RESPONSE TO THE COVID INQUIRY

Thank you for the opportunity to contribute to the inquiry into the Commonwealth Government's response to the COVID-19 pandemic.

I am a lawyer by profession, a small business owner, and a mother of two, pre-school aged children. I am also an engaged citizen who closely followed the development of covid policy, particularly the interactions of the federal system, the separation of powers, and ministerial responsibility as regards the approval, procurement, and provision of COVID-19 vaccines.

My submission is particularly concerned with the failure of the Government, its agents and assigns, to make a covid vaccine available to under 5-year-olds, which failure is ongoing as at the time of writing.

HISTORY OF PAEDIATRIC COVID VACCINATION

A covid vaccine for children aged 6 months to 5 years old was first approved by the US Food and Drug Administration on 17 June 2022.[1]

Vaccination for the 5-11 years' cohort had been approved by the Australian Therapeutic Goods Administration ("TGA") and recommended by ATAGI in December 2021, and the rollout began in Australia on 10 January 2022, albeit with significant supply delays.

As the parent of two children under the age of 5, the additional 6-month wait for the vaccine for their age group to be approved seemed interminable. The relief when the vaccine was finally approved in the US was immense – there was hope that once the corresponding approvals were processed in Australia, we would finally be able to protect our children.

Both Moderna & Pfizer-BioNTech subsequently sought emergency approval in Australia, with TGA approving Moderna Spikevax for children aged 6 months-6 years on 19 July 2022. Pfizer Comirnaty for children aged 6 months - 5 years was subsequently approved on 29 September 2022.

On 3 August 2022, ATAGI released their recommendations that only children with severe immunocompromise, disability, and those who have complex and/or multiple health conditions which increase the risk of severe COVID-19 were to be vaccinated. The rollout to those children commenced on 5 September 2022.

In late 2023, most Australian children under 5 years of age are still unable to be vaccinated against COVID-19.

This submission contends that these children have been, and continue to be, overlooked, neglected, discriminated against, and exposed to undue and unnecessary risk of harm, including death.

ATAGI's RECOMMENDATIONS

In examining ATAGI's 3 August 2022 recommendations regarding the 6 months – 5 year age group, the stated rationale can be summarised as essentially that 'these children have a very low likelihood of severe illness from COVID-19', however, their reasoning is open to scrutiny.

ATAGI's summary of recommendations included the following statements:

1. *The very low risk of severe COVID-19 (e.g., hospitalisation due to COVID-19) in healthy children aged 6 months to <5 years. This age group is one of the least likely age groups to require hospitalisation due to COVID-19.*

   The evidence shows that children under 5 years of age were most likely to require hospitalisation. *Figure 1: CDC, Monthly rates of C-19 associated hospitalisation, 2021-22,* shows rates of hospitalisation for 0-4 well above other age groups for whom vaccination was permitted (5-17 years)[2].

   21,176 Australian children (aged 0-4) were hospitalised with a covid diagnosis in 2021-22, which number represents 1.4% of that population cohort (compared to 0.85% of the population aged 5-14)[3].

2. *A relatively low rate of paediatric inflammatory multisystem syndrome (PIMS-TS) following COVID-19 in children aged 6 months to <5 years compared to older children.*

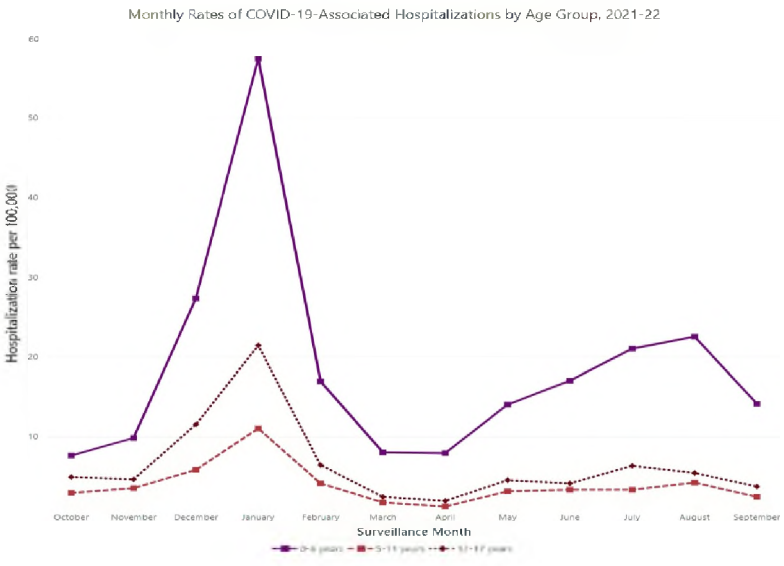

Figure 1

[1] U.S. Food and Drug Administration, FDA News Release, 17 June 2022 (https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-moderna-and-pfizer-biontech-covid-19-vaccines-children)

[2] https://www.cdc.gov/coronavirus/2019-ncov/covidnetdashboard/de/powerbi/dashboard.html, accessed 27 November 2023.

[3] AIHW Admitted Patient Care, Table 9, Separations with a COVID diagnosis, 2021–22, https://www.aihw.gov.au/reports-data/myhospitals/sectors/admitted-patients

PIMS-TS is only one, and a relatively rare, complication of COIVD-19.[4] It is submitted that using PIMS cases as the measure of the severity of Covid-19 in children would underestimate the severity/impact on children. One must wonder whether the consideration that a rare complication is slightly rarer in a certain age group, is good reason to deny access to vaccines to an entire cohort. Further, vaccine effectiveness at reducing MIS-C/PIMS-TS has been demonstrated to be in the order of 91%[5] - 94%[6]. The rate of vaccine-induced PIMS-TS is far lower than the rate occurring after infection with COVID-19.[7] How much unnecessary suffering could have been prevented by the timely and widespread vaccination of children of all age groups?

3. *Up to one in four children in this age group had a fever following vaccination with Moderna vaccine, with higher rates seen in those with a history of previous COVID-19.*

   Whilst fever in small children is a concerning occurrence, the Commonwealth's own immunisation handbook states that up to 15% of young children receiving MMR vaccine may develop a high fever. Indeed, every single vaccination currently listed on the childhood immunisation schedule has fever listed as a side effect and parents are conditioned to be cognisant of the risk of fever after vaccination. Can it be true that a slight increase in the rate of the transient risk of fever over other vaccines could outweigh all of the benefits gleaned from vaccination?

   That higher rates were seen in children with a history of COVID-19 suggests only that a child's infection history may have been a relevant consideration, and that vaccination decisions should have been a decision for a child's parents and doctors, based on their individual risk profile.

4. *There is insufficient evidence to suggest that vaccination of infants and children would impact community transmission.*

   Even if this is true, which is not established by the evidence, there is no reason that this should be a consideration. The health of children and the risk/benefit to them of receiving vaccination should have been the primary consideration. If this was not the case, one must question whether ATAGI's terms of reference were appropriate, in the public interest, and in line with Australia's obligations under Article 3 of the United Nations Convention on the Rights of the Child (UNCRC).

5. *ATAGI notes that there are currently constraints on the global availability and domestic supply of the Moderna vaccine for children aged 6 months to <5 years, which may persist until an alternative brand, variant-based or bivalent vaccines become available for this age group. Vaccine supply was one, among many, considerations in the ATAGI advice for this age group.*

   While this may have been the case in August 2022, it is not true that global supply has continued to be an issue some 16 months since these recommendations were made. Indeed, updated vaccines have since been developed and distributed, and yet our children are still waiting to be allowed access to any covid vaccine at all.

EVIDENCE FOR VACCINATING UNDER 5s

COVID-19 is a leading cause of death in children and young people. Covid causes *'substantially more deaths annually than any vaccine preventable disease historically in the recent period before vaccines became available'* and COVID-19 is the leading infectious cause of death in children and young people in the US.[8] Australia strongly recommends (and funds) the influenza vaccine for children under 5, yet Covid is thought to kill 10 times more people than influenza.

Kompaniyets L, Bull-Otterson L, Boehmer TK, et al. in a Morbidity and Mortality Weekly Report published by the US CDC, referenced the significant risk of post-covid related symptoms and conditions and stated that *"COVID-19 prevention strategies, including vaccination for all eligible persons aged ≥6 months, are critical to preventing SARS-CoV-2 infection and subseguent illness, and reducing the public health impact of post-COVID symptoms and conditions among persons aged 0–17 years".*[9]

ATAGI suggest that their main concern is the reduction in hospitalisation and severe disease, yet Rosa Duque, et al. found that the Pfizer (BNT162b2) paediatric vaccine provided substantial protection from COVID-19-associated hospitalization and moderate-to-severe disease due to a SARS-CoV-2 in paediatric populations that had low exposure to prior SARS-CoV-2 variants, with vaccine effectiveness of 93.1% after 2 doses analysed during the Omicron BA.2 wave in Hong Kong.[10]

A recent study showed that vaccine effectiveness of monovalent mRNA vaccines against confirmed infection during an Omicron XBB surge was 63.3% in fully vaccinated, infection-naive children and 74.6% against reinfections in previously

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[4] La Torre F, Taddio A, Conti C, Cattalini M. *Multi-Inflammatory Syndrome in Children (MIS-C) in 2023: Is It Time to Forget about It?* Children (Basel). June 2023, 10(6):980, https://doi.org/10.3390%2Fchildren10060980.

[5] Zambrano LD, et al, *Effectiveness of BNT162b2 (Pfizer-BioNTech) mRNA Vaccination Against Multisystem Inflammatory Syndrome in Children Among Persons Aged 12-18 Years - United States, July-December 2021.* MMWR Morb Mortal Wkly Rep. 2022 Jan 14;71(2):52-58, https://doi.org/10.15585%2Fmmwr.mm7102e1

[6] Nygaard U, Holm M, et al. *Incidence and clinical phenotype of multisystem inflammatory syndrome in children after infection with the SARS-CoV-2 delta variant by vaccination status: a Danish nationwide prospective cohort study.* Lancet Child Adolesc Health. 2022 Jul;6(7):459-465, https://doi.org/10.1016%2FS2352-4642(22)00100-6

[7] Yousaf AR, Cortese MM, et al. *Reported cases of multisystem inflammatory syndrome in children aged 12-20 years in the USA who received a COVID-19 vaccine, December 2020 through August 2021: a surveillance investigation.* Lancet Child Adolesc Health. 2022 May;6(5):303-312. https://doi.org/10.1016%2FS2352-4642(22)00028-1

[8] Flaxman, et al., *Assessment of COVID-19 as the Underlying Cause of Death Among Children and Young People Aged 0 to 19 Years in the US*, JAMA Netw Open. 2023;6(1):e2253590, https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2800816

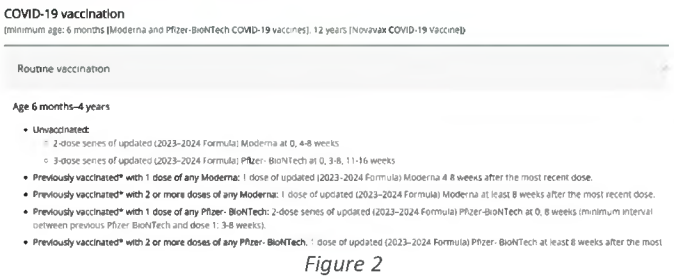
[9] Kompaniyets L, Bull-Otterson L, Boehmer TK, et al. *Post–COVID-19 Symptoms and Conditions Among Children and Adolescents — United States, March 1, 2020–January 31, 2022.* MMWR Morb Mortal Wkly Rep 2022; 71:993–999. DOI: http://dx.doi.org/10.15585/mmwr.mm7131a3

[10] Jaime S. Rosa Duque, Daniel Leung, Ka Man Yip, Derek H.L. Lee, Hung-kwan So, Wilfred H.S. Wong, Yu Lung Lau, Cell Reports Medicine 4, https://doi.org/10.1016/j.xcrm.2023.100936.

infected children with at least 1 vaccine dose.[11]

On 16 November 2023, the US CDC updated their Child and Adolescent Immunization Schedule to routinely include COVID-19 vaccinations (*Figure 2*).

There is clear benefit to vaccinating and regularly boosting all children over 6 months of age. The United States, Canada, Israel, China, Hong Kong, Cuba, Venezuela, Singapore, Ireland, Japan, Taiwan, Thailand and others vaccinate their children against COVID. Why have our children been denied the protection that covid vaccination would provide?


COVID-19 vaccination
(minimum age: 6 months [Moderna and Pfizer-BioNTech COVID-19 vaccines]; 12 years [Novavax COVID-19 Vaccine])

Routine vaccination

Age 6 months–4 years

- Unvaccinated:
  - 2-dose series of updated (2023–2024 Formula) Moderna at 0, 4–8 weeks
  - 3-dose series of updated (2023–2024 Formula) Pfizer-BioNTech at 0, 3–8, 11–16 weeks
- Previously vaccinated* with 1 dose of any Moderna: 1 dose of updated (2023–2024 Formula) Moderna 4 8 weeks after the most recent dose.
- Previously vaccinated* with 2 or more doses of any Moderna: 1 dose of updated (2023–2024 Formula) Moderna at least 8 weeks after the most recent dose.
- Previously vaccinated* with 1 dose of any Pfizer-BioNTech: 2-dose series of updated (2023–2024 Formula) Pfizer-BioNTech at 0, 8 weeks (minimum interval between previous Pfizer-BioNTech and dose 1: 3-8 weeks).
- Previously vaccinated* with 2 or more doses of any Pfizer-BioNTech: 1 dose of updated (2023–2024 Formula) Pfizer-BioNTech at least 8 weeks after the most

Figure 2

COMMENTARY

Whilst this is a necessarily brief summary of the available evidence, there is more than sufficient evidence to conclude:

1. The reasoning used by ATAGI's to deny vaccination to the 6 months to 5 years cohort was faulty, took into account irrelevant considerations, did not consider the best interests of the child, was not adequately updated as new information came to light, and does not explain why Australian children under 5 are, to this day, being denied access to vaccination when their peers overseas are regularly receiving updated vaccines and boosters.
2. There is no administrative review mechanism to challenge ATAGI's reasoning or decisions. As a ministerially appointed committee, they serve at the Minister's behest, on terms set by the Minister. Whilst the ability of the Minister to seek expert advice is sensible, an apolitical structure with full accountability is essential to ensure that errors and oversights can be identified and rectified. The children of Australia have suffered because of the faulty reasoning used by ATAGI to deny them access to safe and effective vaccines. The WHO database suggests that 16 children in the 0-4 year age group have died. Could timely access to vaccines have prevented any of those deaths?
3. If it could be said that the reasons cited by ATAGI for denying under 5's access to vaccines was a result of their restricted Terms of Reference, then this simply highlights that a political process where the Minister appoints a committee to provide an answer within a limited scope, is not an appropriate way to manage a pandemic of a novel pathogen. The vaccine approval and recommendation process must be completely apolitical, transparent, and accountable.
4. ATAGI's restriction of vaccines to children with certain conditions or based upon limited definitions of who is deemed to be 'at risk', placed Australian children and their families at unnecessary risk. The recommendations failed to take into account children's individual risk factors (e.g., not having had a prior covid infection, living with an immunocompromised, aged, or otherwise at-risk person). There should have been a procedure by which vaccination decisions could have been made by parents, in consultation with their child's treating doctors, based upon the individual child's best interests. Further, a policy which allows vaccination of a 5-year-old but denies protection to a 4 year 11-month-old discriminates on the basis of age.
5. ATAGI have not accurately represented the burden of severe disease, have misrepresented, downplayed and/or failed to consider the significant risk of post-Covid related symptoms and conditions (e.g., immune dysfunction, increased rate of diabetes, etc.) and failed to consider whether those risks may have been mitigated by vaccination.
6. Failure to make vaccines widely available has led to anti-vaccine sentiment as people began to doubt the safety and efficacy of the vaccines (e.g., if the vaccines worked, the government would recommend that we vaccinate our kids). There is some evidence that this sentiment is now extending to other childhood vaccines, which outcome was entirely foreseeable and preventable.
7. Communications to the Minister and his department were repeatedly answered with generic platitudes, failing to respond to the specific matters raised in the correspondence, and refusing to provide any useful information that would have allowed parents to make informed decisions for their children.
8. It is patently clear that the entire point of having the Minister appoint a committee to advise on these issues is so that that the committee can hide behind the terms of reference that the Minister gives them, and the Minister can hide behind the resultant recommendations of the committee so that, ultimately, no-one can be held accountable. This is unacceptable in an advanced democracy.
9. Given the clear evidence of the benefits of vaccination, ATAGI's refusal to allow under 5s to be vaccinated is incomprehensible. The stated reasons do not stand up to scrutiny. What logical rationale exists to deny vaccination to children under 5? One must wonder whether one possible implicit consideration on ATAGI's part, was that which was explicitly stated by JCVI in the UK, namely that, *"there is an argument for allowing the virus to circulate amongst children which could provide broader immunity to the children and boost immunity in adults"*.[12] Similar sentiments were expressed publicly by Prof Paul Kelly (*Insiders*, ABC, 15 March 2020) and Prime Minister Scott Morrison. This inquiry should seek to reassure parents that their children weren't, and aren't, being used as disease vectors to spread COVID-19 through the community in the futile and unethical pursuit of herd or hybrid immunity.
10. The Minister should immediately rectify these egregious errors by providing for a primary series of vaccines to be rolled out to all children under 5, and by permitting all children to be regularly boosted with the latest available vaccines. ATAGI, in its present form, should immediately be disbanded and replaced with a fully transparent, representative and accountable public body tasked with representing the best interests of Australian children, and the Australian public as a whole.

[11] Wee LE, Tang N, Pang D, et al. *Effectiveness of Monovalent mRNA Vaccines Against Omicron XBB Infection in Singaporean Children Younger Than 5 Years*. JAMA Pediatr. Published online October 16, 2023, https://doi.org/10.1001/jamapediatrics.2023.4505.

[12] Minutes of the JCVI COVID-19 Subcommittee, 11 May 2021, https://app.box.com/s/1lo4032vy09krs6cma1rcbf39vhht8mu/file/1312150185047.