A submission by **CO**VERSE to the
Australian Government Department of Industry, Science and Resources
public consultation on
Understanding our RNA potential[1]

For questions about **CO**VERSE visit coverse.org.au

About **CO**VERSE

COVERSE is the national peak body representing Australians who have been adversely impacted by COVID-19 vaccines (including the mRNA vaccines).[2] The 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.[3]

For a full understanding of the issues affecting Australians who have been negatively impacted by harms caused by these vaccines and surrounding environment, the Department is encouraged to read our range of public submissions,[4] in particular we attach our submissions to:

- House of Representatives Standing Committee on Health, Aged Care and Sport: *Inquiry into Long COVID and Repeated COVID Infections* (2022-2023)[5]
- Senate Finance and Public Administration Committees: *Public Governance, Performance and Accountability Amendment (Vaccine Indemnity) Bill 2023*[6]

Regarding the RNA industry in Australia, our community of COVID-19 vaccine-injured Australians, particularly those who have been severely impacted by mRNA vaccines, are a primary community stakeholder to be considered in the discussions around Australia's RNA industry. The views and experiences of this group of Australians should be considered central in all discussions relating to RNA technologies, particularly given the potential, and demonstrated fact, for these technologies to inflict real harms on otherwise healthy Australians.

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[1] consult.industry.gov.au/rnadiscussion
[2] coverse.org.au
[3] www.acnc.gov.au/charity/charities/ef2b7613-c6d1-ed11-a7c7-00224893b304
[4] coverse.org.au/submissions
[5] "Vaccines, Long Vaccine Syndrome, and Long COVID-19", submission by **CO**VERSE to the Australian Parliament *Inquiry into Long COVID-19 and Repeated COVID-19 Infections*, coverse.org.au/long-covid-inquiry
[6] media.coverse.org.au/documents/vaccine-indemnity-bill/060 COVERSE.pdf

Safety is paramount

The Department's discussion paper makes reference to the need for adequate safety testing of RNA products designed for use in humans. There would not be an Australian who would disagree with these sentiments

However, the experiences of those Australians who continue to suffer devastating impacts on account of their COVID-19 vaccinations tell a very different story than what has been portrayed by governments around the world, suggesting that current government, scientific, and medical paradigms have been inadequate to assess the safety of these products or to help those who have been impacted.

In the context of discussion of the RNA industry in Australia, as a patient organisation we can speak about our experiences with regards to industry and government failures and shortfalls, and we hope that these experiences can inform the future of this industry so that no other Australians should suffered the terrible harms that we continue to endure.

Systemic failures

Sadly, with regards to the COVID-19 vaccines, there has been a litany of worrying issues raised by whistleblowers, patients, and scientists that have gone unacknowledged and uninvestigated by relevant government authorities (and vaccine manufacturers). These include:

- Claims of clinical trial mismanagement and fraud[7]
- Claims of cover-ups of large number of serious adverse reactions during clinical trials[8]
- Clinical trial participants who experienced severe adverse reactions having their cases either misrepresented or simply removed from pharmaceutical company reports to regulatory agencies[9]
- Contamination of vaccines with potentially dangerous levels of DNA fragments[10]
- Governments and drug regulators colluding with vaccine manufacturers on preparing media statements, public messaging campaigns, and political talking points[11]
- Drug regulators being aware of specific adverse reactions yet failing to warn the public[12]

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[7] COVID-19-19: Researcher blows the whistle on data integrity issues in Pfizer's vaccine trial. *BMJ*, 2nd November 2021, doi:10.1136/bmj.n2635

[8] "Serious irregularities in clinical trials in Argentina". Deutsche Welle, 29th May 2023, www.dw.com/es/graves-irregularidades-en-ensayos-clínicos-en-argentina/video-65761028 (with English subtitles: youtu.be/rIp7uj_f0EE)

[9] "4 clinical trial participants", Dearly Discarded Podcast, Episode 13, 8th August 2022, odysee.com/@React19Clips:b/Dearly-Discarded_4InjuredTalk_45min-cut-smaller:7

[10] Sequencing of bivalent Moderna and Pfizer mRNA vaccines reveals nanogram to microgram quantities of expression vector dsDNA per dose. Preprint, 10th April 2023, doi:10.31219/osf.io/b9t7m

[11] "Notification and subsequent investigation conducted as part of the TGA review of reports of deaths in nursing home residents in Norway after Pfizer BioNTech vaccination." TGA, FOI 4073, www.tga.gov.au/resources/publication/publications/documents-released-under-section-11c-freedom-information-act-1982-jul-2022-jun-2023

[12] "Officials Neglect COVID-19 Vaccines' Side Effects". *Wall St Journal*, 12th May 2023, www.wsj.com/articles/the-covid-vaccines-neglected-side-effects-neuropathy-nih-fda-cdc-transparency-react19-8afa87b1

- Drug regulators and other public health actors prioritising research and public awareness campaigns that address vaccine hesitancy over disclosing emerging adverse vaccine reactions to the public and the medical community resulting in vast unnecessary harms due to lack of early interventions

Most importantly, from the patient perspective the lack of recognition or support from industry, the scientific and medical communities, and government, is unfathomable.

Despite causality assessments being clear cut in many of our cases, having this properly acknowledged and documented by *anyone* has been incredibly difficult, owing to the social-political environment surrounding the pandemic and the vaccines in particular (a problem that exists all over the world, not just in Australia). This has led to significant underreporting of vaccine-caused harms, which alone calls into question the data underpinning government assurances that these vaccines retain a positive safety profile.

Additionally, **the TGA has publicly acknowledged that they do not routinely follow-up reports of vaccine reactions**.[13] In fact, across our community of vaccine-injured Australians we are yet to hear of a single instance of contact from the TGA for further information, symptom progression, or for any sort of investigation.

This is in part a shortfall of our *passive* surveillance system, but largely it comes down to the TGA's lack of proactiveness. Surely, during the largest vaccine rollout in history, of new vaccine technologies which were under provisional approval, this agency might have at least thought to up their game and proactively investigate each case that is reported to them? This has simply not happened.

A recent *active* study in Switzerland demonstrated that when hospital staff were given a COVID-19 vaccine booster,[14] and these staff were clinically assessed (regardless of any post-vaccine symptoms), that 1 in 35 experienced cardiac injury and that the majority of these were women. Of the cohort, they also found that approximately 1 in 400 developed probable myocarditis.

These numbers are in stark contrast to public health statements, which claim that such injuries are "exceedingly rare, occur largely in young males, and are mild and self-resolving".

In our patient community, we find that such injuries are rarely mild, rarely self-resolving (with most still suffering), and that, as demonstrated in this Swiss study, the majority of those affected are women.

In short, the real world patient experience suggests that pharmacovigilance in this country (and, indeed, around the world) has shockingly failed to adequately capture and acknowledge the extent of harms caused by the COVID-19 vaccines. This further calls into question the data underlying public health claims of the positive safety profile of these products.

Moving forward

While thousands of Australians remain disabled and unsupported by the Australian Government, we recognise that the RNA industry will continue to grow regardless, and that some applications of these technologies will be able to solve health problems that have thus far eluded medical science.

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[13] For example, see x.com/radofaletic/status/1630093364241776640, though similar has been expressed during Senate Estimates.

[14] "Sex-specific differences in myocardial injury incidence after COVID-19 mRNA-1273 booster vaccination". European Journal of Heart Failure, 20th July 2023, doi:10.1002/ejhf.2978

Our ongoing experience, however, strongly suggests that the current drug safety environment has utterly failed to properly acknowledge, assess and report on the large numbers and wide range of serious issues caused by the COVID-19 vaccines.

If Australia's RNA industry is to put patient safety first, and to earn the trust of Australian voters and health consumers, then it is clear that current pharmacovigilance paradigms and systems will be unable to achieve these aims.

We strongly urge those involved with RNA technologies in Australia to incorporate the real experiences and the recommendations from patients (and their organisations such as **CO**VERSE) whose lives have been forever damaged by the mRNA COVID-19 vaccines.