



**Office of the Hon Mark Butler MP
Minister for Health and Aged Care**

Ref No: MC23-001859

Mr Russell Broadbent MP
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Dear Mr Broadbent

Thank you for your correspondence of 18 January 2023 to the Minister for Health and Aged Care, the Hon Mark Butler MP, on behalf of your constituents regarding suspected adverse events suffered as a result of vaccinations for COVID-19. The Minister has asked that I respond on his behalf.

The health and safety of all people in Australia continues to be a key priority for the Australian Government as it has been throughout the pandemic. I appreciate the concern you have expressed for the safety and wellbeing of your constituents, and I am sorry to hear of their poor health.

COVID-19 can be a very serious illness and is especially dangerous for vulnerable people in our community. Evidence supports that being vaccinated is one of the best ways to protect all individuals and those in our local community from becoming very sick or dying from the disease. Enormous amounts of real-world data from both here and overseas demonstrates the benefits of COVID-19 vaccination outweighs the potential risks.

All of the COVID-19 vaccines in use in Australia have been through a rigorous assessment process to ensure their safety and efficacy by the Therapeutic Goods Administration (TGA). Before any COVID-19 vaccine is approved for use in Australia, it is tested in large clinical trials and then subject to the TGA's stringent assessment and approval processes. These trials, involving tens of thousands of participants, have shown that Australia's COVID-19 vaccines are safe and effective in preventing people from developing symptomatic COVID-19 and protect individuals against severe illness or death associated with COVID-19 infection. The approval of vaccines is subject to strict conditions, such as the requirement for sponsors to continue providing information to the TGA on longer term efficacy and safety from ongoing clinical trials and post-market assessment. Emerging clinical trial evidence, as well as real world data, then continues to be monitored by technical experts.

The TGA's role in safety monitoring and evaluation of COVID-19 vaccines is also informed by the advice of the Advisory Committee on Vaccines, an independent committee of external experts relating to the safety, quality and efficacy of vaccines supplied in Australia.

The role of the TGA in monitoring safety is complemented by the Australian Technical Advisory Group on Immunisation (ATAGI). This group comprises medical experts in infectious disease, immunisation, primary care and public health. One of ATAGI's key roles is to monitor emerging evidence on safety of vaccines including by working closely with the TGA and other National Immunisation Technical Advisory Groups from around the world. ATAGI closely monitors local and international epidemiological data in relation to COVID-19 and vaccines and meets regularly to consider emerging evidence and information, including regular safety monitoring updates from the TGA. ATAGI may update and publish its advice and recommendations if there is a clear link – with serious implications – between a vaccine and certain risk factors.

The TGA's robust procedures enable a quick detection, investigation, and response to any potential safety issues if and when they arise. The Adverse Event Management System dataset is used by the TGA staff to help identify possible safety concerns as it is usually not possible to establish a definite relationship between a particular adverse event following immunisation and a particular vaccine on the basis of an individual report alone. If the TGA identifies a signal, it undertakes a detailed evaluation to establish the possible role of the medicine or vaccine in causing the adverse event.

COVID-19 vaccine safety data are monitored and reviewed as part of safety monitoring surveillance undertaken by the TGA. In addition to the TGA's published safety reports that collate and monitor safety information from Australia and overseas, the National Centre for Immunisation and Research and Surveillance (NCIRS) oversee data collected through AusVaxSafety. This comprehensive program reports fortnightly on active vaccine safety surveillance of the COVID-19 vaccines in use in Australia to ensure their ongoing safety. More information on this program is located online using the search terms 'AusVaxSafety'.

In relation to pregnancy, neither the TGA nor other major regulators have found any evidence that COVID-19 vaccination increases the risk of having a miscarriage, including from analysis of data in Australia. Similarly, post-market global surveillance data from large numbers of pregnant women, as well as other international research, has not identified any significant safety concerns with mRNA COVID-19 vaccines given at any stage of pregnancy. In particular, there is no evidence of decreased fertility, increased risk of miscarriage, or birth defects.

Like other medicines however, COVID-19 vaccines can cause side effects. Most side effects are mild and temporary. If people have questions or concerns about potential side effects, they should speak to their doctor. The TGA encourages doctors and consumers to report suspected side effects following immunisation with COVID-19 vaccines. Every report is valuable and contributes to safety monitoring.

The COVID-19 Vaccine Claims Scheme is established as a time-limited claims scheme to respond to the circumstances of the COVID-19 pandemic. It is designed to ensure that people who have suffered a recognised moderate to significant adverse effect, as a direct result of a TGA approved COVID-19 vaccine, have faster access to compensation rather than pursuing a costly and complex court process which would require fault or negligence to be established.

A person may be eligible for compensation under the Scheme if they suffer a COVID-19 vaccine administration related harm where the harm is clinically diagnosed, sustained during the physical act of performing the administration and was most likely caused by the administration of the COVID-19 vaccine.

The Department of Health and Aged Care is unable to provide individual medical advice regarding an individual's specific circumstances. Taking this into consideration, should you wish to meet with department officials to discuss your concerns further, please contact [REDACTED] Deputy Chief of Staff to the Minister for Health and Aged Care, who will arrange a meeting. [REDACTED] be contacted by email at [REDACTED]

Thank you for writing on this matter.

Yours sincerely

[REDACTED]
Chief of Staff

20/02/2023