



**Senator GERARD RENNICK**  
LNP Senator for Queensland

Questions on Notice to the Federal Department of Health by Senator Gerard Rennick (Senate Estimates 2021).

Question	Date Submitted	Answer	Date Answered	PDR Number	Notes
Why can't rapid testing be used at aged care centres, hospitals etc. for entering workers to try and reduce outbreaks of COVID-19?	6/08/2021	On 9 October 2020, the Public Health Laboratory Network (PHLN) and the Communicable Diseases Network Australia (CDNA) (expert standing committees of the Australian Health Protection Principal Committee) published a joint statement on the use of rapid antigen tests. The Statement notes that rapid antigen tests may have a role as a screening test for COVID-19 in certain contexts and settings, to be determined by jurisdictional public health authorities. Importantly, the use of rapid antigen tests would be complementary to, and not a replacement for, RT-PCR testing. Their use must also be considered in line with the Testing Framework for COVID-19 in Australia, which describes the epidemiological contexts in which rapid antigen tests may be appropriate for use. Some industry groups are in discussion with states and territories and the Commonwealth to determine whether rapid antigen tests have a role in detecting presumptive COVID-19 cases, when used in conjunction with PCR tests and other public health measures, in certain high risk settings. The role of the Commonwealth Government is to approve rapid antigen tests for supply in Australia through the Therapeutic Goods Administration. PHLN and CDNA, advice is provided on appropriate use.	8/11/2021	SQ21-000591	SQ21-000591
Was it wise for the Labor Opposition to compromise safety by putting pressure on the TGA to roll out the vaccine before the TGA approved it?	6/08/2021	The TGA acts independently at all times in order to fulfil its mandate of stringently assessing the safety and efficacy of medicines.	20/07/2021	SQ21-000599	SQ21-000599

<p>Given Swine Flu had a median death rate of 48 and Covid has a median death rate of around 80 plus, why are governments reacting differently now to how they reacted to Swine Flu in 2009 regarding lockdowns, quarantining and vaccinations?</p>	<p>6/08/2021</p>	<p>Swine flu (H1N1) was a novel influenza A and COVID-19 is a novel coronavirus. These are two very different types of viruses and have distinct viral characteristics, necessitating different responses to protect the Australian population.</p> <p>The H1N1 virus associated with the 2009 'Swine flu' pandemic was less transmissible, associated with milder disease, and had a lower case fatality rate, with an estimated 284,000 (151,700 – 575,400) total deaths worldwide during the first 12 months of virus circulation in each country. Conversely, SARS-CoV-2 has a higher case fatality rate, and is associated with more severe disease (particularly in older populations). As at 15 June 2021, there have been over 3.8 million deaths from COVID-19 worldwide, with an estimated two million deaths occurring within the first 12 months.</p> <p>As the 2009 H1N1 'Swine Flu' pandemic was the second known H1N1 pandemic in history (the first being the 1918 Spanish flu), there was at least some population immunity in certain population cohorts (those &gt;60 years old) that protected against severe disease. This is why, unlike seasonal influenza, the 2009 H1N1 pandemic primarily affected younger population groups.</p> <p>As the 2009 H1N1 pandemic was caused by an influenza virus, there were known pharmacological options for management (namely anti-viral medications) which reduced length of hospital stay, and reduced the risk of progression to severe disease.</p> <p>Vaccine development processes were already established, allowing a vaccine to be very quickly developed. Mass vaccination</p>	<p>23/09/2021</p>	<p>SQ21-000603</p>	<p>SQ21-000603</p>
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<p>Should deaths when people had comorbidities be counted as COVID-19 deaths or comorbidities? I note the Health Department in my prior QoN quoted 91% of people who died from COVID-19 in ICU had comorbidities and a median age of 86.</p>	<p>6/08/2021</p>	<p>The COVID-19 Communicable Diseases Network Australia (CDNA) Series of National Guidelines for Public Health Units states that a COVID-19 death is defined for surveillance purposes as a death in a probable or confirmed COVID-19 case, unless there is a clear alternative cause of death that cannot be related to COVID-19 (e.g. trauma). There should be no period of complete recovery from COVID-19 between illness and death. Where a coroner's report is available, these findings are to be observed. For example, if a person is acutely experiencing a COVID-19 infection and during this time they suffer a heart attack and suddenly die, then their death would be reported as a COVID-19 death if it is determined that the COVID-19 infection triggered the heart attack. Attributing the acute cause of death in the context of underlying comorbid chronic conditions is determined clinically on a case by case basis and if someone is experiencing an acute COVID-19 infection that exacerbates an underlying medical condition, then it would still be reported as a COVID-19 death as the COVID-19 infection was the immediate cause of their death despite underlying conditions. Usually on the death certificate there is space to list underlying conditions a person had in the time period in the lead up to their death. There are a number of checks and balances at a medical professional level when signing death certificates. Doctors are professionally trained to attribute death especially in circumstances where there is no ambiguity as to why someone has died based on their clinical history. In the event there is significant doubt around the cause of death, and,</p>	<p>8/11/2021</p>	<p>SQ21-000605</p>	<p>SQ21-000605</p>
<p>Does mask prevention depend on the quality of mask? If so, which masks should or should not be used?</p>	<p>6/08/2021</p>	<p>The Infection Control Expert Group (ICEG) provides advice on the type of mask to be worn in certain circumstances. Advice for on the use of personal protective equipment (PPE) for health care workers in the context of COVID-19 has recently been updated and is available on the Department of Health's website. PPE is a critical part of infection prevention and control. However, it should be considered as the last line of defence within a broader 'Hierarchy of Controls' framework. This includes implementing measures to minimise the risk of the virus spreading, for instance isolating cases and ensuring workplace practices are COVID-safe. Non-sterile face masks (including respirators) that are intended, by their manufacturer, to prevent the transmission of diseases between people, or are intended to be used in a healthcare environment, are medical devices. Masks identified as medical devices are regulated by the Therapeutic Goods Administration (TGA) under the Therapeutic Goods Act 1989.</p>	<p>23/07/2021</p>	<p>SQ21-000606</p>	<p>SQ21-000606</p>

<p>Has the Australian Red Cross taken serology tests on blood taken in Q4 2019 to determine if Covid was in the community at that time?</p>	<p>6/08/2021</p>	<p>The Australian Red Cross Lifeblood has been an active participant in national and targeted sero-surveys of population immunity to SARS-COV2 to inform clinical and public health responses. These seroprevalence surveys are undertaken by the Australian Partnership for Preparedness Research on Infectious Disease Emergencies (APPRISE), which is funded by the National Health and Medical Research Council, and for the national survey funding was also provided by the Department of Health (Health). These serosurveys have used donated blood collected during the first phase of the pandemic (up to August, 2020). It is understood these surveys have not tested donor blood samples from quarter 4 of the 2019 calendar year. However, the Australian Red Cross Lifeblood has advised that it has retrieved and stored about 2,000 specimens from donors who donated during this period in case such testing is required. Results from the Sydney survey were published in the Medical Journal of Australia? and with analyses from the national serosurvey being finalised. Serosurveillance is one of the key surveillance approaches adopted as part of the Australian National Disease Surveillance Plan for COVID-19, which has been endorsed by the Communicable Diseases Network Australia, with the objective of understanding population level protection. As part of the national serosurvey, Health has sought advice from APPRISE regarding future serosurvey options, including identification of the most suitable SARS -CoV-2-specific antibody test, and is currently considering future serosurveys requirements.</p>	<p>23/07/2021</p>	<p>SQ21-000607</p>	<p>SQ21-000607</p>
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What percentage of the population need to be vaccinated before state governments stop closing borders and locking down residents? i.e. what percentage would achieve herd immunity?	6/08/2021	There is no set percentage at which herd immunity is achieved. Even at relatively high vaccination rates, modelling has shown that herd immunity may not be achieved against more transmissible variants of COVID-19. However, modelling has shown that increasing vaccination, coupled with intermittent public health measures can effectively reduce the spread of COVID-19. States and territories continue to have primary operational responsibility for public health and emergency response measures within their respective jurisdictions, such as lockdowns and border restrictions, under their public health legislation. On 6 August 2021, National Cabinet agreed to a four-step National Plan to transition Australia's COVID-19 response. The National Plan provides a graduated pathway to transition Australia's COVID-19 response from its current pre-vaccination settings focused on continued suppression of community transmission, to post-vaccination settings focused on public health management of COVID-19, consistent with other infectious diseases. The National Plan will move between phases once Australia reaches key vaccination thresholds – moving to Phase B once 70 per cent of the Australian population 16 years of age and older is fully vaccinated and Phase C once 80 per cent of the population is fully vaccinated.	9/06/2021	SQ21-000608	SQ21-000608
What is the normal number of trials a drug or vaccine have to go through before being approved for use? i.e. Phase 1 trials, Phase 2 etc.	6/08/2021	Before a drug or vaccine is registered for use, it is tested extensively during its development and then in thousands of individuals via clinical trials. For instance, tens of thousands of individuals participated in the Phase II/III and Phase III clinical trials for the AstraZeneca and Pfizer COVID-19 vaccines: o AstraZeneca: two phase III clinical trials submitted to the Therapeutic Goods Administration (TGA) for evaluation followed approximately 10,300 and 12,390 participants respectively (see: <a href="http://www.tga.gov.au/auspar/auspar-chadox1-s">www.tga.gov.au/auspar/auspar-chadox1-s</a> ). o Pfizer: the phase II/III clinical trial submitted to the TGA for evaluation followed 44,000 participants (see: <a href="http://www.tga.gov.au/auspar/auspar-bnt162b2-mrna">www.tga.gov.au/auspar/auspar-bnt162b2-mrna</a> )	24/08/2021	SQ21-000609	SQ21-000609
Has the AstraZeneca or Pfizer vaccines gone through the standard testing or have they been fast tracked?	6/08/2021	(see next answer)	24/08/2021	SQ21-000610	SQ21-000610
If fast tracked, what testing was avoided?	6/08/2021	(see next answer)	24/08/2021	SQ21-000610	SQ21-000610

When did testing on these vaccines begin and how many trials were undertaken?	6/08/2021	<ul style="list-style-type: none"> <li>• The Therapeutic Goods Administration (TGA) is responsible for assessing all vaccines (including those being developed for COVID-19) before they can be used in Australia, and vaccines are only registered if the benefits greatly outweigh the risks.</li> <li>• The AstraZeneca and Pfizer COVID-19 vaccines have been fully scrutinised by the TGA in accordance with all ordinary processes to ensure compliance with strict standards of safety, quality and efficacy.</li> <li>• COVID-19 vaccine applications are being treated with the greatest priority so resources were redirected to their evaluation and testing as quickly as possible without any compromise to the process.</li> <li>• COVID-19 vaccines are being assessed under the 'provisional approval' pathway.</li> <li>• To receive provisional registration, the TGA must establish the safety and efficacy of the vaccine based on preliminary clinical data. This includes demonstrating that the benefit of early availability of the vaccine outweighs any inherent risks associated with the fact that additional data is still required.</li> <li>• The TGA has made a full and thorough assessment of the data which includes clinical studies, non-clinical and toxicology studies, as well as chemistry, and manufacturing information for the Pfizer and AstraZeneca COVID-19 vaccines.</li> <li>• The clinical trials conducted for the AstraZeneca and Pfizer COVID-19 vaccines and independently assessed by the TGA are given in the publicly available Product Information (PI) on the</li> </ul>	24/08/2021	SQ21-000610	SQ21-000610
The Pfizer vaccine is a mRNA vaccine that delivers a genetic code to produce a spike protein and the AstraZeneca vaccine is a recombinant vaccine that puts the code for the spike protein into a complete different virus, both with the aim of stimulating an immune response. Is this correct?	6/08/2021	(see next answer)	8/11/2021	SQ21-000611	SQ21-000611
How long have these methods been used for therapeutic purposes?	6/08/2021	<p>For COVID-19, there are four main categories of vaccines in clinical trials: whole virus, protein subunit, viral vector and nucleic acid (e.g., mRNA). Each type of vaccine is designed to teach the body's immune system to safely recognise and block the virus which causes COVID-19. The Pfizer vaccine is classified as a messenger RNA (mRNA) vaccine or ribonucleic acid (RNA) vaccine, while the AstraZeneca vaccine is a viral vector vaccine. Descriptions of the type of vaccines and how they work are publicly available on various websites, including: Australian Government Department of Health, at: <a href="http://www.health.gov.au/initiatives">www.health.gov.au/initiatives</a></p>	8/11/2021	SQ21-000611	SQ21-000611

The original form of the influenza vaccine developed in the 1960s and still in widespread use delivered the whole virus (rather than just a spike protein), which has been weakened or killed, and then allowed the body to recognise and respond to it. Is this correct?	6/08/2021	<ul style="list-style-type: none"> <li>• Inactivated (killed) whole virus influenza vaccines have been available since the 1930s.</li> <li>• Live attenuated (i.e. weakened) influenza vaccines were also developed in the 1930s and have been used since the 1950s to protect humans against seasonal influenza.</li> <li>• However, all influenza vaccines currently supplied in Australia for public use are inactivated surface antigen vaccines, or inactivated split virion vaccines, rather than inactivated or live attenuated whole virus vaccines.</li> </ul>	9/06/2021	SQ21-000612	SQ21-000612
The traditional vaccines given for measles, mumps, rubella, chickenpox etc. contain a weakened version of a germ that causes a disease. Is it correct that the mRNA and AZ vaccines use different methods than those vaccines that most people get as a child?	6/08/2021	(see next answer)	9/06/2021	SQ21-000613	SQ21-000613
How long are the vaccines effective for? Could studies please be cited?	6/08/2021	Inactivated vaccines use a killed version of a germ, while live attenuated vaccines use a weakened version of a germ. There are no inactivated or live attenuated vaccines for COVID-19 approved for use in Australia by the Therapeutic Goods Administration (TGA). The Pfizer and Moderna vaccines use an mRNA platform. The AstraZeneca vaccine is a viral vector vaccine. These vaccines contain a segment DNA or MRNA that leads to the recipient making a small portion only of virus, against which the immune response is formed. Research is still ongoing to determine how long COVID-19 vaccines will provide protection for an individual, and the degree of efficacy that is maintained. In April 2021, Pfizer announced data ahead of publication from their ongoing Phase 3 trial that showed that there was at least six months protection against symptomatic COVID-19 observed for the Pfizer vaccine, retaining 91.3 per cent efficacy. In May 2021, it was reported that the AstraZeneca vaccine works well as a third booster dose, although data from any studies has not yet been released. Further study results for Pfizer and AstraZeneca are expected as the global roll out continues.	9/06/2021	SQ21-000613	SQ21-000613
Will the population need to be revaccinated on a regular basis?	6/08/2021	(see next answer)	9/06/2021	SQ21-000626	SQ21-000626
If so, how often?	6/08/2021	The Australian Government continues to meet with vaccine manufacturers and monitor international developments to determine if revaccination is likely to be required for ongoing immune response. Vaccine manufacturers are investigating options to provide boosters, with some targeting specific variants of concerns, and others looking to use a booster dose of their current vaccination.	9/06/2021	SQ21-000626	SQ21-000626

To what percentage do vaccines stop transmission? Could studies please be cited.	6/08/2021	The primary purpose of COVID-19 vaccines is to prevent individuals from severe disease and death from the SARS-CoV-2 virus. Both the AstraZeneca and Pfizer vaccines provide significant protection against symptomatic disease. There is evidence that in addition to substantially reducing severe disease, vaccination also results in a significant reduction in the chance of transmitting the virus to others. In March 2021, Public Health Scotland reported preliminary results of a study of over 140,000 households of healthcare workers who had received at least one dose of Pfizer or AstraZeneca. Those who were vaccinated and became infected with SARS-CoV-2 were 30–54 per cent less likely to pass the SARS-CoV-2 virus onto their household members, compared to transmission from unvaccinated healthcare workers. In April 2021, Public Health England reported preliminary results of a large study of COVID-19 transmission involving more than 365,000 households in the UK with a mix of vaccinated and unvaccinated members. Individuals who tested positive to COVID-19, but had been immunised with one dose of either the Pfizer or AstraZeneca COVID-19 vaccine, had a reduced likelihood of infecting others by 40–50 per cent compared to transmission rates from unvaccinated individuals.	9/06/2021	SQ21-000627	SQ21-000627
To what extent has new variants reduced vaccine efficacy?	6/08/2021	TBA		SQ21-000628	SQ21-000628
Has testing of the vaccine be performed on people with arrhythmia or hemolysis? If not, given the clotting that's occurring, would it be wise to do so?	6/08/2021	<p>For the AstraZeneca vaccine:</p> <ul style="list-style-type: none"> <li>• Clinical trial data submitted to the TGA to support registration of the vaccine included participants with irregular heartbeat (arrhythmia) or haemolysis. However, the clinical trials were not designed to assess participants with arrhythmia or haemolysis specifically.</li> <li>• Given that the clinical trial data already included trial participants with irregular heart beat (arrhythmia) or haemolysis, and with the current very low rate of clotting adverse events after immunisation with this vaccine, it would be challenging to design a clinical trial to investigate these rare events. However, there are studies ongoing to better understand the exact mechanism of clotting condition such as Thrombosis with Thrombocytopenia Syndrome (TTS).</li> </ul> <p>For Pfizer vaccine:</p> <ul style="list-style-type: none"> <li>• The clinical trial data submitted to the TGA to support registration of this vaccine did not specifically identify study participants with arrhythmias or haemolysis.</li> <li>• No clotting adverse events have been reported in association with the Pfizer vaccine, so a clinical trial to investigate clotting is not required at this time</li> </ul>	9/06/2021	SQ21-000629	SQ21-000629



In the TGA's reporting of vaccines, 210 died after receiving the vaccine. What did these people die from – the vaccine or other comorbidities?	6/08/2021	(see next answer)	9/06/2021	SQ21-000614	SQ21-000614
Has a causal relationship been established as to what these people died from?	6/08/2021	(see next answer)	9/06/2021	SQ21-000614	SQ21-000614
If they died of comorbidities, why is the TGA excluding them from deaths related to the vaccine given the common practice of reporting people dying with COVID-19 as though they died from Covid?	6/08/2021	Due to patient confidentiality, we are unable to provide the causes of death for individual reports of death following vaccination. Detailed investigation of the cause of death is the role of the state or territory Coroner. All deaths that are reported as possibly being linked to vaccination are included in the TGA database. The number of deaths reported in a period of time following COVID-19 vaccination is included in the TGA weekly safety report. Individual reports are reviewed by an expert team of clinical staff. This review may include gathering and considering clinical information on the patient's current and past medical history, risk factors, and medications at the time of vaccination, as well as any tests such as pathology and clinical notes. This may also involve discussion with the relevant state and territory Health Departments, the individual's health professional(s) and/or the coroner. In some cases the TGA seeks advice from a panel of external medical specialists and community representatives. Since the vaccine rollout, to 15 August 2021, the TGA has only found seven cases where the individuals' death have been causally linked to the COVID-19 vaccine out 460 reports of death from the 15.3 million doses of the COVID-19 vaccines. All seven cases were linked to the COVID-19 Vaccine AstraZeneca now called Vaxzevria: six of the deaths were related to thrombosis with thrombocytopenia syndrome (TTS) and one was related to immune thrombocytopenia (ITP), both of which are very rare adverse events. For other reports of death, our review of cases and the advice of an external Vaccine	9/06/2021	SQ21-000614	SQ21-000614

<p>When it comes to comparing deaths from vaccines to a background death rate of the entire population, shouldn't the bar be higher for vaccines to ensure that a causal relationship is established?</p>	<p>6/08/2021</p>	<p>Each year in Australia there are about 160,000 deaths, equating to 13,300 a month or 3,050 each week. By chance, many people will experience new illnesses or die from a pre-existing condition shortly after vaccination, especially if they are elderly. To distinguish between coincidental deaths and deaths linked to the vaccine, the TGA uses data from reports of death in a number of ways. This includes review of individual reports, comparing the reported number of deaths with the expected background rate, and analysing the data on adverse events associated with reports of death to identify possible safety signals. To conduct an 'observed versus expected analysis', the number of expected deaths is extrapolated for the vaccinated population to determine if the rate of deaths reported exceeds that which is expected in a population of that size. To date, the observed number of deaths reported after vaccination is less than the expected number of deaths. In addition to reviewing reports of deaths, the TGA looks for patterns of adverse events which indicate a possible safety concern. This analysis includes all reports, including those with fatal outcomes. If a safety signal is identified, it is investigated further to determine if there is a causal relationship with a vaccine. Serious adverse events, including those with potentially fatal outcomes, are prioritised for review. Since the vaccine rollout, to 15 August 2021, the TGA has only found seven cases where the individuals' death was linked to vaccination out of 15.3 million doses of the COVID-19 vaccines. All seven cases were linked to the COVID-19 Vaccine AstraZeneca</p>	<p>9/06/2021</p>	<p>SQ21-000615</p>	<p>SQ21-000615</p>
<p>Are the adverse reactions recorded by the TGA reported on a voluntary basis? Will they include all reactions or only those reported?</p>	<p>6/08/2021</p>	<p>There are mandatory reporting requirements in law for sponsors of medicine and vaccines (i.e. pharmaceutical companies). Sponsors are required to report serious adverse events to the TGA within 15 days of them becoming aware. In addition, sponsors must notify the TGA of serious safety issues within 72 hours. The TGA does not have mandatory reporting requirements for health professionals or consumers – these reports are made voluntarily. However, some states and territories do have mandatory reporting requirements for health professionals to notify adverse events following immunisation to their public health units and these reports are passed onto the TGA. Furthermore, the vaccination agreements struck between the Commonwealth and GPs providing vaccination services required a commitment from the GP to report all adverse events to the TGA.</p>	<p>9/06/2021</p>	<p>SQ21-000616</p>	<p>SQ21-000616</p>

<p>Have the vaccines received full approval or provisional approval? If the latter, what is the difference?</p>	<p>6/08/2021</p>	<p>Due to the nature of the COVID-19 pandemic, COVID-19 vaccines are eligible to apply for a provisional registration status. To receive provisional registration, the Therapeutic Goods Administration (TGA) must establish the safety and efficacy of the vaccine based on preliminary clinical data. The data is preliminary in the sense that some important information, such as the duration of protection from infection or serious illness may not yet be available. This includes demonstrating that the benefit of early availability of the vaccine outweighs any inherent risks associated with the fact that additional data is still required. Provisional registration of vaccines approved through this pathway is limited to a period of two years. The sponsor can apply for two extensions, however, up to a maximum of six years. Data from ongoing trials will be key to providing robust evidence of the longer-term data including duration of protection against COVID-19 and to support a sponsor's application to transition their COVID-19 vaccine to full registration status. As at 23 June 2021, the following two COVID-19 vaccines have been included in the Australian Register of Therapeutic Goods (ARTG) as provisionally registered vaccines: Pfizer Australia Pty Ltd's COMIRNATY – BNT162b2 (mRNA vaccine) AstraZeneca Pty Ltd's COVID-19 Vaccine AstraZeneca (viral vector vaccine).</p>	<p>23/07/2021</p>	<p>SQ21-000617</p>	<p>SQ21-000617</p>
<p>Is the TGA considering allowing two difference vaccines to be used simultaneously? Has sufficient testing been performed to allow this?</p>	<p>6/08/2021</p>	<p>As at 22 June 2021, the Department of Health recommends that individuals receive two doses of the same COVID-19 vaccine to complete their vaccination course. The Therapeutic Goods Administration (TGA) has not received any clinical data or other evidence to demonstrate whether mixing doses of COVID-19 vaccines is safe and effective. As at 22 June 2021, there are no published international studies on the effectiveness of a combination of vaccines in preventing coronavirus infections.</p>	<p>8/11/2021</p>	<p>SQ21-000618</p>	<p>SQ21-000618</p>

Why doesn't the Australian Government hold pharmaceutical companies liable for their vaccines? If the vaccines are safe, then why is their liability waived? Most companies who sell faulty products that aren't safe are held liable, so why aren't pharmaceutical companies?	6/08/2021	All the COVID-19 vaccine supply agreements with the various manufacturers require the Commonwealth to provide an indemnity for certain liabilities that may arise, these indemnities were provided as a condition of Australia getting access to the vaccines. However, any contractual agreements with individual companies cannot stop individuals seeking to litigate, should an individual seek to do this in the future.  The Therapeutic Goods Administration (TGA) is responsible for monitoring the safety of all vaccines approved for use in Australia. The TGA closely assesses safety data prior to approval, and continue to monitor the safety of vaccines after they are registered in Australia so that any safety concerns can be detected and responded to. More information, including the TGA's COVID-19 vaccine safety monitoring plan, can be found at: <a href="http://www.tga.gov.au/covid-19-vaccine-safety-monitoring-and-reporting">www.tga.gov.au/covid-19-vaccine-safety-monitoring-and-reporting</a> .	23/09/2021	SQ21-000619	SQ21-000619
Why are drug makers the ones who design and perform the drug testing? Isn't this a conflict of interest? Shouldn't an independent body who doesn't stand to benefit financially from the drugs be the ones who do the testing?	6/08/2021	Developing a medicine or vaccine is a complex process involving several stages from the initial design phase to the final testing phases, and is financed by the pharmaceutical industry (i.e. the sponsor of the medicine). Sponsors are required to comply with regulatory requirement provided at all stages of the medicine design process. This is to ensure that all research and clinical work has been conducted in an ethical manner, and that data are credible and accurate. The Therapeutic Goods Administration (TGA) does not design medicines or conduct clinical studies. However, these studies must meet TGA requirements in order for TGA to consider a medicine or vaccine for approval. The role of the TGA is to provide key independent assessment of the safety, quality and efficacy data submitted by the sponsor. This may include further testing of the medicine or vaccine and review of testing data prior to the release of the first batches of a new product. The sponsor of the medicine is required to submit a comprehensive developmental dossier application for their medicine. This dossier usually consists of clinical studies, non	9/06/2021	SQ21-000620	SQ21-000620
Do drug companies pay foreign owned social media companies to regulate posts about vaccines?	6/08/2021	The Department does not have information about the subject of this question.	20/07/2021	SQ21-000593	SQ21-000593
Who regulates the social media companies to ensure they aren't censoring valid information and free speech?	6/08/2021	TBA			

Why do some vaccines last the best part of a lifetime while the flu shot only lasts for a few months?	6/08/2021	Vaccination experts recommend that everyone over six months is vaccinated annually to reduce their chance of contracting influenza. Unlike some other vaccine-preventable diseases, the influenza virus is always changing so the influenza vaccine changes too. The strains used in seasonal influenza vaccines can change from year to year depending on which viruses are predicted to circulate in each upcoming season.	22/07/2021	SQ21-000621	SQ21-000621
Why can't the CSL vaccine be used given it only resulted in false positive? Assuming it has fewer side effects than other drugs, why isn't that the key benchmark?	6/08/2021	TBA		SQ21-000622	SQ21-000622
Is the AMA affiliated with the Immunisation Coalition who along with many of its members are funded by pharmaceutical companies? If so, how can the AMA remain impartial when providing advice regarding vaccines or any other drugs for that matter?	6/08/2021	The AMA is not an agency of the Health Portfolio. The question should be referred to the AMA.	23/07/2021	SQ21-000623	SQ21-000623
Given the use of the AstraZeneca vaccine has been stopped or paused in other countries, why should Australians feel safe getting it?	6/08/2021	TBA		SQ21-000624	SQ21-000624
Why isn't there a standardised testing protocol for Covid – advice from the Health department says “It is a dangerous practice to try to generalise the interpretation of a pathology result across different IVDs, unless there is a formal internationally agreed reference standard for that purpose. This does not exist for SARS-COV-2 RNA detection by RT-PCR.” 1.) The following link on this website: <a href="http://www.health.gov.au/sites/default/files/documents/2020/03/coronavirus-covid-19-information-for-clinicians.docx">www.health.gov.au/sites/default/files/documents/2020/03/coronavirus-covid-19-information-for-clinicians.docx</a> says that “it should be noted that PCR tests cannot distinguish between “live” virus and non-infective RNA.” Does this mean the PCR tests can show positive results for viruses other than Covid? I also note the following comments from the WHO and I quote: “Diagnostic testing for SARS-CoV-2 states that careful interpretation of weak positive results is needed. a.) The cycle threshold (Ct) needed to detect virus is inversely proportional to the patient’s viral load. Where test results do not correspond with the clinical presentation, a	6/08/2021	The Australian Government is supported by the Australian Health Protection Principal Committee (AHPPC) and its standing committees, including the Public Health Laboratory Network (PHLN) and the Communicable Diseases Network Australia (CDNA). Together the expert members of these groups have published the Testing Framework for COVID-19 in Australia, available on the Department of Health website. This document provides a national framework to guide local approaches to testing that states and territories can apply to fit their local epidemiological context. In line with Australian national guidelines, the primary approach to identifying people with active COVID-19 infection is based on testing those with characteristic clinical symptoms and then groups that are more likely to reveal the presence of undetected community transmission. Individuals with symptomatic COVID-19 disease will display symptoms that are similar to a range of infections caused by other respiratory viruses. Therefore, testing is required to accurately report case ascertainment to public health authorities (noting it is a nationally notifiable disease) and to describe the prevalence of COVID-19 in the Australian community. Put another way, because the symptoms for COVID-19 are not specific, diagnostic testing using RT-PCR is essential to identify persons infected. PHLN has also published testing guidance for SARS-CoV-2 (the virus that causes COVID-19) which is dynamic and updated as new evidence and best practice testing methodologies and techniques are verified. The PHLN guidance can be found here	8/11/2021	SQ21-000625	SQ21-000625

<p>If COVID-19 debris is found in the sewerage, does this mean Covid has been in the community and people have recovered from COVID-19 without detection?</p>	<p>6/08/2021</p>	<p>Fragments of the virus (SARS-CoV-2) that causes COVID-19 can be detected in wastewater. This non-infectious genetic material shed by people infected with COVID-19 can be detected for some days before the onset of symptoms or detections from clinical testing, and may persist for many weeks after recovery from COVID-19.</p> <p>A detection of SARS-CoV-2 from a wastewater sample indicates that a person <u>currently or recently</u> infected with SARS-CoV-2 was present in the community and shedding viral particles into the sewer. It does not confirm that there is active, infectious COVID-19 at the time of detection.</p> <p>Wastewater surveillance, which involves frequent sampling, can also provide information that assists in determining whether the shedding event was a transient occurrence, for example a recovering traveller 'passing through', or whether there is a more persistent source of shedding within the catchment. This can assist in identifying locations or facilities for further public health investigation.</p> <p>Wastewater surveillance complements existing clinical surveillance methods. It does not replace clinical diagnostic methods.</p>	<p>23/09/2021</p>	<p>SQ21-000600</p>	<p>SQ21-000600</p>
<p>Should positive Covid tests be reported by Ct (cycle threshold) number so that the severity of cases can be ascertained by the public?</p>	<p>6/08/2021</p>	<p>In Australia, nucleic acid amplification testing (NAAT) using polymerase chain reaction (PCR) on a respiratory sample collected by a throat and bilateral deep nasal (or nasopharyngeal) swab is the gold standard test for the acute diagnosis of SARS-CoV-2 infection. This test method is very sensitive and detects nucleic acid sequences specific to the virus. During the testing process, the PCR amplifies a highly specific target region of the SARS-CoV-2 genome so that it can be detected. Each amplification reaction is known as a cycle. The cycle threshold (Ct) value of a reaction is the cycle number when the fluorescence of a PCR product can be detected above the background signal. Each PCR assay may have a different Ct value that is used for detecting SARS-CoV-2. Ct values for one In Vitro Diagnostic (IVD) Device should not be compared with Ct values from other platforms. Ct values are IVD Device dependant and require interpretation by a qualified pathologist or medical laboratory scientist. This means there is no 'set' Ct value to aim for across all platforms. There are also nucleic acid amplification devices used in Australia for the diagnosis of SARS-CoV-2 infection which do not record a Ct value.</p>	<p>8/11/2021</p>	<p>SQ21-000601</p>	<p>SQ21-000601</p>

<p>Why did Australians trying to return to Australia from India first test positive to COVID-19 then test negative the following day? Shouldn't there be a more accurate diagnostic tool for detecting Covid?</p>	<p>6/08/2021</p>	<p>All travellers to Australia must provide evidence of a negative COVID-19 polymerase chain reaction (PCR) test result, where the test was conducted no more than 72-hours prior to the scheduled flight. Nucleic acid amplification testing (NAAT) using PCR on a respiratory sample collected by a throat and bilateral deep nasal, or nasopharyngeal swab is the gold standard test for the acute diagnosis of SARS-CoV-2 infection. This test method is very sensitive and detects nucleic acid sequences specific to the virus. PCR testing must be conducted in accordance with the manufacturer's instructions for use and has been comprehensively validated by pathology laboratories both locally and internationally. Although PCR tests are the most accurate tests for the acute diagnosis of SARS-CoV-2, no test has 100 per cent sensitivity or specificity in all clinical circumstances. The likelihood of false positive and false negative results occurring is very low, however may occur due to:</p> <ul style="list-style-type: none"> <li>• laboratory error, for example assigning an incorrect PCR test result to a person's sample</li> <li>• sample contamination. This can affect one or many patient samples in a run</li> <li>• incorrect sampling collection method undertaken resulting in poor sample quality</li> <li>• off-target (non-specific) reactivity in the PCR test. It is also possible that on the day after a positive detection for SARS-CoV-2 ribonucleic acid (RNA) in a specimen, there is no detectable SARS-CoV-2 RNA in another specimen as the person's infection resolves. In Australia, all properly accredited Australian pathology</li> </ul>	<p>8/11/2021</p>	<p>SQ21-000602</p>	<p>SQ21-000602</p>
<p>Ivermectin has been given to millions of people in recent decades and has a proven safety record. Numerous peer reviewed studies based on RCT tests have shown symptom relief and rapid reductions in mortality and hospitalisation. What steps are required in order to make Ivermectin available to those Australians who wish use it, subject to doctor-patient consultation, rather than vaccines?</p>	<p>6/08/2021</p>	<p>(see next answer)</p>	<p>24/08/2021</p>	<p>SQ21-000604</p>	<p>SQ21-000604</p>
<p>Who can apply to get Ivermectin approved as a prophylaxis for COVID-19 in Australia?</p>	<p>6/08/2021</p>	<p>(see next answer)</p>	<p>24/08/2021</p>	<p>SQ21-000604</p>	<p>SQ21-000604</p>
<p>The National Institutes of Health (NIH) has dropped its recommendation against Ivermectin for treatment of COVID-19, and the agency now advises it can't recommend for or against its use, leaving the decision to physicians and their patients. Why can't Australia adopt the same approach?</p>	<p>6/08/2021</p>	<p>(see next answer)</p>	<p>24/08/2021</p>	<p>SQ21-000604</p>	<p>SQ21-000604</p>

<p>Dr Tess Lawrie, consultant to the WHO, Robert Borody, Robert Clancy and numerous other health professionals are on record saying that Ivermectin is not only safe to use but is effective. Given these views, why does the National Covid Evidence Taskforce recommend against Ivermectin in consultation with an individual's GP?</p>	<p>6/08/2021</p>	<p>It is a key priority to provide all Australians with access to safe and effective COVID-19 vaccines. The Government is committed to providing a safe and effective vaccine to everyone living in Australia. The rollout and distribution of COVID – 19 vaccines will occur in line with Australia's COVID-19 Vaccine National Rollout Strategy. The Government is working closely with the Australian Technical Advisory Group on Immunisation, the Therapeutic Goods Administration and all state and territory health departments to ensure that monitoring of COVID-19 vaccine safety is of the highest possible standard in Australia. The Government is also committed to investigating safe and effective possible treatments for SARS-CoV-2 (the virus responsible for COVID-19), and is closely monitoring worldwide research relating to treatments for patients with COVID-19. The Department of Health funds the National COVID-19 Clinical Evidence Taskforce, which is continuously identifying and analysing research on various treatments for COVID-19 in order to provide national evidence based guidelines for the clinical care of people with COVID-19 (<a href="http://www.covid19evidence.net.au">www.covid19evidence.net.au</a>). The recommendations and their rationale are on the taskforce website. In regards to ivermectin, the current evidence is not of sufficient quality or certainty to support its safe and effective use for the prevention or treatment of COVID-19. Despite some emerging data suggesting that ivermectin may potentially provide both prophylactic and therapeutic benefit, more robust, well-designed randomised controlled trials are still needed before ivermectin</p>	<p>24/08/2021</p>	<p>SQ21-000604</p>	<p>SQ21-000604</p>
<p>According to both the VAERS and WHO database on adverse events, the Covid vaccines have had more reported deaths than all other vaccines put together in the last 30 years. How can the TGA and various levels of government say the Covid vaccines are safe when they have a mortality rate higher than any other vaccine ever produced?</p>	<p>05/11/21</p>				
<p>Does the health department agree that the Covid vaccines have caused much higher death rates than normal vaccines based on data from the WHO and US adverse events databases?</p>	<p>05/11/21</p>				
<p>Given this data, how is it that the TGA is allowing the vaccines to be administered to young people especially given their very low risk of dying from Covid? Surely the relative risk for young healthy people doesn't justify them taking the vaccine?</p>	<p>05/11/21</p>				



<p>A letter from the Chief Health Officer of WA Health Service Providers, dated mid-October, sent to health workers, says that adverse events haven't been reported via the appropriate channels and that they have a statutory responsibility to report adverse events within 72 hours. Why are health workers being reminded of this so far into the rollout of the vaccine and given this under reporting, do you have confidence that all adverse events are being reported to the TGA in other States?</p>	<p>05/11/21</p>				
<p>Why are people who experienced serious adverse reactions from their first shot being forced to take the second shot rather than being given an exemption? I have received overwhelming feedback saying that the only exemption provided is for anaphylaxis and that strokes, paralysis, clotting, myocarditis etc is not a reason for an exemption.</p>	<p>05/11/21</p>				
<p>Why hasn't the government provided financial assistance to those people who can no longer work because of the adverse reaction and why does it only start for claims above \$5000? Surely people shouldn't have to cough up \$5000 of their own money for a vaccine reaction that they were told was safe and in many cases were forced to take?</p>	<p>05/11/21</p>				
<p>The immunisation handbook says people can't be coerced or manipulated into taking the vaccine – why is the Federal Government allowing employers and Premiers to force people to take the vaccine when the Federal Government advice says otherwise?</p>	<p>05/11/21</p>				

<p>Given both the short-term and long-term risks of the vaccine are not well understood how can people make a proper informed decision as to the potential risks and benefits? How can a proper decision be made when longitudinal studies haven't been completed and the placebo group was vaccinated in the initial trials by big pharma rendering comparisons impossible?</p>	<p>05/11/21</p>				
<p>Regarding alternative options being explained to a person taking the vaccine, are the case fatality rates being explained to younger people against adverse events for the age group? It would appear that the adverse event rates for younger age groups from the vaccine are higher than Covid case fatality rates.</p>	<p>05/11/21</p>				
<p>A 2013 report from Merck to the TGA shows that Ivermectin is tolerated at 120mg doses - up to 10 times higher than what is recommended for Scabies/Covid. In my conversations with Prof Skerrit, he was concerned about the safety of 12mg a day - why didn't he consider this report back in 2013 which showed that safety was not an issue for doses of between 30mg and 90mg 3 times a week before banning GPs from prescribing it? I note that while the assessment involved healthy people, doctors were prescribing Ivermectin for healthy people either as a prophylactic or as early treatment when people were still relatively healthy.</p>	<p>05/11/21</p>				
<p>Prof Skerrit said in estimates that Ivermectin was toxic. At what levels is Ivermectin toxic and can the Professor name the number of people who have died from Ivermectin where it has been prescribed by a doctor?</p>	<p>05/11/21</p>				

Why did the TGA order 150 million booster shots? That's 6 times greater than our population. Does the TGA plan on administering 6 rounds of booster shots and why, given that many experts have said that a) Covid will be more like the common cold next year and; b) if the vaccines are safe and effective why is there a need for a booster shot?	05/11/21				
Why is the TGA reviewing vaccines for 5-11 year olds? What's the point of giving children that young vaccines given no one that age has died from Covid?	05/11/21				
Given clotting is a well-known side effect of taking the vaccine, is the TGA requiring all people receiving the vaccine to undergo a D-dimer test to ensure that they do not experience clotting?	05/11/21				
Why are people in palliative care being counted as Covid deaths when they caught Covid in the ward?	05/11/21				
How do you reconcile this with the fact that you've only counted ten deaths out of the 600 reported deaths from the vaccine? How can 98% of the people or medical professionals reporting deaths be wrong?	05/11/21				
Why does the TGA trust Merck and Pfizer given both have been fined billions for pushing dodgy drugs or trying to bribe doctors to sell their drugs?	05/11/21				
How much has the Commonwealth Government paid out in indemnity costs for adverse events from vaccines to date?	05/11/21				
How many claims have been made to the Federal Government's vaccine indemnity scheme?	05/11/21				

How can doctors say with certainty that an adverse event occurring shortly after a person has taken the vaccine isn't related to the vaccine injection?	05/11/21				
If the person has no underlying conditions shouldn't the onus of proof be on the government to prove it wasn't the vaccine?	05/11/21				
Is clotting a side effect of the Covid vaccines?	05/11/21				
Does clotting cause strokes, heart attacks, paralysis, neurological conditions and intense pain?	05/11/21				
Why are people who have had serious adverse reactions to the first shot being forced to take a second shot? How exactly can anyone guarantee it won't make the existing adverse reaction worse?	05/11/21				
What scientific papers exist to show that people who have had an adverse reaction to one shot aren't going to have another reaction to the second shot?	05/11/21				
Why are essential workers, whether medical or other being silenced by governments with threats of dismissal from speaking about their own adverse events or the adverse events of their friends? Is this not government censorship and why is it occurring?	05/11/21				
Shouldn't the TGA wait to see if the first 2 doses are safe and effective before starting the rollout of booster shots?	05/11/21				
In light of the information coming to hand about adverse events for young people, is the TGA going to reconsider recommending booster shots for young people?	05/11/21				
Does the TGA know if there is a cumulate build-up of vaccine toxins in the body from multiple doses?	05/11/21				
Are only fully qualified and trained immunisation nurses administering the vaccine rollout?	05/11/21				

How many vaccine shots must a person receive before they are immune from Covid?	05/11/21				
If no immunity can be guaranteed, then how many shots are the TGA and relevant authorities going to make mandatory?	05/11/21				
If the number of booster shots required for immunity isn't known then how can the conditions in the immunisation handbook that says potential risks and benefits of the vaccine have to be explained, along with alternative options, be satisfied?	05/11/21				
How can all the risks of the vaccines be explained when longitudinal studies haven't been done and it's unknown how many booster shots are to be given?	05/11/21				
Why are doctors not giving exemptions to people who have had serious adverse reactions? Is it because they are fearful of being deregistered from AHPRA who have said that health workers cannot speak out against the vaccine rollout?	05/11/21				
Isn't forcing medical staff to administer vaccines against their will via threats of deregistration if they speak up about adverse events a violation of s51(xxiiiA) of the constitution that says, "the provision of maternity allowances, widows' pensions, child endowment, unemployment, pharmaceutical, sickness and hospital benefits, medical and dental services (but not so as to authorize any form of civil conscription), benefits to students and family allowances"?	05/11/21				

Should Chief Health Officers, politicians and former politicians disclose potential conflicts of interest in pharmaceutical companies? For e.g. Dr Jeanette Young's husband Professor Graeme Nimmo connection to Pfizer, Former PM Kevin Rudd held the position of President for the Asia Society Policy Institute which is funded by Pfizer.	05/11/21				
Why doesn't the Australian company Vaxine, the developer of Covax, get greater government support?	05/11/21				
At what stage of approval is the Covax vaccine?	05/11/21				
Why has the TGA approved vaccines for children as young as 12 when they have very little risk of dying from the disease and longitudinal studies on the vaccines, which are using novel technology, have not been completed?	05/11/21				
Doctors and Nurses have been told by AHPRA that if they say anything against the vaccine rollout, they will be deregistered. Why is that?	05/11/21				
Does speaking out against the vaccine rollout include talking about adverse events from the vaccines?	05/11/21				
I have spoken to numerous people who have stated that doctors have said that they don't think they should get the vaccine yet won't write an exemption for fear of being deregistered. Why is that?	05/11/21				
Of the over 600 reported deaths from the vaccines – how many were prepared by medical professionals and how many by unqualified medical professionals?	05/11/21				
Can I please get a copy of all the files of the reported deaths from vaccines sent to the TGA?	05/11/21				

I have been told by a barrister that a doctor is wanting legal advice because he is being told by AHPRA that he has to recommend the vaccine. Why are doctors being coerced into giving the vaccine?	05/11/21				
The Pfizer trials looked solely at dose ranging and antibody response. There is nothing whatsoever on preventing illness, hospitalisation or death. Why didn't they measure clinical endpoints rather than just antibody responses? i.e. How does Pfizer know enough antibodies were produced to actually kill ALL the antigens?	05/11/21				
Why is the indemnity scheme waiting until next year to pay out compensation forcing people to fund their own medical bills (including drugs by the same pharmaceutical companies that made the vaccines)?	05/11/21				
Why does the indemnity scheme only start at \$5,000? Should vaccine victims be compensated from the first dollar they have incurred because of the vaccine injuries?	05/11/21				
Why are vaccines mandatory for young healthy people when there is a fair argument to say the risk of injury from the vaccine is greater than the risk of injury from Covid?	05/11/21				
Why does the Government/TGA wait for a deep-pocketed sponsor to present a comprehensive package that justifies the approval of a new drug? Shouldn't there also be a focus on existing drugs that can also provide treatments?	05/11/21				
Given the spike protein has a broadly positive charge, how have pharmaceutical companies proved that the protein won't be active or prone to be attracted to negatively charged molecules and therefore cause clotting?	05/11/21				

The NSW Deputy Premier has said that if the people wanted to continue to go to restaurants etc, i.e. maintain their civil liberties, then they needed to get 6 monthly booster shots. What evidence is there that the Coronavirus won't mutate rendering the current batch of booster shots redundant?	05/11/21				
For how long will Health Authorities blackmail people by withholding their civil liberties if they don't get booster shots?	05/11/21				
Why doesn't the TGA have mandatory reporting requirements for reporting adverse events? Shouldn't it be mandatory given that the vaccines have only received provisional approval and data from ongoing trials are being assessed on an ongoing basis?	05/11/21				
Can the Health department provide details of the contents of the vaccines - if not how can people make informed consent?	05/11/21				
If vaccines are supposed to provide immunity, then why did Singapore with over 80% of the population vaccinated see an explosion in cases?	05/11/21				
Why has the government committed to spending billions for 150 million booster shots when scientists have said that Covid will be more like the common cold next year?	05/11/21				
Why is the Federal government buying booster shots before testing on the booster shots had even been completed?	05/11/21				
In regards to the purchase of the booster shots, what studies did the TGA/Health Minister rely on to ensure their safety? Please cite studies.	05/11/21				



Why did Australia commit to purchasing up to millions of booster shots, when there are 50 million Novavax, 25 million Moderna, and millions of unused AstraZeneca and Pfizer vaccines yet to be administered for a country with a population of only 25 million?	05/11/21				
When will the Novavax vaccine be available?	05/11/21				
Why has Moderna been approved by the TGA for children, when the FDA has not approved it and certain Nordic countries have withdrawn it?	05/11/21				
How much did the Australian government spend on Remdesivir?	05/11/21				
How many trials did the TGA review before approving Remdesivir?	05/11/21				
Why did the government buy Remdesivir when the WHO did not recommend it?	05/11/21				
Why has the government committed to buying 300,000 Molnupiravir doses when testing on side effects has not been completed, noting that some studies indicate that it causes mutations?	05/11/21				
How many trials did the TGA review before approving Molnupiravir?	05/11/21				
How much has the government spent on Molnupiravir?	05/11/21				
Merck cut the trial on Molnupiravir short because it was shown to cut hospital admissions/stays. Efficacy is only one part of testing, the other being safety. Why has the TGA approved Molnupiravir given no long-term safety testing was carried out on the drug?	05/11/21				
What satisfied the National Covid Clinical Evidence Taskforce that Molnupiravir works? It went straight to the TGA and they've provisionally approved on only Phase 2 trials that were cut short with no long-term safety data collected.	05/11/21				

Why can the government commit to spending billions on drugs that haven't been subjected to long term testing for safety or efficacy but not maternity wards in regional Australia?	05/11/21				
Why doesn't Google/YouTube have to disclose their interest in the AstraZeneca vaccine and who regulates their censorship of vaccine information on social media?	05/11/21				
If the TGA can regulate comments around health advice by Federal MPs like Craig Kelly then why don't they regulate warnings on social media posts about vaccine safety by foreign-owned social media companies?	05/11/21				
Data on the AUS Vac safety websites show much higher incidences of adverse events than the TGA website. Could the differences in numbers of reported incidences please be explained?	05/11/21				
Did the TGA verify or perform a forensic analysis of the patient-level trial data from Pfizer when they made their application for provisional registration, or did they merely take Pfizer's word that the study data submitted was a true representation of 44,000 clinical records?	05/11/21				
Could a report of that analysis please be provided?	05/11/21				
If no analysis of the trial data was made then why would the government give immunity to Pfizer and sign off on the vaccines given their history of infringements and penalties for bribing doctors to sell drugs etc?	05/11/21				
If a serious adverse event occurs receiving after a vaccine and that adverse event is not listed as a recognised side effect then is the adverse event treated as though it wasn't caused by the vaccine?	05/11/21				

Are doctors excluding adverse events from recorded vaccine injuries on the basis that it isn't on the list of recognised side effects?	05/11/21				
Given the vaccines have been rolled out for less than a year how can the TGA know what is a recognised side effect and what isn't?	05/11/21				
Given trials were accelerated and are still continuing why is the TGA declaring that a particular adverse event such as a stroke or paralysis isn't a side effect of the vaccine?	05/11/21				
How many days does Covid remain undetected by PCR tests as a result of the incubation period?	05/11/21				
Why do Australians have to quarantine for 14 days if PCR testing is so accurate – assuming an incubation period of a few days, then isn't 14 days too long?	05/11/21				
Does the PCR test detect the difference between live and dead virus?	05/11/21				
Does the Covid virus use reverse transcriptase to convert RNA into DNA and 2) does it do this inside the cell's nucleus as opposed to the cytoplasm?	05/11/21				
Has the TGA/Health Department analysed the management of Covid by the Indian state of Uttar Pradesh and understood why they have allegedly been able to eliminate Covid?	05/11/21				
If so, what was the reason that Uttar Pradesh health authorities were able to reduce covid cases in their state?	05/11/21				
Can the TGA name five countries where the mRNA vaccines have eliminated Delta or Covid?	05/11/21				

How long are the vaccines effective for? Is it fair to say that the AstraZeneca appears to be longer lasting given that cases in Israel and Singapore, who used Pfizer, have exploded whereas cases in the UK who used AZ have levelled out?	05/11/21				
In 2009, Pfizer among other large pharmaceutical companies disclosed payments to doctors and other medical professionals for consulting and speaking on its behalf and also some sponsorship of clinical trials. Does Pfizer and/or other pharmaceutical companies still pay doctors to speak on its behalf and for sponsorship of clinical trials?	05/11/21				
Are payments of this nature being tracked by Australian authorities to ensure there are no conflicts of interests when advice by medical authorities is given to government officials?	05/11/21				
Why is AZ being withdrawn despite the fact it is cheaper than Pfizer, doesn't need to be stored at cold temperature, is manufactured in Australia, and appears to have longer lasting protection than Pfizer?	05/11/21				
Why aren't antibody tests taken before giving vaccines to determine if it is necessary to give vaccines?	05/11/21				
Has testing been done on the impact of vaccines on people who are taking blood pressure tablets?	05/11/21				
I note documents that show that Pfizer demanded secret upfront payments for its Covid vaccine. Why did the federal government hide documents that show Pfizer was more interested in extortion than ensuring the safety of the vaccine?	05/11/21				

<p>Can the details of purchase contract agreements for the Covid vaccines between the federal government and the pharmaceutical companies please be provided? Details should include the purchase prices and any indemnity agreements.</p>	<p>05/11/21</p>				
<p>If the vaccines are safe and effective why has the federal government indemnified pharmaceutical companies from any liability for ineffectiveness or safety?</p>	<p>05/11/21</p>				
<p>Both Israel and Singapore have seen an explosion in cases and in the case of Singapore, deaths, after reaching high levels of vaccinations with the Pfizer vaccine. Why has the Pfizer vaccine failed to stop Covid and what is the possibility that Australians who took the Pfizer jab need to take another booster shot of Pfizer?</p>	<p>05/11/21</p>				
<p>An earlier study conducted by Monash University showed that Ivermectin inhibits the importin proteins responsible for transferring the Sars virus into the cell nucleus where it is then replicated. Given this discovery shouldn't there be an emphasis on further research given the safety profile of Ivermectin is well understood unlike the Covid vaccines, Remdesivir or Molnuprivar, which have very little long term safety data of their effects on humans?</p>	<p>05/11/21</p>				
<p>I note that Ivermectin hasn't been banned in other countries – why the need to ban it here noting that if other countries can overcome their problems in terms of production why can't Australia?</p>	<p>05/11/21</p>				

I note that a number of databases (VAERS/Vigibase) show the reported deaths from the Covid vaccines exceed the cumulative number of reported deaths of other vaccines in the last 30 years. How can the TGA justify approving vaccines with such a high mortality rate and adverse event rate in comparison with other vaccines?	05/11/21				
How much testing was done on pregnant women in regards to the safety of Covid vaccines before they were approved and can studies please be cited?	05/11/21				
Most vaccines last from between at least a decade to a lifetime. Why are booster shots necessary for the Covid vaccines given they have only recently been administered in the last six months?	05/11/21				
Given the vaccines were tested and approved when the main Covid strain was the Alpha variant, how much testing has been performed on the effectiveness of the vaccines in regards to the Delta variant? Can studies please be cited.	05/11/21				
How can the booster shots be tested for new strains that haven't yet occurred?	05/11/21				
Before the Covid Vaccines were approved, what studies did the TGA/Health department rely on to determine their safety? How many of these were conducted by the vaccine companies themselves versus independent examples? Could studies please be cited.	05/11/21				

<p>Did these studies quantify how effective these vaccines were in providing immunity? For example, did the studies stipulate the percentage of antigens they destroyed. The reason for this question is that most vaccines provide immunity by effectively destroying the pathogen, whereas the Covid vaccines seem to reduce the impact of Covid but doesn't stop transmission completely presumably because it doesn't destroy the pathogen.</p>	<p>05/11/21</p>				
<p>In September 2020, the World Health Organisation stated that vaccines wouldn't be ready until mid-2021 because safety tests would take a number of months. Yet, within days that Joe Biden was announced the winner of the 2020 US election a number of pharmaceutical companies announced they had received approval for Covid vaccines. How is it that safety tests were accelerated without comprising safety?</p>	<p>05/11/21</p>				
<p>How is it that a number of vaccines were suddenly approved for Covid-19 within a matter of weeks of each other despite pharmaceutical companies not being able to discover just one vaccine for a Coronavirus in the two decades preceding?</p>	<p>05/11/21</p>				
<p>To provide the public with greater details around Covid cases shouldn't cases be reported by age, comorbidity, CT number, excess deaths from prior years and whether it was contracted indoors or outdoors?</p>	<p>05/11/21</p>				

Who in the Health department is responsible for regulating health advice on social media? In particular why was Peter Daszak allowed to be a moderator for Facebook despite the fact he was employed by the Eco Health Alliance who worked on/funded gain of function research at the Wuhan Laboratory and has been caught covering up allegations that the Covid virus was man made in that very laboratory?	05/11/21				
Why are foreign social media companies allowed to censor health advice when they themselves are not health experts and many have conflicts of interest such as YouTube whose parent company has ownership interests in the AstraZeneca Vaccine?	05/11/21				
Are autopsies performed on all the people who die within 28 days of the taking the vaccine? If not, why not given the need to establish the safety profile of the vaccines since testing was accelerated and new technology was being used?	05/11/21				
The 23 <sup>rd</sup> September TGA Vaccine report had a reporting rate of 2.5 per thousand doses. That is a quarter of 1%. Shouldn't the TGA make reporting mandatory for all doses of vaccines so that the impact on the entire population is understood?	05/11/21				
I note that the reporting rate of 2.5 per thousand is down from 3.7 per thousand mid-year. Why has the reporting rate dropped? Is it because doctors have been forced to keep quiet about adverse events from the vaccines?	05/11/21				
Why are the more traditional vaccines better at preventing transmission than the mRNA vaccines?	05/11/21				
Why do the more traditional vaccines prevent the recipient from getting the disease whereas the Covid vaccines don't?	05/11/21				



Studies have shown that antibodies provide better long-term immunity than vaccines. Why aren't people tested for Covid antibodies before getting the vaccine to avoid unnecessary vaccinations or potential damage to the immune system?	05/11/21				
To what extent do masks reduce transmission of the Covid virus?	05/11/21				
To what extent do lockdowns work in preventing Covid transmission noting that despite the fact Victoria went into a short sharp lockdown, the number of Covid transmissions accelerated faster than NSW which had a slower lockdown?	05/11/21				
In regards to the use of Ivermectin in Australia, the TGA initially requested it needed data from Australian trials before it be approved (when there were few cases in Australia), yet it has relied on data from foreign studies to approve Covid vaccines and treatments. What is the reason for the inconsistency?	05/11/21				
Is Jane Halton still advising the Prime Minister on Vaccine solutions? If so, isn't that a conflict of interest between her role as Chair of the Coalition for Epidemic Preparedness which is funded by the Bill and Melinda Gates Foundation, who have significant investments in vaccine companies?	05/11/21				
Is Jane Halton still the Chair of the National Review of Hotel Quarantine? If so, isn't that a conflict of interest, given her board position with Crown Resorts?	05/11/21				

Ms Gill Callister, the Head of AHPRA is also an adjunct professor at Monash University. Monash receives funding from the Bill and Melinda Gates foundation that also owns shares in vaccine companies. Isn't there a conflict of interest between Ms Callister's role in advising Health workers not to speak against the vaccine rollout on one hand, and the pressure from Monash not to speak against the interests of one their donors?	05/11/21				
Given most experts say the CT number above which nucleotides are not infectious is around 35, why are the states using a CT number of around 40-45? Is this overstating cases?	05/11/21				
Can the Red Cross/CSL analyse results from the national serosurvey for the Dec 19 Quarter to determine if Covid was in the community then - if not, why not?	05/11/21				
Is the Federal government funding 50% of the health costs relating to Covid? If so, could a breakup of expenses paid to each state and for what purpose please be provided? I.e. how much has been spent on testing, vaccines, hospital support and military support.	05/11/21				
In regard to the administration of vaccines – is the same dosage given to people regardless of weight and age?	05/11/21				
If the Vaccine produces antibodies that kill the virus why can vaccinated people still transmit the disease?	05/11/21				
If a Vaccinated person can transmit the virus then the vaccine has not killed the virus has it?	05/11/21				
Does the vaccine stop the Covid virus from entering the cell's nucleus?	05/11/21				
How many covid deaths were in palliative care wards?	05/11/21				
What is the average age of people who died where death was a reported outcome from vaccines?	05/11/21				

How much does a PCR test cost the government?	05/11/21				
How much does a Rapid Antigen test cost the government?	05/11/21				
How many of the circa over 600 deaths from vaccines have had an autopsy performed to determine cause of death?	05/11/21				
Can the TGA please disclose its sources of funding by entity?	05/11/21				
Is it true that the ACE2 receptor is highly activated in people with diabetes and if so, given Covid enters cells via the ACE2 receptor, are people with diabetes and obesity more prone to getting seriously ill from Covid?	05/11/21				
Studies have shown that mRNA has crossed the blood brain barrier and to all parts of the body - has the long-term impacts of this been tested?	05/11/21				
On the National Covid Evidence Taskforce Website, studies show that Ivermectin reduces a) all-cause mortality from 39 to 20 in 1000, b) ICU admission from 115 to 61 in 1000, c) increase in viral clearance from 752 to 895 in 1000 to name a few. Given these results and that Ivermectin has a well-known safety profile why won't the TGA allow doctors to prescribe it? If the answer is because the trials were biased can the bias be explained trial by trial.	05/11/21				
Since when did Health Bureaucrats have the power to interfere in the doctor-patient relationship?	05/11/21				
Do people employed by the TGA, the National Evidence Clinical Covid Taskforce and health advisory agencies have to disclose conflicts of interests? Specifically in regards to payments received from pharmaceutical companies?	05/11/21				
How many people employed by the TGA, the National Evidence Clinical Covid Taskforce, and health advisory agencies had previously worked for pharmaceutical companies?	05/11/21				

Bill Gates and Pharmaceutical companies have funded a number of universities including Monash, which has many of its academics on government advisory boards. Bill Gates has also invested in Vaccine companies. What steps has the government taken to ensure that vaccine advice given by universities and their academics isn't tainted by the inherent conflict of interest when it isn't in the interests of their donors?	05/11/21				
Given the TGA says it reviewed Toxicology reports of Covid vaccines and was satisfied with them, is the TGA still satisfied with them given the large number of adverse events/reported deaths in comparison to prior vaccines?	05/11/21				
In the safety report provided by Pfizer provided via this link- <a href="#">FOI 2183 document 9 (tga.gov.au)</a> why is so much information blacked out?	05/11/21				
I note that the safety report relies on studies conducted on mice and in vitro studies but very little data from human studies? Why is that?	05/11/21				
As per the safety report no biodistribution studies were performed with the BNT162 vaccine candidates. Assuming this is true how can the TGA be sure that the vaccines won't cause adverse events on other internal organs and why did the TGA approve the vaccine given these studies weren't done?	05/11/21				
As per the safety report no RNA or protein metabolism or excretion studies were conducted – how does the TGA know that the vaccine spike proteins are cleared from the body rather than becoming ingrained in the body, possibly causing mutations later?	05/11/21				
Why did the safety report cover up the summary of macroscopic vaccine related findings in male and female animals?	05/11/21				

<p>I note the safety report says “Therefore, two mutations in the S2 domain within the central helix domain were included that lead to a “heads up” stabilized, pre-fusion conformation variant of S protein which can induce a stronger neutralizing antibody response than the native S protein”. Does this mean the S protein in the vaccine is not the same as the S protein in the native vaccine?</p>	<p>05/11/21</p>				
<p>I note the study says “RNA itself, and the lipids used in the BNT162 vaccines have no carcinogenic or tumorigenic potential. Furthermore, according to ICH S1A (ICH S1A Guideline: “Guideline on the Need for Carcinogenicity Studies of Pharmaceuticals”, November 1995), no carcinogenicity studies are required for therapeutics that are not continuously administered. Therefore, no carcinogenicity studies were performed.” Yet page 337 of the sixth edition of “Biology” authorised by Campbell and Reece says that a virus can cause cancers. Applying the precautionary principal, shouldn’t studies have been conducted to test for carcinogenic properties?</p>	<p>05/11/21</p>				
<p>The study said “Macroscopic and microscopic evaluation of male and female reproductive tissues were included in the GLP repeat-dose toxicity study testing BNT162a1, BNT162b1, BNT162b2, and BNT162c1 in rat (Section 5.3.1). No changes in these tissues were reported. Specific fertility and embryofetal development studies are ongoing.” Why was testing in regards to reproductive tissues only performed on rats and not humans before approval? Or have subsequent studies been performed and if so, can they be cited?</p>	<p>05/11/21</p>				

As per the study, why was no dedicated immunotoxicity study conducted? I assume this applies to humans as well?	05/11/21				
As per the study, "Based on the tolerability profile observed with the 100 µg dose level after Dose 1, an internal decision was made not to give Dose 2 at 100 µg." What dosage is the vaccine administered at?	05/11/21				
I note the study initially concluded "The intended initial indication is as vaccine for the prevention of COVID-19 in adults aged 18 yrs or older." Have further studies been conducted to verify the safety for people younger than 18?	05/11/21				
If so, how many tests have been conducted and were these conducted by independent organisations or the pharmaceutical companies themselves?	05/11/21				
I note much of the data in regards to human trials has been censored. Why was that?	05/11/21				
I note in the study conclusions that it says "The BNT162 vaccine candidates have not been evaluated for carcinogenic or mutagenic potential, or for impairment of fertility or embryonic/foetal development." Given mRNA has never been used before as a vaccine wasn't it incredibly reckless to approve these vaccines without testing for these side effects?	05/11/21				
Why did the Pfizer studies only look at antibody response rather than the impact of its vaccines on actually stopping antigens as measured by clinical endpoints such as preventing illness, hospitalisation and death? If Pfizer studies did show clinical endpoints outcomes can links please be provided?	05/11/21				

How can the pharmaceutical companies say that the vaccines have between 60-90% efficacy when only a small percentage are hospitalised (<5%) and less than a percent (the majority with comorbidities) die from Covid?	05/11/21				
Given most people recover from Covid in a short time frame how can pharmaceutical companies claim that their recovery was due to the vaccine and not natural immunity?	05/11/21				
Of the study that Pfizer conducted, what percentage of people were healthy?	05/11/21				
Have studies in human populations been conducted on the impact of repeat booster shots? If so, how many booster shots?	05/11/21				
Have studies in animal populations been conducted on the impact of repeat booster shots?	05/11/21				
If so, was the study performed with up to 6 booster shots given Australia ordered 150 million booster shots or 6 times its population?	05/11/21				
In explaining why the Indian State of Uttar Pradesh has been successful, Prof Skerrit indicated it may have been their Social Health policy rather than Ivermectin. If their Social health policies are so successful why hasn't Australia adopted the same polices, or if similar policies are in place why aren't they working as well as Uttar Pradesh?	05/11/21				
I note that sponsors of vaccines are required to comply with regulatory requirements at all stages of the medicine design process. I note that placebo groups for Covid vaccine trials were vaccinated thus preventing proper analysis of long-term side effects. How does the TGA intend to monitor the long-term side effects of Covid Vaccines which to date have resulted in more reported deaths than any other vaccine?	05/11/21				

In a prior Qon, the Health Department said that there are different testing platforms for Covid. Why are there different platforms being used to test Covid and why is there no set "Ct" number across platforms?	05/11/21				
How is it possible to make comparisons if the Covid testing process isn't standardized?	05/11/21				
Could the different specifications for each testing platform along with the cut off for each cycle threshold please be provided?	05/11/21				
Which states use which testing platforms?	05/11/21				
Can the difference in molecular makeup and shape between the Covid virus and other influenza viruses please be explained? i.e. why is it so much deadlier than other influenza viruses?	05/11/21				
Which receptor do other Influenza viruses use to enter cells?	05/11/21				
Do the Covid vaccines induce a T-cell response or just a B-cell response? Could studies be cited.	05/11/21				
If they induce a T-cell response why aren't the T-cells killing the virus given that vaccinated people can still pass the virus on?	05/11/21				
Is vaccine efficacy being tracked in Australia by comparing the number of people who have been vaccinated and caught Covid back to the type of Vaccine they have taken?	05/11/21				
I note that the Future Fund has around \$180 million invested in Pfizer shares. Isn't this a conflict of interest?	05/11/21				
If I am forced to get a vaccine and have an adverse reaction, am I responsible for ongoing health costs? If so, why given the government has said that the Covid vaccines are safe and effective?	05/11/21				



If an employee has an adverse reaction and is unable to work, can I sue my employer or government officials that have made it mandatory for me to be vaccinated or lose my job?	05/11/21				
Can a breakout of adverse events reported to the TGA be provided by decade age group and by vaccine type?	05/11/21				
Are medical staff being told to check for aspiration to ensure the vaccine is being administered correctly into the muscle rather than into a blood vessel?	05/11/21				
Is this requirement set out in the immunization handbook?	05/11/21				
Is immunity given to all vaccine companies or just some in particular?	05/11/21				
The TGA has said "Like all COVID-19 applications, the TGA's evaluation of this application will be a 'rolling review' where data will be evaluated as it comes to hand." Given the number of adverse events especially myocarditis and pericarditis, why is the TGA not looking at alternative safer treatments such as Ivermectin that don't have as severe side effects as the Covid vaccines?	05/11/21				
Have the Covid vaccines passed the phase 2 assessment and if so could the TGA please provide their batch number?	05/11/21				
Why would the TGA need to go as far as banning doctors from prescribing Ivermectin which has previously been approved for use by the TGA and is allowed to be prescribed by the NIH in the USA?	05/11/21				
Does the TGA believe that our Australian-trained doctors do not know what they are doing when they are prescribing Ivermectin?	05/11/21				

How would the TGA know what is best for the patient when they have not personally assessed the patient, and do not have any results with them to make that call? Surely it should be left for the doctor who is seeing the patient to make that call.	05/11/21										
Professor Skerritt stated in estimates "At high doses ivermectin is toxic". Is that not the case for almost all the drugs on the market?	05/11/21										
How many people have died from ivermectin if prescribed by a doctor?	05/11/21										
Can the health department confirm whether the Federal government contract with Pfizer for its Covid vaccine contained exclusivity clauses that prevented the Federal government from using other treatments for Covid?	05/11/21										
Has the Australian government threatened media agencies with loss of government advertising if they were to talk negatively about the vaccines?	05/11/21										
Why did the TGA approve the vaccine for patients who fit into missing information category (listed out as per below) if the information was missing? Below table was redacted from document: <a href="https://www.tga.gov.au/sites/default/files/foi-2389-06.pdf">https://www.tga.gov.au/sites/default/files/foi-2389-06.pdf</a>	05/11/21				<p><b>2.2. Summary of the Safety Concerns</b></p> <p>The safety concerns proposed in the COVID-19 mRNA vaccine EU RMP (version 1.0, dated 21 December 2020) are presented in Table 3.</p> <p><b>Table 3. Summary of Safety Concerns in the EU RMP</b></p> <table border="1"> <tr> <td><b>Important Identified Risks</b></td> <td>Anaphylaxis</td> </tr> <tr> <td><b>Important Potential Risks</b></td> <td>Vaccine-associated enhanced disease (VAED) including Vaccine-associated enhanced respiratory disease (VAERD)</td> </tr> <tr> <td><b>Missing Information</b></td> <td> <ul style="list-style-type: none"> <li>Use in pregnancy and while breast feeding</li> <li>Use in immunocompromised patients</li> <li>Use in frail patients with co-morbidities (e.g. chronic obstructive pulmonary disease (COPD), diabetes, chronic neurological disease, cardiovascular disorders)</li> <li>Use in patients with autoimmune or inflammatory disorders</li> <li>Interaction with other vaccines</li> <li>Long term safety data</li> </ul> </td> </tr> </table>	<b>Important Identified Risks</b>	Anaphylaxis	<b>Important Potential Risks</b>	Vaccine-associated enhanced disease (VAED) including Vaccine-associated enhanced respiratory disease (VAERD)	<b>Missing Information</b>	<ul style="list-style-type: none"> <li>Use in pregnancy and while breast feeding</li> <li>Use in immunocompromised patients</li> <li>Use in frail patients with co-morbidities (e.g. chronic obstructive pulmonary disease (COPD), diabetes, chronic neurological disease, cardiovascular disorders)</li> <li>Use in patients with autoimmune or inflammatory disorders</li> <li>Interaction with other vaccines</li> <li>Long term safety data</li> </ul>
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Why did the TGA sign vaccine contracts with foreign pharmaceuticals before phase three trials were completed but not with the Australian company Vaxine for the Covax-19 product?	05/11/21										
Have autopsies been performed on all people who have died within 28 days of receiving a COVID vaccine?	08/11/21				<p>There are no safety concerns for Australia that are additional to those proposed in the EU RMP.</p> <p><b>2.2.1. Australia Specific Safety Concerns</b></p> <p>Not applicable.</p> <p><b>2.2.2. Proposed Changes to the Australia-specific Safety Concerns</b></p> <p>Not applicable.</p>						
What was the time frame of the initial Pfizer trial – can dates be specified?	08/11/21										
How many people worked on the Pfizer trial and what was the staff to trial candidate ratio?	08/11/21										

What testing was done on the manufacturing process to ensure that batches/vaccines would not be contaminated?	08/11/21				
Did the TGA review the manufacturing process and can the audit report of this process by the TGA please be provided?	08/11/21				
I note that Ivermectin hasn't been banned in other countries – why the need to ban it here noting that if other countries can overcome their problems in terms of production why can't Australia?	08/11/21				
I note that a number of databases (VAERS/Vigibase) show the reported deaths from the Covid vaccines exceed the cumulative number of reported deaths of other vaccines in the last 30 years. How can the TGA justify approving vaccines with such a high mortality rate and adverse event rate in comparison with other vaccines?	08/11/21				
How much testing was done on pregnant women in regards to the safety of Covid vaccines before they were approved and can studies please be cited?	08/11/21				
Most vaccines last from between at least a decade to a lifetime. Why are booster shots necessary for the Covid vaccines given they have only recently been administered in the last six months?	08/11/21				
Senator Gerard Rennick					