowing Moderna to bypass the PBAC while competitors remained subject to strict regulatory requirements may have skewed procurement outcomes, undermined fair competition, and reduced public choice.

This preferential approach may have had knock-on effects on the local biotechnology sector, which deserves equal opportunity to contribute to national vaccine resilience.

4. Public Trust and Program Outcomes Have Been Impacted

The deviation from normal safety and review processes likely contributed to growing public concerns around vaccine safety and government transparency. In the context of ongoing vaccine injury claims and scrutiny of mRNA technology, such decisions can significantly undermine public confidence in government-led health initiatives. The well documented decline in childhood vaccination rates may be directly attributed to this loss of trust. The perception that pharmaceutical manufacturers can avoid scrutiny through exclusive contracts further threatens the legitimacy of future programs.

For our community - those living with vaccine-induced harm - trust is already fragile. Administrative decisions that dilute oversight or avoid transparency further erode this trust.

5. Influence of Deregulatory Thinking in Program Implementation

A May 2024 peer-reviewed publication, co-authored by the former head of the Therapeutic Goods Administration, the former Chief Health Officer of Victoria, and a Senior Director at Moderna, explicitly advocates for reduced regulatory oversight of mRNA vaccines. The article calls for accelerated and more flexible approval processes, raising significant concerns about the potential weakening of established safety and evaluation frameworks.

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[3] *https://www.theguardian.com/australia-news/2024/dec/10/moderna-mrna-vaccine-exempt-advisory-committee-pbac-scott-morrison*

Citation: Skerrit, J. et al. (2024). *The Platform Technology Approach to mRNA Product Development and Regulation*. Vaccines, 12(5), 528[4].

It is deeply concerning that such views may have directly influenced administrative decisions related to Moderna's procurement and the apparent removal of established PBAC and ATAGI safeguards. In light of this troublingly close relationship between key members of regulatory bodies and industry stakeholders, we are further concerned about the neutrality and integrity of the procurement process as a whole. We urge the ANAO to examine whether:

- Individuals or organisations promoting reduced regulation have played a role in the administrative or strategic development of this program;
- Conflict of interest frameworks have been applied appropriately to those advising on mRNA-related projects or facilities;
- There is adequate independence between commercial entities and those providing scientific or policy advice to government departments involved in this project.

We believe it is critical that administrative decisions be made independently and based on evidence, particularly where new biomedical technologies and long-term public health outcomes are concerned.

6. Missed Opportunities and Opportunity Costs

Given the scale of investment, the ANAO should consider what alternatives were explored. For example:

- Could a smaller, diversified procurement mix have improved system resilience?
- Could funds have been allocated toward Long COVID research, care for the vaccine-injured, or health system strengthening?

Assessing what was *not* funded is critical to determining whether this procurement was effective.

7. Lack of Provisions for Australians Harmed by the Procurement Outcome

A critical measure of procurement effectiveness, particularly in the health sector, is whether risks and adverse outcomes are responsibly anticipated and addressed. In this context, it is ethically troubling that neither Moderna nor the Australian Government has demonstrated any commitment to establishing meaningful pathways for care, treatment, or compensation for Australians who may be harmed by products manufactured through this agreement.

This is not a theoretical concern. The Government's discontinued COVID-19 Vaccine Claims Scheme has been widely criticised for its inaccessibility, lack of transparency, and failure to meet the needs of those adversely affected. The absence of robust, forward-looking provisions for injury redress in such a large, long-term, and publicly funded procurement undermines both ethical responsibility and administrative preparedness.

Conclusion and Recommendation

In light of the above, we respectfully submit that the 2021–22 procurement of Moderna's onshore mRNA manufacturing capacity may not have met key effectiveness criteria due to:

[4] *https://doi.org/10.3390/vaccines12050528*

- Inconsistent application of regulatory safeguards;
- Lack of transparency in process and outcomes;
- Preferential treatment that may have distorted market fairness;
- Diminished public confidence in oversight mechanisms.
- Failure to include provisions for those adversely affected by the products of this partnership.

We urge the ANAO to give full consideration to these administrative issues as part of its performance audit. The effectiveness of such a significant procurement must be measured not only in delivery, but in how well it upholds the principles of good governance, transparency, and public trust.

Thank you for undertaking this important review.