14 December 2023

Robyn Kruk AO
Independent Chair
Commonwealth Government Covid-19 Response Inquiry

Member of the public submission:

Introduction:

We seek to raise a number of matters which we believe will help inform both current and future responses to population threats such as those that occurred following the declaration of the COVID-19 emergency/pandemic. Specifically, we seek to draw attention to vaccine approval, distribution, public health messaging, treatment pathways and the compensation scheme instigated for the management of COVID-19.
The Commonwealth response in procuring vaccines and the role of government in informing the general public of any associated risks should be the focus of extensive examination. Early understanding of mortality associated with COVID-19 led to compulsory vaccine mandates, while in hindsight it is likely that there was an over-estimation of 'lives saved' or inaccuracies in the estimation of the balance of risks, especially for our younger population. True informed consent could not be established given the novel nature of the new virus, however emerging evidence of vaccine risk was not countered by explicit public messaging or a repositioning of Australia's COVID-19 strategy. For example, to continue offering the AstraZeneca ('AZ') vaccine (ChAdOx1nCoV-19 Oxford-AstraZeneca) without a significant education campaign to health professionals and the general public most likely contributed to delayed diagnosis and in some cases death. Supply chain logistics for the availability of essential drugs for the management of mild, moderate or catastrophic side effects appeared unorganised despite engagement between public and private hospitals facilities. State/Commonwealth responsibilities across the health sector during this time demonstrated the fragmentation that exists, with primary care and aged care receiving messaging from the Commonwealth while the hospital sectors were largely responding to State requirements.

It would be our preference to speak to the issues raised to ensure there is sufficient clarity in the detail provided given the limitations associated with a written submission.

Sporadic distribution of vaccines:

- Procurement of vaccines was managed by the Commonwealth
- State distribution appeared uneven and became further skewed by local authorities determining rollout requirements. For example, large public hospitals made choices for other services within district areas as to both the type of vaccine and the quantity that would be distributed at any given time. This unusual methodology restricted vaccine roll-out and delivery efficiency. The lack of a standard approach again demonstrated the State/Commonwealth fragmentation interfering with process proficiency. During a national emergency of this nature, there should be provision for a single, unified and consistent national approach.

Public Health messaging:

- Despite being established in 1998, the emergence of the Australian Technical Advisory Group on Immunisation (ATAGI) rose in prominence during the pandemic. ATAGI in itself was an example of a centralised approach to providing public and health professional confidence in what was being asked of the population during this period. Coupled with weekly reports from the Therapeutic Goods Administration (TGA), both departments offered a cohesive narrative at least for the first year - 2020. Information became less clear with inconsistencies appearing between State advisors, Chief Medical Officers and the Commonwealth, researchers and epidemiologists. By June 2021, and with with each new variant that emerged, information became inconsistent and often confusing.
- Initial advice – vaccinate as soon as possible regardless of age then was amended to being vaccinated outweighed any risk associated with a vaccine. As the Delta variant emerged, the advice was made more general again – seek whichever vaccine may be available. While international data identified an increasing risk profile for both dominant vaccines (AZ and Pfizer), messaging became more confused with recommendations to visit a GP to assess personal risk (despite the triggers for severe or catastrophic

reaction being unknown – which remains the case). The developing risk settings led to public confusion and impacted vaccine uptake, with a community divide occurring between 'anti-vaxers' and those vaccinated, further compounding confusion through fear. The AZ vaccine was eventually withdrawn November 2023.

May 2021:

https://www.health.gov.au/news/joint-statement-from-atagi-and-thanz-on-thrombosis-with-thrombocytopenia-syndrome-tts-and-the-use-of-covid-19-vaccine-astrazeneca

"TTS is a rare condition with a different mechanism to most other causes of thrombosis and/or thrombocytopenia. Among case reports, there are no known markers for increased risk for TTS.

Based upon this, the following groups of people can receive COVID-19 Vaccine AstraZeneca:

- *People with a past history of venous thromboembolism in typical sites, such as deep vein thrombosis or pulmonary embolism*
- *People with a predisposition to form blood clots, such as those with Factor V Leiden, or other non-immune thrombophilic disorders*
- *People with a family history of clots or clotting conditions*
- *People currently receiving anticoagulant medications*
- *People with a history of ischaemic heart disease or cerebrovascular accident*
- *People with a current or past history of thrombocytopenia.*

Vaccination against COVID-19 remains the best way to prevent severe illness and death from COVID-19. The benefits of vaccination are many and include protection against severe illness and death from COVID-19 for the individual, as well as indirect benefits for the community. The risk of potential outbreaks of COVID-19 is ever-present. The Australian population remains largely unimmunised and susceptible to COVID-19 risks."

ATAGI – October 2021

"ATAGI stresses that vaccination is a key public health intervention to prevent infection, transmission and severe disease due to SARS-CoV-2. ATAGI recommends COVID-19 vaccination for all Australians from 12 years of age."

"ATAGI also noted that the TGA have been reporting a detailed breakdown of Australia's confirmed and probable TTS cases weekly using the CDC Criteria. ATAGI noted these data suggest that the severity of TTS appears to be higher in younger women. These differences by sex are not seen in older people."

TGA – 2 November 2023

"The Vaxzevria (AstraZeneca) vaccine is no longer available for use in Australia. Almost 14 million doses of Vaxzevria (AstraZeneca) were administered when it was in use."

Treatment and Drug Supplies:

Drugs required to treat severe and catastrophic complications of the AZ vaccine were in short supply. For example, intravenous Bivalirudin® required special sourcing despite being a mainline treatment for Vaccine-induced Immune Thrombotic Thrombocytopenia (VITT) and formed part of the recommended THANZ protocol https://www.thanz.org.au/documents/item/590 and https://www.thanz.org.au/documents/item/591

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TTS, also known as vaccine induced thrombotic thrombocytopenia (VITT), is a rare newly identified condition with a different mechanism to other causes of thrombosis. Among case reports, there are no known markers for increased risk for TTS/VITT.

The risk of TTS is not likely to be increased in people with the following conditions, and people in these groups can receive COVID-19 Vaccine AstraZeneca:

TTS can be treated effectively. Guidance on the identification and management of TTS is available from the Thrombosis and Haemostasis Society of Australia and New Zealand.

- Subsequent supply of ongoing drugs therapies for the management of unresolved risk factors relating to VITT has also complicated care regimes: https://www.tga.gov.au/safety/shortages/information-about-specific-shortages/about-warfarin-shortage-2023
- Disruption to critical supply chains continues as an issue with over 400 drugs in short or no supply in Australia. Lack of a central procurement model for critical supplies – PPE, medication, medical devices to ensure uninterrupted supply (and continue with a 'war chest') appears unsuccessful. Larger volume purchasing would likely prioritise Australia for available stock/shipment.

Impact and ongoing care needs

- The Commonwealth recognition of ongoing health care needs for those who suffered vaccine induced injuries/conditions has been slow or non-existent. While there has been superficial discussion around mental health support for those with 'long COVID' symptoms, other conditions and their on-going care have been largely ignored, with patients incurring significant debt and time imposts to manage unresolved health impacts e.g. weekly to monthly blood tests – clotting profiles: medications e.g. warfarin; iron deficiency secondary to anticoagulation treatments especially in women. In a number of cases, the trigger for the antibody response that was responsible for clot formation (which remains unknown) remains active and therefore has a 'lifelong' consequence for those impacted.
- The Commonwealth through the development of an Australian Centre for Disease Control should give consideration to a scheme not dissimilar to that provided to Veterans (Gold Card) for those with proven

vaccine injuries to ameliorate the disease burden over the person's lifetime and provide the person with certainty of access to ongoing treatment.
https://www.dva.gov.au/get-support/health-support/veteran-healthcare-cards/veteran-gold-card

Legal indemnity and interpretation

- A spokesman for the federal health department said the government was [redacted] and had agreed to indemnify the drug companies due to [redacted] (https://www.smh.com.au/politics/federal/morrison-government-grants-indemnity-for-covid-19-vaccine-side-effects-20201008-p5636o.html).
- By indemnifying the vaccine companies AstraZeneca and Pfizer, the Commonwealth has contractually agreed to cover any losses or damage caused by these companies, specifically any adverse reactions to their vaccines.
- The Commonwealth's COVID-19 Vaccine Compensation Scheme appears to have failed in assuming this onus. The scheme was poorly conceived placing significant obligation upon especially those with already proven vaccine injuries (i.e. reported to TGA); is inadequately staffed and operated, and fails in achieving timely and regular communication with claimants and ultimately, does not adhere to the High Court's interpretation of an indemnity's 'make good' obligation *in Andar Transport Pty Ltd v Brambles Ltd*.
- There is a sense of abandonment by the Commonwealth government with the scheme itself being impersonal. There appears to be a general lack of oversight of assessments, outcomes, and determinations. (For example: a claim filed on [redacted], and followed up [redacted] and [redacted] has not had any review or acknowledgement response. (To date not a single communication in response, not even a simple automated confirmation email upon submission). Services Australia's approach is simply – do not ask. https://www.servicesaustralia.gov.au/how-to-make-claim-under-covid-19-vaccine-claims-scheme?context=55953

Data, learning and lost momentum

- The impact of COVID-19 upon the various population groups is one that requires greater examination including but not limited to: the community divide created for those who objected to vaccination and those that followed mandates; those who contracted long COVID-19; those that incurred vaccination injuries and ongoing conditions; those that were prevented from visiting loved ones in hospital or at funerals and the overall investment to prevent lives lost.
- New vaccines are emerging to deal with SARS-Cov2 variants – have we applied the same public disclosure and monitoring 'guard rails' to their release? Vaccine 'technology' should be explored with greater care until rare and catastrophic side effects causative factors are better understood. In both instances, greater public disclosure is required.

Research

- The Commonwealth should require drug companies to continue researching the effects of their vaccines even after roll-out to ensure that they find what triggers and creates such significant adverse events. While Australia's mortality rate was lower, this appears to be related to the timing off the vaccine roll out in Australia and our ability to take advantage of international learnings rather than a 'best practice' outcome.
- A 'mandatory investigation' clause should be included in any agreement that considers the transfer of liability/indemnity arrangements to ensure that complete onus is not taken away from the pharmaceutical companies. More importantly, this would better align with their manufacturer responsibilities under the Australian Consumer Law ('ACL').
- Australia's product liability regime for 'defective goods' is set out in the ACL. 'Goods' have a safety defect if their 'safety is not such as persons generally are entitled to expect'. Under the ACL, a manufacturer is liable to compensate an individual if the goods have a 'safety defect' and the individual suffers injuries because of the defect. This means that as the manufacturer of the vaccine, drug companies have a responsibility to research and understand why their goods are defective.

We request this submission remain private – no publication of names.

We may be contacted - details:

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