ATTACHMENT 1 - Summary of Medical Literature

As addressed in paragraph 4 of our Feedback, to protect the public, the Department must discern the bias or conflicts of interest that any of its advisors may have should they withhold or fail to include the findings such as the following from their reports.

The following information is also relevant to considerations of the Directions, which we suggest are unfortunately no longer productive:

1. Where ATAGI's rapidly changing guidance is now for only one dose for a primary course and against the use of the allegedly defective[1] Vaxzevria (i.e. AstraZeneca Covid-19 vaccine) which was made mandatory at the time;

2. for one example, this year a recent study of Cleveland Clinic's active surveillance data of 40,000 healthcare workers in USA found

    a. "Risk of COVID-19 was lower among those previously infected with an XBB or more recent lineage, and **increased with the number of vaccine doses previously received";[2]**

3. one other example, an article by Queensland's Professor Emeritus of Immunology in the *Australian Journal of General Practice* very recently published in April 2024 shows autoimmune effects are likely and not yet fully understood:

    a. "Multiple studies have shown an increased risk of myocarditis after vaccination with mRNA encoding SARS-CoV-2 spike protein. mRNA vaccines can result in spike protein expression in muscle tissue, the lymphatic system, cardiomyocytes and other cells after entry into the circulation. ***Recipients of two or more injections of the mRNA vaccines display a class switch to IgG4 antibodies. Abnormally high levels of IgG4 might cause autoimmune diseases, promote cancer growth, autoimmune myocarditis and other IgG 4-related diseases (IgG4-RD) in susceptible individuals***." and

    b. "Understanding the persistence of viral mRNA and viral protein and their cellular pathological effects after vaccination with and without infection is clearly required. ***Because Covid-19 vaccines were approved without long-term safety data and might cause immune dysfunction,*** it is perhaps premature to assume that past SARS-CoV-2 infection is the sole common factor in long COVID."[3]

4. On 17 June 2024, a recent international collaboration of medical practitioners was published which tasked independent experts to review autopsy results from deaths following vaccination[4] and published the following results and discussions:

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[1] Dyer C. Patients launch legal action against AstraZeneca over its covid-19 vaccine BMJ 2023; 380 :p725 doi:10.1136/bmj.p725

[2] Nabin K Shrestha, Patrick C Burke, Amy S Nowacki, Steven M Gordon, Effectiveness of the 2023-2024 Formulation of the Coronavirus Disease 2019 mRNA Vaccine, Clinical Infectious Diseases, 2024;, ciae132, https://doi.org/10.1093/cid/ciae132.

[3] Tindle R. Long COVID: Sufferers can take heart. Aust J Gen Pract. 2024 Apr;53(4):238-240. doi: 10.31128/AJGP-07-23-6896. PMID: 38575546.

[4] Nicolas Hulscher, Paul E. Alexander, Richard Amerling, Heather Gessling, Roger Hodkinson, William Makis, Harvey A. Risch, Mark Trozzi, Peter A. McCullough, A Systematic REVIEW of Autopsy findings in deaths after covid-19 vaccination, Forensic Science International, 2024, 112115, ISSN 0379-0738, https://doi.org/10.1016/j.forsciint.2024.112115.

a. "We found that 73.9% of deaths were directly due to or significantly contributed to by COVID-19 vaccination."

b. "Our data suggest a high likelihood of a causal link between COVID-19 vaccination and death."

c. "These findings indicate the urgent need to elucidate the pathophysiologic mechanisms of death with the goal of risk stratification and avoidance of death for the large numbers of individuals who have taken or will receive one or more COVID-19 vaccines in the future."

5. A recent review in *British Medical Journal Public Health,*[5] after reviewing mortality rates, was unimpressed by the outcomes of COVID-19 countermeasures in countries that deployed measures like the Directions, concluding:

    a. "In conclusion, excess mortality has remained high in the Western World for three consecutive years, despite the implementation of COVID-19 containment measures and COVID-19 vaccines. This is unprecedented and raises serious concerns."

6. A recent study published in the *European Journal of Dermatology*[6] found an increased risk of a chronic autoimmune disease in the vaccinated compared to unvaccinated (despite exposure of SARS-CoV-2 to both groups)

    a. "... the incidence of vitiligo in the vaccination group was 2.22-fold higher than that in the non-vaccination group (adjusted HR [aHR]: 2.22; 95% confidence interval [CI]: 1.54-3.19)."

7. A recent study published in *Cardiovascular Pathology* and then on on 10 June 2024[7] found through forensic testing methods that otherwise undetectable and potentially fatal heart damage was the result of vaccine-induced inflammatory action, in discussion it stated:

    a. "Fibrin-rich thrombi were detected in the pericardium specimen"; and

    b. "The vaccination-induced inflammatory reaction could have led to the formation of a pericardial thrombus, which caused local circulatory disturbances and repeated cardiac tamponade."

8. A group of medical experts conducted forensic analysis of the Pfizer Covid-19 vaccine phase III trial data which was released via order of a Texan Court following extensive Freedom of Information litigation. They essentially allege fraud against the sponsor, as peer-reviewed and published in the *International Journal of Vaccine Theory, Practice, and Research* on 17 October 2023[8]:

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[5] Saskia Mostert, Marcel Hoogland, Minke Huibers, Gertjan Kaspers - Excess mortality across countries in the Western World since the COVID-19 pandemic: 'Our World in Data' estimates of January 2020 to December 2022: BMJ Public Health 2024;2:e000282.

[6] Kim JS, Jeong CY, Lee GJ, Yeom SW, Nam KH. Risk of vitiligo in patients with SARS-CoV-2 vaccination or infection: a nationwide cohort study. Eur J Dermatol. 2024 Apr 1;34(2):150-157. doi: 10.1684/ejd.2024.4646. PMID: 38907545.

[7] Ryo Kaimori, Haruto Nishida, Takaaki Yahiro, Takashi Miura, Takahiro Iwami, Tsutomu Daa, Recurrent cardiac tamponade following coronavirus disease 2019 mRNA vaccination: a case report, Cardiovascular Pathology, 2024, 107668, ISSN 1054-8807, https://doi.org/10.1016/j.carpath.2024.107668.

[8] Michels, Corinne & Perrier, Daniel & Kunadhasan, Jeyanthi & Clark, Ed & Gehrett, Joseph & Gehrett, Barbara & Kwiatek, Kim & Adams, Sarah & Chandler, Robert & Stagno, Leah & Damian, Tony & Delph, Erika & Flowers, Chris. (2023). Forensic analysis of the 38 subject deaths in the 6-Month Interim Report of the Pfizer/BioNTech BNT162b2 mRNA Vaccine Clinical Trial. International Journal of Vaccine Theory, Practice, and Research. 3. 973-1008. 10.56098/ijvtpr.v3i1.85.

a. “5. Of the 38 deaths reported in the 6-Month Interim Report of Adverse Events, 21 BNT162b2 vaccinated subjects died compared to 17 placebo subjects.

b. “6. Delayed reporting of the subject deaths into the Case Report Form, which was in violation of the trial protocol, allowed the EUA to proceed unchallenged.”

9. A group of independent medical practitioners re-assessed the aggregate trial data for the mandated Moderna and Pfizer Covid-19 vaccinations as listed on the National Institute of Health’s National Library of Medicine (i.e. USA’s clinicaltrials.gov) and published that the increase of Adverse Events of Special Interest in the vaccinated group was greater than the reduction of adverse outcomes. This finding was peer reviewed and published on 1 August 2022 in the prestigious and mostly impartial journal *Vaccine*[9] with key excerpts that follow:

    a. "In the Moderna trial, the excess risk of serious AESIs (15.1 per 10,000 participants) was higher than the risk reduction for COVID-19 hospitalization relative to the placebo group (6.4 per 10,000 participants). [3] In the Pfizer trial, the excess risk of serious AESIs (10.1 per 10,000) was higher than the risk reduction for COVID-19 hospitalization relative to the placebo group (2.3 per 10,000 participants)."; also

    b. "Rational policy formation should consider potential harms alongside potential benefits. [29] To illustrate this need in the present context, we conducted a simple harm-benefit comparison using the trial data comparing excess risk of serious AESI against reductions in COVID-19 hospitalization. We found excess risk of serious AESIs to exceed the reduction in COVID-19 hospitalizations in both Pfizer and Moderna trials."

10. A publication in *Scientific Reports* as corrected on 20 January 2023[10] published the an early peer-reviewed indication of an adverse and counter-intuitive auto-immune phenomenon referred to as Antibody Dependent Enhancement (ADE) in some highly vaccinated sera over time, specifically:

    a. “Although sera collected from mRNA-vaccinated individuals exhibited neutralizing activity, some sera gradually exhibited dominance of ADE activity in a time-dependent manner. None of the sera examined exhibited neutralizing activity against infection with the Omicron strain. Rather, some ADE of Omicron infection was observed in some sera.”

11. An earlier study conducted on around 40,000 Cleveland Clinic healthcare workers found a concerning association between the number of doses a healthcare worker had received and their risk of contracting COVID-19. Published in *Open Forum of Infectious Diseases* on 19 April 2023 after 7 months of peer-review,[11] excerpts include:

    a. “This is not the only study to find a possible association with more prior vaccine doses and higher risk of COVID-19.”

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[9] Joseph Fraiman, Juan Erviti, Mark Jones, Sander Greenland, Patrick Whelan, Robert M. Kaplan, Peter Doshi, Serious adverse events of special interest following mRNA COVID-19 vaccination in randomized trials in adults, Vaccine, Volume 40, Issue 40, 2022, Pages 5798-5805, ISSN 0264-410X, https://doi.org/10.1016/j.vaccine.2022.08.036.

[10] Shimizu, J., Sasaki, T., Koketsu, R. et al. Reevaluation of antibody-dependent enhancement of infection in anti-SARS-CoV-2 therapeutic antibodies and mRNA-vaccine antisera using FcR- and ACE2-positive cells. Sci Rep 12, 15612 (2022). https://doi.org/10.1038/s41598-022-19993-w.

[11] Shrestha NK, Burke PC, Nowacki AS, Simon JF, Hagen A, Gordon SM. Effectiveness of the Coronavirus Disease 2019 Bivalent Vaccine. Open Forum Infect Dis. 2023 Apr 19;10(6):ofad209. doi: 10.1093/ofid/ofad209. PMID: 37274183; PMCID: PMC10234376.

b. “We still have a lot to learn about protection from COVID-19 vaccination, and in addition to a vaccine’s effectiveness it is important to examine whether multiple vaccine doses given over time may not be having the beneficial effect that is generally assumed.”

c. “The risk of COVID-19 also increased with time since the most recent prior COVID-19 episode and with the number of vaccine doses previously received.”

12. The study team that published the negative correlation referenced above later controlled for propensity to test as published in November 8 2023 in *PLOS ONE*[12] and found the same concerning negative correlation; when assessing data on infection rates amongst active healthcare workers. It’s results are summarised in abstract:

    a. “COVID-19 occurred in 1475 (3%) of 48 344 employees during the 100-day study period. The cumulative incidence of COVID-19 was lower in the “not up-to-date” than the “up-to-date” state. On multivariable analysis, being “up-to-date” was not associated with lower risk of COVID-19 (HR, 1.05; 95% C.I., 0.88–1.25; P-value, 0.58). Results were very similar when those 65 years and older were only considered “up-to-date” after 2 doses of the bivalent vaccine.”

13. Increased IgG4 antibody responses have been associated with “immune down-regulation” or “immune tolerance” because IgG4 antibodies are generally defined in biological and immunology glossaries as anti-inflammatory and non-neutralising and often associated with allergens, not viruses. The association between vaccination doses and increases IgG4 antibody responses was published, at the latest, in peer-reviewed medical literature on 22 December 2022 in *Science Immunology* and discovered:[13]

    a. “To explore whether the rise in IgG4 antibody levels was specific for the homologous mRNA vaccination regimen used, we analyzed sera from an independent cohort (26, 27), in which we compared the immunogenicity of homologous and heterologous vaccination regimens with Comirnaty and the adenoviral vector-based vaccine ChAdOx1 (AZD1222, Vaxzevria) (see Table S1). Five to six months after the second immunization, spike-specific IgG4 antibodies were again detectable in half of the sera of the BNT-BNT cohort, but only in one of the 51 sera from the two other vaccine cohorts (Fig. S2)."

    b. “This class switch was associated with a reduced capacity of the spike-specific antibodies to mediate antibody-dependent cellular phagocytosis and complement deposition. Because Fc-mediated effector functions are critical for antiviral immunity, these findings may have consequences for the choice and timing of vaccination regimens using mRNA vaccines, including future booster immunizations against SARS-CoV-2.”

14. Also a research article originally peer-reviewed and published in the American Heart Association journal *Circulation* on 4 January 2023 discovered full-length vaccine induced spike protein in the cardiomyocytes (heart cells) of a child suffering from myocarditis, summarising the following:

[12] Shrestha NK, Burke PC, Nowacki AS, Gordon SM (2023) Risk of Coronavirus Disease 2019 (COVID-19) among those up-to-date and not up-to-date on COVID-19 vaccination by US CDC criteria. PLOS ONE 18(11): e0293449. https://doi.org/10.1371/journal.pone.0293449

[13] Pascal Irrgang et al. ,Class switch toward noninflammatory, spike-specific IgG4 antibodies after repeated SARS-CoV-2 mRNA vaccination.Sci. Immunol.8,eade2798(2023).DOI:10.1126/sciimmunol.ade2798

a. “Cases of adolescents and young adults developing myocarditis after vaccination with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)–targeted mRNA vaccines have been reported globally, but the underlying immunoprofiles of these individuals have not been described in detail.”

b. “A notable finding was that markedly elevated levels of full-length spike protein (33.9±22.4 pg/mL), unbound by antibodies, were detected in the plasma of individuals with postvaccine myocarditis, whereas no free spike was detected in asymptomatic vaccinated control subjects (unpaired t test; P<0.0001).”

15. A large and highly funded assessment of data from the Global COVID Vaccine Safety Project assessed around a dozen Adverse Events of Special Interests using passive surveillance data and found statistically significant increases up to 1100% in cardiac tissues for vaccinated over expected for some groups in some regions (according to supplementary data of the Victoria, Australia reporting system). The article was published in the journal *Vaccine* on 2 April 2024,[14] and although limited by only assessing around a dozen adverse events, from the thousands of Adverse Events of Special Interest that ought be monitored, it summaried:

    a. “OE ratios with LBCI > 1.5 were observed for Guillain-Barré syndrome (2.49, 95 % CI: 2.15, 2.87) and cerebral venous sinus thrombosis (3.23, 95 % CI: 2.51, 4.09) following the first dose of ChAdOx1 vaccine. Acute disseminated encephalomyelitis showed an OE ratio of 3.78 (95 % CI: 1.52, 7.78) following the first dose of mRNA-1273 vaccine. The OE ratios for myocarditis and pericarditis following BNT162b2, mRNA-1273, and ChAdOx1 were significantly increased with LBCIs > 1.5.”

    b. “Potential underreporting across countries may have led to an underestimation of the significance of potential safety signals.”

16. Another relatively recent peer-reviewed publication dated 28 February 2024 and published in the journal *Frontiers in Immunology*[15] which informs concerns regarding IgG4 class-switching, publishing:

    a. “Of special relevance to our data (Supplementary Figure 1), Piotr Rzymski et al. reported that (9) among subgroups of Vax hospitalized patients (representing 1% of all hospitalized), mortality rates increased with additional vaccine doses and increased post-vaccination time (although deceased Vax patients represented only 0.2% of all hospitalized patients and 1% of all deceased individuals in the studied period).”

    b. “...in COVID-19 patients mortality rates were 37% (NVax, n=89) and 70% (Vax, n=23). Among COVID-19 patients, mortality rate was significantly higher among Vax vs. NVax patients (p=0.002). The Charlson’s Comorbidity Index score (CCI) was also significantly higher among Vax vs. NVax COVID-19 patients. However, the mortality risk remained significantly higher (p=0.02) when we compared COVID-19 Vax vs. NVax patients with similar CCI score, suggesting that additional factors may increase risk of mortality. Higher levels of SARS-CoV-2 Abs were noted among survivors,

[14] K. Faksova, D. Walsh, Y. Jiang, J. Griffin, A. Phillips, A. Gentile, J.C. Kwong, K. Macartney, M. Naus, Z. Grange, S. Escolano, G. Sepulveda, A. Shetty, A. Pillsbury, C. Sullivan, Z. Naveed, N.Z. Janjua, N. Giglio, J. Perälä, S. Nasreen, H. Gidding, P. Hovi, T. Vo, F. Cui, L. Deng, L. Cullen, M. Artama, H. Lu, H.J. Clothier, K. Batty, J. Paynter, H. Petousis-Harris, J. Buttery, S. Black, A. Hviid, COVID-19 vaccines and adverse events of special interest: A multinational Global Vaccine Data Network (GVDN) cohort study of 99 million vaccinated individuals, Vaccine, Volume 42, Issue 9, 2024, Pages 2200-2211, ISSN 0264-410X, https://doi.org/10.1016/j.vaccine.2024.01.100.

[15] Adhikari B, Bednash JS, Horowitz JC, Rubinstein MP and Vlasova AN (2024) Front. Immunol. 15:1325243. doi: 10.3389/fimmu.2024.1325243.

suggestive of their protective role. We observed a trend for increased total IgG4 Ab, which promotes immune tolerance, in the Vax vs. NVax patients in week 3."

17. A concerning recent pre-print[16] by a senior German mathematician and his behavioural science colleague conducted an assessment of excess mortality against vaccination rate of regions within their country, and published the following results from their assessment:

    a. "Regarding the increase in excess mortality, an increasingly strong positive correlation with the vaccination rate of a federal state is observed, which reaches a value of r = 0.85 in the third pandemic year, indicating that excess mortality increased the stronger the higher the vaccination rate in a federal state was. An analysis of stillbirths showed exactly the same pattern. No other systematic correlation pattern was observed."

18. A very recent peer-reviewed publication on 30 June 2024 in the journal *Microorganisms*[17] corroborates the findings of the German scientists by assessing Italian mortality data against vaccination status to measure loss of life-expectancy based on vaccination status, with unavoidable limitations, the authorised published the following abstract, discussion, and conclusion:

    a. "With 2 and even with 3/4 doses, the calculated Restricted Mean Survival Time and Restricted Mean Time Lost have shown a small but significant downside for the vaccinated populations."

    b. "We found all-cause death risks to be even higher for those vaccinated with one and two doses compared to the unvaccinated and that the booster doses were ineffective. We also found a slight but statistically significant loss of life expectancy for those vaccinated with 2 or 3/4 doses."

    c. "Further studies are certainly needed. However, despite the limitations described above, the results of this study can be an opportunity to rethink political choices about pandemic management and support greater caution in the future."

19. Australian medical practitioners conducted a narrative review of primary literature relevant to the effect of spike-protein on human health, whether from vaccination or virus, which was peer-reviewed and published on 17 August 2023 in the journal *Biomedicines*.[18] Summaries in abstract, the study is sceptical and critical of the benefits purported by the respondents to inform or justify their actions:

    a. "Spike protein pathogenicity, termed 'spikeopathy', whether from the SARS-CoV-2 virus or produced by vaccine gene codes, akin to a 'synthetic virus', is increasingly understood in Directions of molecular biology and pathophysiology. Pharmacokinetic transfection through body tissues distant from the injection site by lipid-nanoparticles or viral-vector carriers means that 'spikeopathy" can affect many organs. The inflammatory properties of the nanoparticles used to ferry mRNA; N1-methylpseudouridine employed to prolong synthetic mRNA function; the widespread biodistribution of the mRNA and DNA codes and translated spike

[16] Kuhbandner, Christof & Reitzner, Matthias. (2024). Differential Increases in Excess Mortality in the German Federal States During the COVID-19 Pandemic. 10.13140/RG.2.2.13098.18880.
[17] Alessandria, M.; Malatesta, G.M.; Berrino, F.; Donzelli, A. A Critical Analysis of All-Cause Deaths during COVID-19 Vaccination in an Italian Province. Microorganisms 2024, 12, 1343. https://doi.org/10.3390/microorganisms1207134.
[18] Parry PI, Lefringhausen A, Turni C, Neil CJ, Cosford R, Hudson NJ, Gillespie J. 'Spikeopathy': COVID-19 Spike Protein Is Pathogenic, from Both Virus and Vaccine mRNA. Biomedicines. 2023 Aug 17;11(8):2287. doi: 10.3390/biomedicines11082287. PMID: 37626783; PMCID: PMC10452662.

proteins, and autoimmunity via human production of foreign proteins, contribute to harmful effects."

20. A recent study published in November 2023 in *International Journal of Infectious Diseases*[19] found via an active surveillance study that vaccination did not reduce the risk of Post-Covid19 Conditions (PCC) also known as long covid. It actually found a slightly higher incidence of PCC. As abstracted and in discussion:

    a. "Among those infected with a specific variant, the number of preceding vaccinations was not associated with a risk reduction for PCC, whereas previous infection was strongly associated with a lower PCC risk (aOR 0.14, 95% CI 0.07; 0.25)."

    b. "In conclusion, while the Omicron variant was associated with a much lower risk of PCC in our study, the lack of protection by vaccination regarding the occurrence and symptom severity of PCC (in case of an infection) suggest that this condition can become a serious challenge for the health care system during the early endemic phase of SARS-CoV-2"

21. A convenience survey by a Queensland psychiatrist and a Queensland perfusionist published results and discussion in the *Journal of Psychiatry and Psychiatric Disorders* on 31 January 2024 and found significant impacts upon those unable to provide Valid Consent to COVID-19 vaccination, and discussed the following:

    a. "Educated HCW who chose not to take a Covid-19 vaccine, for whatever reason, were sadly lumped together and labelled "vaccine hesitant" or "anti-vaxxers", a derogatory term that insinuates a lack of scientific reason [20, 21]. The cost of non-compliance for them was either prolonged suspension without remuneration or termination. Given the collection of evidence that indicates these vaccines are neither effective at prevention of infection or transmission [22, 23], nor safe, with levels of harm greater than all previous vaccines [9, 24], it seems the mandates have been disproportionately costly for non-compliant individuals and caused significant inequality between the compliant and the non-compliant."

    b. "The reality was that across the state of Queensland, out of the 2,013 exemption applications, only one permanent exemption approval was given (disclosed RTI [12]) and the bar was clearly set very high even for temporary exemptions. Data from this survey indicated that while 324 individuals (87.8%) applied for an exemption, no permanent exemptions were given (despite recommendations against vaccination from medical specialists for at least 51 of these individuals) or having supporting letters from religious leaders."

    c. "The economic and psychosocial devastation of individuals who exercised their medical freedom to not comply with this government vaccine mandate could ultimately have intergenerational consequences beyond those revealed in this study and will certainly be of interest to the world of psychology for years to come."

[19] Sophie Diexer, Bianca Klee, Cornelia Gottschick, Chao Xu, Anja Broda, Oliver Purschke, Mascha Binder, Thomas Frese, Matthias Girndt, Jessica I. Hoell, Irene Moor, Michael Gekle, Rafael Mikolajczyk, Association between virus variants, vaccination, previous infections, and post-COVID-19 risk, International Journal of Infectious Diseases, Volume 136, 2023, Pages 14-21, ISSN 1201-9712, https://doi.org/10.1016/j.ijid.2023.08.019.

22. A recent study published on 22 May 2024 in *Frontiers in Pharmacoepidemiology*[20] found tinnitus was likely a symptom of post-vaccination metabolic disorders:

    a. "First, the frequency of tinnitus reports in the VAERS database is higher for COVID-19 than for other vaccines. Second, the frequency of tinnitus reports was higher for the first than the second dose for the 2-dose vaccines, which would not be expected if the tinnitus and the vaccination were independent. Third, for the 2-dose vaccines, the survey respondents who developed tinnitus after the first does had 50% chance of worsening tinnitus symptoms after the second dose, which is much higher than the frequency of tinnitus for the general population. Fourth, the tinnitus onset was sharply time-locked to the vaccination, with nearly half of the cases occurring within 2 days of the vaccination."

    b. “These findings suggest that COVID-19 vaccination increases the risk of tinnitus ..."

23. On 21 September 2022 two Queenslander scientists, one a veterinarian (like the former head of the TGA, Prof Skerrit) and another a PhD microbiologist published a brief Australian Review of COVID-19 vaccines that was scathing, specifically stating:

    a. “The mRNA vaccines were supposed to remain at the injection site and be taken up by the lymphatic system. This assumption proved to be wrong. During an autopsy of a vaccinated person that had died after mRNA vaccination it was found that the vaccine disperses rapidly from the injection site and can be found in nearly all parts of the body [1].”

    b. “Multiple recent studies have indicated that the vaccinated are more likely to be infected with Omicron than the unvaccinated. A study by Kirsch (2021) from Denmark suggests that people who received the mRNA vaccines are up to eight times more likely to develop Omicron than those who did not [40]. This and a later study by Kirsch (2022a) conclude that the more one vaccinates, the more one becomes susceptible to COVID-19 infection [41].”

    c. “According to Kostoff [52] the number of deaths attributable to each inoculation is five times higher in the most vulnerable 65+ demographic than deaths attributable to COVID–19. With decreasing age, the risk of death from COVID-19 decreases drastically. Combined with the longer-term effects of the inoculations, most of which are still unknown, this increases the risk-benefit ratio, perhaps substantially, in the lower age groups.”

    d. “COVID-19 vaccines cause more side effects than any other vaccine, a fact that is attributed to its interactions with the immune system. Not only does spike protein produce unwanted side effects, but mRNA and nanoparticles do as well. Seneff et al [15] enumerated Covid-19 vaccine effects on the innate immune system, importantly a decrease of type I interferon signalling, as well as disturbances in the regulation of protein synthesis affecting the formation of immune cells and the apoptosis of tumor cells.”

[20] Wang Weihua , Yellamsetty Anusha , Edmonds Robert M. , Barcavage Shaun R. , Bao Shaowen, COVID-19 vaccination-related tinnitus is associated with pre-vaccination metabolic disorders, Frontiers in Pharmacology, 15, 2024, 10.3389/fphar.2024.1374320, ISSN:1663-9812.

24. FOI 2389-06 from the Australian Government published the submission of Pfizer Australia Pty Ltd dated January 2021[21] is a copy of the information relied on for provisional approval of the mandatory COVID-19 vaccines. It showed a significant lack of safety testing and did not outline a cogent basis for any authority to claim it would stop transmission, see for example excerpt from page

    a. "**Genotoxicity**
    No genotoxicity studies were conducted for the vaccine. This is in line with relevant guidelines for vaccines. There were also no genotoxicity studies with the novel excipients. The sponsor stated that the novel lipid excipients are not expected to be genotoxic based on in silico analysis (Derek Nexus 6.1.0, Derek Knowledgebase 2020 version 1.0 and Sarah Nexus 3.1.0, Sarah Model 2020.1 Version 1.8) of the novel lipids and their primary metabolites (reports not provided)."

    b. "**Carcinogenicity**
    Carcinogenicity studies were not conducted. This is acceptable based on its duration of use. The novel lipid excipients are not expected to be carcinogenic based on the low exposure, duration of exposure, absence of structure alerts for mutagenicity (see discussion above)."

    c. "**Immunotoxicity**
    No dedicated immunotoxicity study was conducted. An in vitro study on stimulation of cytokine release in human PBMC cells provided inconclusive results. As expected, immune-stimulatory effects were observed in pharmacology and repeat dose toxicity studies. No vaccine-related systemic intolerance or mortality was observed in the studies."

    d. TGA here relied on antibodies to justify provisional approval, but at the same time cited research regarding SARS-CoV which recognised the necessity of T Cell immune responses, such as a publication in September 2010 in the *Journal of Virology* which stated:[22]

        i. "We demonstrated that T cells are responsible for virus clearance, as intravenous adoptive transfer of SARS-CoV-immune splenocytes or in vitro-generated T cells to SCID or BALB/c mice enhanced survival and reduced virus titers in the lung."

25. Following a series of case studies showing vaccinal spike protein in the brain of people who suffered neurological symptoms or encephalitis post-vaccine, a team of Korean scientists looked into whether the COVID-19 vaccines (as mandated) contributed to neurological conditions, including Alzheimer's Disease. A study was published on 28 May 2024 in the *QJM: An International Journal of Medicine*:[23]

    a. "The mRNA vaccine group exhibited a significantly higher incidence of AD (Odds Ratio [OR]: 1.225; 95% Confidence Interval [CI]: 1.025-1.464; $p = 0.026$) and MCI (OR: 2.377; CI: 1.845-3.064; $p < 0.001$) compared to the unvaccinated group."

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[21] Nonclinical Evaluation Report, BNT162b2 [mRNA] COVID-19 vaccine (COMIRNATYTM), Submission No: PM-2020-05461-1-2 Sponsor: Pfizer Australia Pty Ltd, January 2021, Therapeutic Goods Administration - Department of Health of Commonwealth of Australia <https://www.tga.gov.au/sites/default/files/foi-2389-06.pdf>.

[22] Zhao J., Zhao J. & Perlman S. (2010) T cell responses are required for protection from clinical disease and for virus clearance in severe acute respiratory syndrome coronavirus-infected mice. J. Virol. 84: 9318–9325.

[23] Jee Hoon Roh, Inha Jung, Yunsun Suh, Min-Ho Kim, A potential association between COVID-19 vaccination and development of alzheimer's disease, QJM: An International Journal of Medicine, 2024;, hcae103, https://doi.org/10.1093/qjmed/hcae103.

b. “Preliminary evidence suggests a potential link between COVID-19 vaccination, particularly mRNA vaccines, and increased incidences of AD and MCI. This underscores the need for further research to elucidate the relationship between vaccine-induced immune responses and neurodegenerative processes, advocating for continuous monitoring and investigation into the vaccines' long-term neurological impacts.”

26. There are thousands of scientific publications, however a searchable compilation has been created by the React 19 organisation: https://react19.org/science.

If the above literature surprises the Department, we recommend that the Department ask their advisors to show cause as to why the above literature may have been excluded from advice.