

## ISSUE: COVID-19 Vaccines Deaths

**Key Points:**

- Every death that is reported to the TGA following a COVID-19 vaccination is reviewed to determine whether a regulatory response is necessary, based on the weight of evidence.
- The TGA does not determine cause of death- this is determined by coroners and treating doctors. The TGA does not 'overrule' the cause of death included on the death certificate.
- The causality assessment performed by the TGA is primarily concerned with the relationship between the COVID-19 vaccine and the adverse event that led to death. It is undertaken with the intention of appraising risk-benefit balance at a population-level for the specific vaccine under Australia's regulatory framework for therapeutic goods.
- The process is in line with the World Health Organization causality assessment for adverse events following immunisation framework, and international best practice in regulation of vaccines.
- This process is different to the determination of cause of death for an individual, which is appropriately undertaken by coroners and treating doctors.
- Regardless of the outcome of the individual causality assessment, all fatal adverse event reports are included in analyses to identify and investigate signals. The TGA does not remove any reports of death from the Database of Adverse Event Notifications (DAEN).
- I also note the following SQoNs that we've answered previously on this topic:
  - SQ24-003070- Autopsy reports
  - SQ24-003119- Reported deaths and autopsy reports
  - SQ24-000230 and SQ24-000234- Autopsies and cause of death determination

**IF ASKED****TGA review of fatal cases**

- Every death following a COVID-19 vaccination that is reported to the TGA is reviewed to determine whether a regulatory response is necessary, based on the weight of evidence.
- The TGA considers the evidence for a causal link between the vaccine and the diagnosis.
- **Cause of death** is determined by coroners and treating doctors, not the TGA. The TGA does not 'overrule' the cause of death included on the death certificate.
- Regardless of the outcome of the individual causality assessment, all fatal adverse event reports are included in analyses to identify and investigate signals. The TGA does not remove any reports of death from the Database of Adverse Event Notifications (DAEN).

**Reported death vs causal link to vaccine**

- Reporting of a death to the TGA does not mean the vaccine has caused the death, or the reporting doctor or individual considers the death was caused by a vaccine.
- The TGA strongly encourages consumers and health professionals to have a very low threshold for reporting suspected adverse events, even if there is only a very small chance a vaccine was the cause.
- Under state and territory regulations in NSW, WA, QLD, NT and the ACT, it is mandatory for health professionals to report certain adverse events following immunisation.

**Publication on mortality of COVID-19 vaccines in Victoria between 2021 and 2023**

- This SAEFVIC article published in Vaccine in 2024 reviews fatal reports following COVID-19 vaccination in Victoria between 2021 and 2023.<sup>1</sup>
- The study found mortality reporting mostly reflected the health status of the population receiving COVID-19 vaccines. Fatal reports occurred in individuals that were aged over 60 years, lived in residential aged care facilities, and had known comorbidities relevant to the underlying cause of death.
- Notably, the majority of reports were categorised by the treating team and/or forensic pathologist as having a likely alternative cause of death.
- The article concluded careful review of deaths possibly associated with vaccination continues to be important to improve understanding of the safety of vaccines.

**2024 publication on deaths prevented in NSW due to COVID-19 vaccination**

- A 2024 publication by Lin et al (2024)<sup>2</sup> assessed the impact of Australia's COVID-19 vaccination campaign. This study found in people over 50 years of age:
  - mortality rates were up to 11 times lower in vaccinated compared to unvaccinated individuals, with the level of protection greatest in people who received a booster dose, and
  - vaccination prevented an estimated 17,760 deaths between November 2021 to July 2022 in NSW alone.

**Coronial inquest into myocarditis death** <sup>s 22</sup>

- The TGA is aware that the Victorian Coroner held an inquest into this case.
- The TGA cannot comment on individual cases but can speak to the process used to assess individual adverse event reports. The TGA considers the evidence for a causal link between the vaccine and the reported adverse event. This regulatory causality assessment:
  - **is not intended** to determine the cause of death, which is the role of the coroner and treating health professional, but
  - **is intended** to characterise the strength of evidence to support a causal relationship between a vaccine and an adverse event, and to inform relevant regulatory actions.
- Myocarditis is a known but rare adverse event associated with mRNA vaccines. This risk is included in the vaccines' Product Information (PI), including the potential for it to occur more frequently in younger males, noting it also occurs in females, and the possibility of severe outcomes.

**Individual reports** See [SQ24-003120](#) – Reported death from COVID-19 vaccine in relation to ADR 598851.

- Every death following a COVID-19 vaccination reported to the TGA undergoes a review by TGA staff to assess the likelihood that a vaccine contributed to the reported cause of death.
- This review considers the strength of the evidence available and is not designed to determine if an event was linked, but rather whether the clinical conditions that led to a fatal outcome represent an emerging safety signal for the vaccine. If further information is required to complete the assessment it is requested from the reporter and/or the relevant state or territory health authority and/or coroner.

- To guarantee the privacy of patients and the sensitive health information contained in those reports the TGA does not comment on individual cases.
- Disclosure of personal information may reduce public willingness to submit reports and thereby substantially prejudice the TGA's ability to regulate therapeutic goods.

#### **Australian Bureau of Statistics mortality data and excess deaths**

- **There is no credible evidence to suggest COVID-19 vaccines have contributed to excess deaths in Australia or overseas.** See 'AMPS Campaign' brief for details ([D25-4790211](#)).
- Independent analysis of Australian death data by the Actuaries Institute found that the timing, shape and age pattern of excess mortality does not support a link to vaccination.
- The Australian Institute of Health and Welfare (AIHW) report on 'Health system spending on the response to COVID-19 in Australia 2019-20 to 2021-22', demonstrated that Australia had one of the lowest global excess death rates (published November 2023):
  - Australia's excess mortality rate (2020-22) ranked 5<sup>th</sup> lowest of 31 studied countries.
  - Excess mortality in Australia was 4.4% in this period, compared to an average excess mortality of 14% across 30 countries, including the USA and UK.
  - Global excess mortality data do not correlate with high vaccination rates - in general, countries with high vaccination rates had lower rates of excess mortality.
    - Noting a further study published by Lin et al. on 16 April 2024 found that Australia achieved one of the highest vaccination rates in the world, with more than 85% of its eligible population fully vaccinated with at least 2 doses.<sup>2</sup>
- *[only if asked about discrepancy in number of reported deaths]* The ABS underlying cause of death data include 16 deaths reported by a health professional or coroner as being a COVID-19 vaccine-related death: 0 in 2023; 15 in the 2021 report; and 1 in 2022. The TGA has confirmed all the COVID-19 vaccine-related deaths included in the ABS report are known to the TGA and have been included in the TGA's safety monitoring, even where no causal link has been found.
  - The difference in numbers is due to how the 2 agencies categorise deaths as being related to a COVID-19 vaccine.
  - The ABS uses the International Classification of Diseases (ICD) to code information on the cause of death identified by health professionals or coroner. There is an ICD code for COVID-19 vaccine-related deaths. Questions on how the cause of death is coded should be directed to the ABS.
  - The information in the ABS report does not change the known safety profile of the COVID-19 vaccines.

#### **Reports in children**

- There are 9 adverse event reports with a fatal outcome following COVID-19 vaccination in children under 18 years of age in the TGA's Database of Adverse Event Notifications (DAEN – medicines).
- Of the 9 reports, none has been determined by the TGA to indicate a causal relationship between the vaccine and the adverse event.

<sup>1</sup> Laemmle-Ruff I et al. (2024) Detailed review of mortality reported following COVID-19 vaccination in Victoria, Australia: 2021-2023, *Vaccine*, 42(26): 126368. Available at: <https://pubmed.ncbi.nlm.nih.gov/39305837/>

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**Batch safety**

- There is no evidence to suggest that any of the deaths reported to the TGA for a COVID-19 vaccine were related to a vaccine quality issue.

**DATA**

- Since the beginning of the vaccine rollout in early 2021, over **72 million doses** of COVID-19 vaccine have been given in Australia. As at 31 October 2025, the TGA has received 1,053 adverse event reports with a fatal outcome. Of these, the number of **deaths in adults where the cause of death was** determined by the TGA to be related to COVID-19 vaccine-associated causes is **incredibly small**.
- These deaths were associated with rare but serious adverse events and have occurred at a rate far lower than the risks associated with COVID-19 itself.
- Assessment by the TGA has determined 14 deaths associated with COVID-19 vaccinations:
  - 13 deaths were identified to have occurred after the first dose of Vaxzevria (AstraZeneca) as follows:
    - 8 thrombosis with thrombocytopenia syndrome (TTS)
    - 2 cases Guillain-Barre syndrome (GBS)
    - 2 rare neurological conditions
    - 1 case of immune thrombocytopenia.
- One death was identified as related to myocarditis after a booster dose of Spikevax (Moderna).
- A further 3 historic reports of possible vaccine-associated death have been identified from the published literature<sup>3</sup>. All 3 cases are reported as deaths related to TTS following administration of Vaxzevria in 2022. One case has been assessed by the TGA as having an alternative non-vaccine-related cause of death. There is insufficient information on the other 2 cases to determine whether they are duplicates of reports already provided to the TGA, so these have been included as cases in the TGA's adverse events management system.

**Important background for this data**

- Causality assessment undertaken by the TGA is primarily concerned with the relationship between the COVID-19 vaccine and the adverse event that led to death, undertaken with the intention of appraising risk-benefit balance for the specific vaccine under Australia's regulatory framework for therapeutic goods.
- The TGA can convene the Vaccine Safety Investigation Group (VSIG), a time-limited group of independent experts, to conduct formal causality assessments between a vaccine and a single adverse event, where a single adverse event report has the potential to change the entire positive benefit-risk balance of the vaccine.
- Critical appraisal of the causal relationship between a vaccine and adverse event may also involve application of clinical and scientific expertise internally within the TGA without progressing to formal causality assessment via a VSIG.
- During the early years of the rollout of COVID-19 vaccines in Australia, the TGA convened the VSIG several times for conditions such as TTS and myocarditis. This was because the risk-benefit

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profile of COVID-19 vaccines were still being characterised, and therefore the potential impact of these conditions on that balance was unknown. Now that the safety profile of COVID-19 vaccines is well-established, and conditions such as TTS and myocarditis are well described in the PI document and the risk mitigated in certain population groups who are most susceptible to these conditions, there is no regulatory purpose for confirming the relationship between the vaccine and the adverse event.

- It is extremely rare for a formal causality assessment process via the VSIG to identify a new safety signal from a single adverse event report, and to confirm beyond doubt that the vaccine caused the adverse event. The purpose of pharmacovigilance is to look for patterns in large numbers of adverse event reports to find new safety signals, and to confirm these signals using population level evidence, comparing rates of the adverse event following vaccination to background rates of the condition in the community (occurring separate to vaccination).

**RECENT SQoNs**

TGA has answered numerous SQoNs on this topic, including:

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- SQ22-000529 – questions related to TGA processes for reviewing deaths.
- SQ21-001218 – questions related to TGA processes; referred to by more recent SQoNs

Division:	Medicines Regulation Division
Cleared by:	Nick Henderson <span style="background-color: #cccccc;">s22</span>
Contact Officer:	Tahli Fenner/Daniel Dascombe
Date:	13 November 2025

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**Commented s22** Wondering if these paras are still useful? Perhaps helpful to re-affirm the safety of COVID-19 vaccines, but we haven't been asked about them specifically in the last few hearings?

**Commented s22** : This QoN is from November 2024 - wondering if we still need this para?

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- To guarantee the privacy of patients and the sensitive health information contained in those reports the TGA does not comment on individual cases.
- Disclosure of personal information may reduce public willingness to submit reports and thereby substantially prejudice the TGA's ability to regulate therapeutic goods.

**Australian Bureau of Statistics mortality data and excess deaths**

- **There is no credible evidence to suggest COVID-19 vaccines have contributed to excess deaths in Australia or overseas.** See 'AMPS Campaign' brief for details ([D25-5659012D25-4790214](#)).
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- Of the 9 reports, none has been determined by the TGA to indicate a causal relationship between the vaccine and the adverse event.

**Commented s22** 9 AE reports with fatal outcomes in patients under 18 years of age, report date up to 31 Dec 2025 - confirmed by AEMDS (Qlik-AEMS app search on 06 Jan 2026)

Data relevant to causal relationship to be confirmed by VSS

**Commented s22** See previous talking points - best to keep wording as is, so as to not incorrectly imply VSIG

**Commented s22** -the last fatal report is from 2022 so I believe these are the same 9 reports previously identified and reviewed (from the talking points on 'death in children following COVID vaccination')

**Commented s22** Lovely - thanks s22

<sup>1</sup> Laemmle-Ruff I et al. (2024) Detailed review of mortality reported following COVID-19 vaccination in Victoria, Australia: 2021-2023, *Vaccine*, 42(26): 126368. Available at: <https://pubmed.ncbi.nlm.nih.gov/39305837/>

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**Batch safety**

- There is no evidence to suggest that any of the deaths reported to the TGA for a COVID-19 vaccine were related to a vaccine quality issue.

**DATA**

- Since the beginning of the vaccine rollout in early 2021 to 31 December 2025, over 742 million doses of COVID-19 vaccine have been given in Australia. As at 31 December 2025, the TGA has received 1,052~~3~~ adverse event reports with a fatal outcome. Of these, the number of deaths in adults where the cause of death was determined by the TGA to be related to COVID-19 vaccine-associated causes is **incredibly small**.
- These deaths were associated with rare but serious adverse events and have occurred at a rate far lower than the risks associated with COVID-19 itself.
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Commented s22 : Confirmed via search of TGA AIR QLIK app 6 Jan 2026

Commented s22 : A total of 1,052 AE reports with fatal outcomes - report date up to 31 Dec 2025 - confirmed by AEMDS (Qlik-AEMS app search on 06 Jan 2026)

Commented s22 : In CM as of 6 Jan 2026 we have not done any assessments against VSIG criteria for COVID-19 vaccines since October 2025 so I presume this is still current

Commented s22 : Dan - s 47E(d)

but will

keep the line in here in case you need it

<sup>3</sup> Clarke L et al. (2023) Vaccine-induced immune thrombotic thrombocytopenia post dose 2 ChAdOx1 nCoV19 vaccination: Less severe but remains a problem. *Vaccine*, 41(20): 3285-3291. Available at: <https://pubmed.ncbi.nlm.nih.gov/37085453/>

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Commented s22 : Only removed as no current PI for Vaxzevria as not registered

RECENT SQoNs

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Commented s22 - please confirm if further recent SQoNs are relevant here

Commented s22 Dan - I believe there were 3 QoNs last hearing, 2 of which s22 has included here, I don't think the other one is relevant to this brief (SQ25-003148 regarding vaccines and autism). Do you agree?

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Division:	Medicines Regulation Division
Cleared by:	Nick Henderson s22
Contact Officer:	Tahli Fenner/Daniel Dascombe
Date:	<del>XX613</del> January November 20265

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- Every death following a COVID-19 vaccination that is reported to the TGA is reviewed to determine whether a regulatory response is necessary, based on the weight of evidence.
- The TGA considers the evidence for a causal link between the vaccine and the diagnosis.
- **Cause of death** is determined by coroners and treating doctors, not the TGA. The TGA does not 'overrule' the cause of death included on the death certificate.
- Regardless of the outcome of the individual causality assessment, all fatal adverse event reports are included in analyses to identify and investigate signals. The TGA does not remove any reports of death from the Database of Adverse Event Notifications (DAEN).

**Reported death vs causal link to vaccine**

- Reporting of a death to the TGA does not mean the vaccine has caused the death, or the reporting doctor or individual considers the death was caused by a vaccine.
- The TGA strongly encourages consumers and health professionals to have a very low threshold for reporting suspected adverse events, even if there is only a very small chance a vaccine was the cause.
- Under state and territory regulations in NSW, WA, QLD, NT and the ACT, it is mandatory for health professionals to report certain adverse events following immunisation.

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#### Publication on mortality of COVID-19 vaccines in Victoria between 2021 and 2023

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- The study found mortality reporting mostly reflected the health status of the population receiving COVID-19 vaccines. Fatal reports occurred in individuals that were aged over 60 years, lived in residential aged care facilities, and had known comorbidities relevant to the underlying cause of death.
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#### 2024 publication on deaths prevented in NSW due to COVID-19 vaccination

- A 2024 publication by Lin et al (2024)<sup>2</sup> assessed the impact of Australia's COVID-19 vaccination campaign. This study found in people over 50 years of age:
  - mortality rates were up to 11 times lower in vaccinated compared to unvaccinated individuals, with the level of protection greatest in people who received a booster dose, and
  - vaccination prevented an estimated 17,760 deaths between November 2021 to July 2022 in NSW alone.

#### Coronial inquest into myocarditis death s 22

- The TGA is aware that the Victorian Coroner held an inquest into this case.
- The TGA cannot comment on individual cases but can speak to the process used to assess individual adverse event reports. The TGA considers the evidence for a causal link between the vaccine and the reported adverse event. This regulatory causality assessment:
  - is **not** intended to determine the cause of death, which is the role of the coroner and treating health professional, but
  - is **intended** to characterise the strength of evidence to support a causal relationship between a vaccine and an adverse event, and to inform relevant regulatory actions.
- Myocarditis is a known but rare adverse event associated with mRNA vaccines. This risk is included in the vaccines' Product Information (PI), including the potential for it to occur more frequently in younger males, noting it also occurs in females, and the possibility of severe outcomes including death.

#### Individual reports See [SQ24-003120](#) - Reported death from COVID-19 vaccine in relation to ADR 598851.

- Every death following a COVID-19 vaccination reported to the TGA undergoes a review by TGA staff to assess the likelihood that a vaccine contributed to the reported cause of death.
- This review considers the strength of the evidence available and is not designed to determine if an event was linked, but rather whether the clinical conditions that led to a fatal outcome represent an emerging safety signal for the vaccine. If further information is required to complete the assessment it is requested from the reporter and/or the relevant state or territory health authority and/or coroner.

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**Commented** s22 This QoN is from November 2024 - wondering if we still need this para?

**Commented** s22 Agreed, with the same rationale as the above comment. This information has recently been provided in the COVID VSIG QoN from the December Estimates hearing also.

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- To guarantee the privacy of patients and the sensitive health information contained in those reports the TGA does not comment on individual cases.
- Disclosure of personal information may reduce public willingness to submit reports and thereby substantially prejudice the TGA's ability to regulate therapeutic goods.

**Australian Bureau of Statistics mortality data and excess deaths**

- There is no credible evidence to suggest COVID-19 vaccines have contributed to excess deaths in Australia or overseas. See 'AMPS Campaign' brief for details ([D25-5659012D25-4790211](#)).
- Independent analysis of Australian death data by the Actuaries Institute found that the timing, shape and age pattern of excess mortality does not support a link to vaccination.
- The Australian Institute of Health and Welfare (AIHW) report on 'Health system spending on the response to COVID-19 in Australia 2019-20 to 2021-22', demonstrated that Australia had one of the lowest global excess death rates (published November 2023):
  - Australia's excess mortality rate (2020-22) ranked 5<sup>th</sup> lowest of 31 studied countries.
  - Excess mortality in Australia was 4.4% in this period, compared to an average excess mortality of 14% across 30 countries, including the USA and UK.
  - Global excess mortality data do not correlate with high vaccination rates - in general, countries with high vaccination rates had lower rates of excess mortality.
    - Noting a further study published by Lin et al. on 16 April 2024 found that Australia achieved one of the highest vaccination rates in the world, with more than 85% of its eligible population fully vaccinated with at least 2 doses.<sup>2</sup>
- [only if asked about discrepancy in number of reported deaths] The ABS underlying cause of death data include 16 deaths reported by a health professional or coroner as being a COVID-19 vaccine-related death: 0 in 2023; 15 in the 2021 report; and 1 in 2022. The TGA has confirmed all the COVID-19 vaccine-related deaths included in the ABS report are known to the TGA and have been included in the TGA's safety monitoring, even where no causal link has been found.
  - The difference in numbers is due to how the 2 agencies categorise deaths as being related to a COVID-19 vaccine.
  - The ABS uses the International Classification of Diseases (ICD) to code information on the cause of death identified by health professionals or coroner. There is an ICD code for COVID-19 vaccine-related deaths. Questions on how the cause of death is coded should be directed to the ABS.
  - The information in the ABS report does not change the known safety profile of the COVID-19 vaccines.

**Reports in children**

- There are 9 adverse event reports with a fatal outcome following COVID-19 vaccination in children under 18 years of age in the TGA's Database of Adverse Event Notifications (DAEN – medicines).
- Of the 9 reports, none has been determined by the TGA to indicate a causal relationship between the vaccine and the adverse event.

<sup>1</sup>Laemmle Ruff I et al. (2024) Detailed review of mortality reported following COVID-19 vaccination in Victoria, Australia: 2021-2023, *Vaccine*, 42(26): 126368. Available at: <https://pubmed.ncbi.nlm.nih.gov/39305837/>

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**Batch safety**

- There is no evidence to suggest that any of the deaths reported to the TGA for a COVID-19 vaccine were related to a vaccine quality issue.

**DATA**

- Since the beginning of the vaccine rollout in early 2021 to 31 December 2025, over **742 million doses** of COVID-19 vaccine have been given in Australia. As at 31 ~~December~~ October 2025, the TGA has received 1,052~~3~~ adverse event reports with a fatal outcome. Of these, the number of **deaths in adults where the cause of death was** determined by the TGA to be related to COVID-19 vaccine-associated causes is **incredibly small**.
- These deaths were associated with rare but serious adverse events and have occurred at a rate far lower than the risks associated with COVID-19 itself.
- Assessment by the TGA has determined 14 deaths associated with COVID-19 vaccinations:
  - 13 deaths were identified to have occurred after the first dose of Vaxzevria (AstraZeneca) as follows:
    - 8 thrombosis with thrombocytopenia syndrome (TTS)
    - 2 cases Guillain-Barre syndrome (GBS)
    - 2 rare neurological conditions
    - 1 case of immune thrombocytopenia.
- One death was identified as related to myocarditis after a booster dose of Spikevax (Moderna).
- A further 3 historic reports of possible vaccine-associated death have been identified from the published literature<sup>3</sup>. All 3 cases are reported as deaths related to TTS following administration of Vaxzevria in 2022. One case has been assessed by the TGA as having an alternative non-vaccine-related cause of death. There is insufficient information on the other 2 cases to determine whether they are duplicates of reports already provided to the TGA, so these have been included as cases in the TGA's adverse events management system.

**Important background for this data**

- Causality assessment undertaken by the TGA is primarily concerned with the relationship between the COVID-19 vaccine and the adverse event that led to death, undertaken with the intention of appraising risk-benefit balance for the specific vaccine under Australia's regulatory framework for therapeutic goods.
- The TGA can convene the Vaccine Safety Investigation Group (VSIG), a time-limited group of independent experts, to conduct formal causality assessments between a vaccine and a single adverse event, where a single adverse event report has the potential to change the entire positive benefit-risk balance of the vaccine.
- A VSIG may be convened to provide specialist immunisation expertise to assist the TGA in investigating and/or managing AEFIs or vaccine safety signals if certain criteria are met, namely: when an AEFI of concern or a safety signal of concern is identified, that the AEFI has the potential to change the favourable risk-benefit profile of the vaccine in a National or State immunisation program, or could threaten public confidence in vaccine safety, AND the case/s is/are considered eligible for assessment/investigation.

<sup>3</sup> Clarke L et al. (2023) Vaccine-induced immune thrombotic thrombocytopenia post dose 2 ChAdOx1 nCoV19 vaccination: Less severe but remains a problem. *Vaccine*, 41(20): 3285-3291. Available at: <https://pubmed.ncbi.nlm.nih.gov/37085453/>

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- [The investigation of a single case report of a serious AEFI, including cases where death is reported as the outcome, is just one part of a broad and comprehensive system of pharmacovigilance for vaccines registered in Australia.](#)
- Critical appraisal of the causal relationship between a vaccine and adverse event may also involve application of clinical and scientific expertise internally within the TGA without progressing to formal causality assessment via a VSIG.
- During the early years of the rollout of COVID-19 vaccines in Australia, the TGA convened the VSIG several times for conditions such as TTS and myocarditis. This was because the risk-benefit profile of COVID-19 vaccines were still being characterised, and therefore the potential impact of these conditions on that balance was unknown. Now that the safety profile of COVID-19 vaccines is well-established, and conditions such as TTS and myocarditis are well described in the PI documents, and the risk mitigated in certain population groups who are most susceptible to these conditions, there is no regulatory purpose for confirming the relationship between the vaccine and the adverse event.
- It is extremely rare for a formal causality assessment process via the VSIG to identify a new safety signal from a single adverse event report, and to confirm beyond doubt that the vaccine caused the adverse event. The purpose of pharmacovigilance is to look for patterns in large numbers of adverse event reports to find new safety signals, and to confirm these signals using population level evidence, comparing rates of the adverse event following vaccination to background rates of the condition in the community (occurring separate to vaccination).

RECENT SQoNs

TGA has answered numerous SQoNs on this topic, including:

- [SQ25-003155- VSIGs for COVID-19 vaccines](#)
- [SQ25-003215- Paediatric COVID-19 vaccines causing death](#)
- SQ24-003070 - Autopsy reports
- SQ24-003120 - Reported death from COVID vaccine
- SQ24-003119 - Reported deaths and autopsy reports
- SQ24-000218 – Tracking batch number for reported deaths
- SQ24-000230 and SQ24-000234 – Autopsies and cause of death determination (note both responses refer to previous SQoN responses)
- SQ24-000230 – Deaths in children
- SQ24-000233 – Statements relating to causality and FOI 4205 (time to death data)
- SQ23-002226 – Reporting of COVID vaccine deaths
- SQ23-001134 and SQ23-001086 – Deaths of children following COVID vaccination and related FOI on topic
- IQ23-000058 – Doctor reported deaths
- SQ23-001101 – Follow up of reported death in the Australian (24-year-old)
- SQ23-001074 – Temporal association between the rollout of the vaccine and excess deaths
- SQ23-000139 – questions about reported deaths in a 7 and 9-year-old
- SQ23-000140 – questions about TGA processes including documents released under FOI
- SQ22-000529 – questions related to TGA processes for reviewing deaths.
- SQ21-001218 – questions related to TGA processes; referred to by more recent SQoNs

**Commented** s22 - please confirm if further recent SQoNs are relevant here

**Commented** s22 Dan - I believe there were 3 QoNs last hearing, 2 of which s22 has included here, I don't think the other one is relevant to this brief (SQ25-003148 regarding vaccines and autism). Do you agree?

**Commented** s22 Thanks s22, agree with this.

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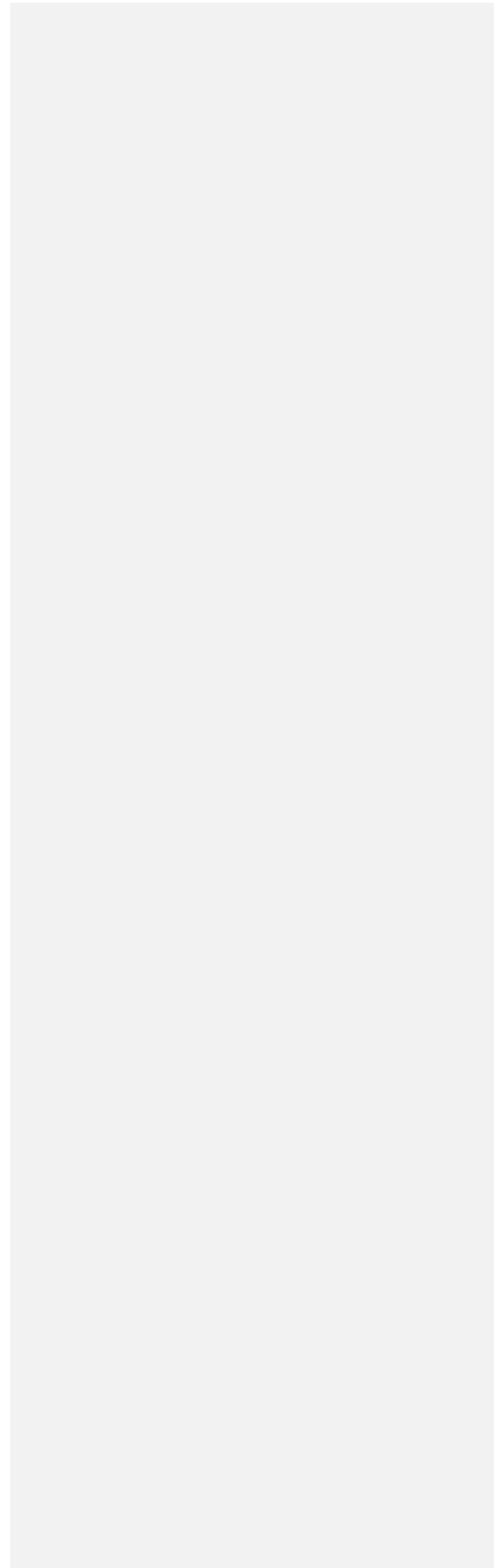
Division:	Medicines Regulation Division
Cleared by:	Nick Henderson s22
Contact Officer:	Tahli Fenner/Daniel Dascombe
Date:	<del>8X2613 January</del> November 20265

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ISSUE: COVID-19 Vaccines Deaths

Key Points:

- Every death that is reported to the TGA following a COVID-19 vaccination is reviewed to determine whether a regulatory response is necessary, based on the weight of evidence.
- The TGA does not determine cause of death - this is determined by coroners and treating doctors. The TGA does not 'overrule' the cause of death included on the death certificate.
- The causality assessment performed by the TGA is primarily concerned with the relationship between the COVID-19 vaccine and the adverse event that led to death. It is undertaken with the intention of appraising risk-benefit balance at a population-level for the specific vaccine under Australia's regulatory framework for therapeutic goods.
- The process is in line with the World Health Organization causality assessment for adverse events following immunisation framework, and international best practice in regulation of vaccines.
- This process is different to the determination of cause of death for an individual, which is appropriately undertaken by coroners and treating doctors.
- Regardless of the outcome of the individual causality assessment, all fatal adverse event reports are included in analyses to identify and investigate signals. The TGA does not remove any reports of death from the Database of Adverse Event Notifications (DAEN).
- I also note the following SQoNs that we've answered previously on this topic include:
  - SQ25-003155 - VSIGs for COVID-19 vaccines Covid VSIG
  - ◆ SQ25-003215 - Paediatric COVID-19 vaccines causing death
  - SQ24-003070 - Autopsy reports
  - SQ24-003119 - Reported deaths and autopsy reports
  - SQ24-000230 - COVID-19 Vaccine autopsies
  - ~~and~~ and SQ24-000234 - Autopsies and cause of death determination COVID-19 Vaccines - TGA FOI 4263 - Determinations on Cause of Death

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TGA review of fatal cases

- Every death following a COVID-19 vaccination that is reported to the TGA is reviewed to determine whether a regulatory response is necessary, based on the weight of evidence.
- The TGA considers the evidence for a causal link between the vaccine and the diagnosis.
- **Cause of death** is determined by coroners and treating doctors, not the TGA. The TGA does not 'overrule' the cause of death included on the death certificate.
- Regardless of the outcome of the individual causality assessment, all fatal adverse event reports are included in analyses to identify and investigate signals. The TGA does not remove any reports of death from the ~~Database of Adverse Event Notifications (DAEN).~~

Reported death vs causal link to vaccine

- Reporting of a death to the TGA does not mean the vaccine has caused the death, or the reporting doctor or individual considers the death was caused by a vaccine.
- The TGA strongly encourages consumers and health professionals to have a very low threshold for reporting suspected adverse events, even if there is only a very small chance a vaccine was the cause.

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- Under state and territory regulations in NSW, WA, QLD, NT and the ACT, it is mandatory for health professionals to report certain adverse events following immunisation.

#### Publication on mortality of COVID-19 vaccines in Victoria between 2021 and 2023

- This SAEFVIC article published in *Vaccine* in 2024 reviews fatal reports following COVID-19 vaccination in Victoria between 2021 and 2023.<sup>6</sup>
- The study found mortality reporting mostly reflected the health status of the population receiving COVID-19 vaccines. Fatal reports occurred in individuals that were aged over 60 years, lived in residential aged care facilities, and had known comorbidities relevant to the underlying cause of death.
- Notably, the majority of reports were categorised by the treating team and/or forensic pathologist as having a likely alternative cause of death.
- The article concluded careful review of deaths possibly associated with vaccination continues to be important to improve understanding of the safety of vaccines.

#### 2024 publication on deaths prevented in NSW due to COVID-19 vaccination

- A 2024 publication by Lin et al (2024)<sup>7</sup> assessed the impact of Australia's COVID-19 vaccination campaign. This study found in people over 50 years of age:
  - mortality rates were up to 11 times lower in vaccinated compared to unvaccinated individuals, with the level of protection greatest in people who received a booster dose, and
  - vaccination prevented an estimated 17,760 deaths between November 2021 to July 2022 in NSW alone.

#### Coronial inquest into myocarditis death s 22

- The TGA is aware that the Victorian Coroner held an inquest into this case.
- The TGA cannot comment on individual cases but can speak to the process used to assess individual adverse event reports. The TGA considers the evidence for a causal link between the vaccine and the reported adverse event. This regulatory causality assessment:
  - is not intended to determine the cause of death, which is the role of the coroner and treating health professional, but
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- Myocarditis is a known but rare adverse event associated with mRNA vaccines. This risk is included in the vaccines' Product Information (PI), including the potential for it to occur more frequently in younger males, noting it also occurs in females, and the possibility of severe outcomes including death.

#### Individual reports See [SQ24-003120](#) | Reported death from COVID-19 vaccine in relation to ADR 508851.

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- This review considers the strength of the evidence available and is not designed to determine if an event was linked, but rather whether the clinical conditions that led to a fatal outcome represent an emerging safety signal for the vaccine. If further information is required to complete the assessment it is requested from the reporter and/or the relevant state or territory health authority and/or coroner.
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#### **Australian Bureau of Statistics mortality data and excess deaths**

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- Independent analysis of Australian death data by the Actuaries Institute found that the timing, shape and age pattern of excess mortality does not support a link to vaccination.
- The Australian Institute of Health and Welfare (AIHW) report on 'Health system spending on the response to COVID-19 in Australia 2019-20 to 2021-22', demonstrated that Australia had one of the lowest global excess death rates (published November 2023):
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  - Excess mortality in Australia was 4.4% in this period, compared to an average excess mortality of 14% across 30 countries, including the USA and UK.
  - Global excess mortality data do not correlate with high vaccination rates - in general, countries with high vaccination rates had lower rates of excess mortality.
    - Noting a further study published by Lin et al. on 16 April 2024 found that Australia achieved one of the highest vaccination rates in the world, with more than 85% of its eligible population fully vaccinated with at least 2 doses.<sup>3</sup>
- [only if asked about discrepancy in number of reported deaths] The [Australian Bureau of Statistics](#) (ABS) underlying cause of death data include 16 deaths reported by a health professional or coroner as being a COVID-19 vaccine-related death: 0 in 2023; 15 in the 2021 report; and 1 in 2022. The TGA has confirmed all the COVID-19 vaccine-related deaths included in the ABS report are known to the TGA and have been included in the TGA's safety monitoring, even where no causal link has been found.
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**Reports in children**

- There are 9 adverse event reports with a fatal outcome following COVID-19 vaccination in children under 18 years of age in the TGA’s ~~Database of Adverse Event Notifications (DAEN – medicines)~~.
- Of the 9 reports, none ~~has~~ **have** been determined by the TGA to indicate a causal relationship between the vaccine and the adverse event.

**Batch safety**

- There is no evidence to suggest that any of the deaths reported to the TGA for a COVID-19 vaccine were related to a vaccine quality issue.

**DATA**

- Since the beginning of the vaccine rollout in early 2021 ~~to 31 December 2025~~, over ~~742~~ **million doses** of COVID-19 vaccine have been given in Australia. As at 31 ~~December~~ **October 2025**, the TGA has received ~~1,0523~~ adverse event reports with a fatal outcome. Of these, the number of **deaths in adults where the cause of death was** determined by the TGA to be related to COVID-19 vaccine-associated causes is **incredibly small**.
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adverse event, where a single adverse event report has the potential to change the entire positive benefit-risk balance of the vaccine.

- [A VSIG may be convened to provide specialist immunisation expertise to assist the TGA in investigating and/or managing adverse events following immunisation \(AEFIs\) or vaccine safety signals if certain criteria are met, namely: when an AEFI of concern or a safety signal of concern is identified, that the AEFI has the potential to change the favourable risk-benefit profile of the vaccine in a National or State immunisation program, or could threaten public confidence in vaccine safety, AND the case/s is/are considered eligible for assessment/investigation.](#)
- [The investigation of a single case report of a serious AEFI, including cases where death is reported as the outcome, is just one part of a broad and comprehensive system of pharmacovigilance for vaccines registered in Australia.](#)
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RECENT SQoNs

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- [SQ24-003120 - Reported death from COVID vaccine](#)
- [SQ24-003119 - Reported deaths and autopsy reports](#)
- [SQ24-000218 - Tracking batch number for reported deaths Does the TGA track reported deaths and adverse events by batch number?](#)
- [SQ24-000230 - COVID-19 Vaccines autopsies](#)
- [and SQ24-000234 - Autopsies and cause of death determination \(note both responses refer to previous SQoN responses\) COVID-19 Vaccines - TGA FOI 4263 - Determinations on Cause of Death](#)
- [SQ24-000230 - Deaths in children](#)
- [SQ24-000233 - Statements relating to causality and FOI 4205 \(time to death data\) COVID-19 Vaccines - TGA FOI 4205 - Database of Adverse Event Notifications \(DAEN\)](#)
- [SQ23-002226 - Reporting of COVID vaccine deaths](#)
- [SQ23-001134 - Deaths of children following covid vaccine](#)
- [and SQ23-001086 - Deaths of children following COVID vaccination and related FOI on topic FOI 4217 - Deaths of children under 18](#)

Commented s22 : please confirm if further recent SQoNs are relevant here

Commented s22 : Dan - I believe there were 3 QoNs last hearing, 2 of which s22 has included here, I don't think the other one is relevant to this brief (SQ25-003148 regarding vaccines and autism). Do you agree?

Commented s22 : Thanks s22 agree with this.

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OFFICIAL

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## HPRG - Senate Estimates Brief

- ~~IQ23-000058 – Doctor reported deaths~~
- SQ23-001101 – Follow up of reported death in the Australian ~~(24-year-old)~~
- SQ23-001074 – Temporal association between the rollout of the vaccine and excess deaths
- SQ23-000139 – ~~Causality assessments of the death of a 7 and 9 years old~~ ~~questions about reported deaths in a 7 and 9 year old~~
- SQ23-000140 – ~~Causality assessment of the 973 reports of deaths~~ ~~questions about TGA processes including documents released under FOI~~
- SQ22-000529 – ~~questions related to TGA processes for reviewing deaths,~~ COVID-19 Vaccine deaths
- SQ21-001218 – ~~Autopsies performed on deaths of patients recently vaccinated~~ ~~questions related to TGA processes; referred to by more recent SQoNs~~

Division:	Medicines Regulation Division
Cleared by:	Nick Henderson <del>s22</del>
Contact Officer:	Tahli Fenner/Daniel Dascombe
Date:	<del>8XX613 January November 20265</del>

OFFICIAL

**ISSUE: COVID-19 Vaccines Deaths****Key Points:**

- Every death that is reported to the TGA following a COVID-19 vaccination is reviewed to determine whether a regulatory response is necessary, based on the weight of evidence.
- The TGA does not determine cause of death - this is determined by coroners and treating doctors. The TGA does not 'overrule' the cause of death included on the death certificate.
- The causality assessment performed by the TGA is primarily concerned with the relationship between the COVID-19 vaccine and the adverse event that led to death. It is undertaken with the intention of appraising risk-benefit balance at a population-level for the specific vaccine under Australia's regulatory framework for therapeutic goods.
- The process is in line with the World Health Organization causality assessment for adverse events following immunisation framework, and international best practice in regulation of vaccines.
- This process is different to the determination of cause of death for an individual, which is appropriately undertaken by coroners and treating doctors.
- Regardless of the outcome of the individual causality assessment, all fatal adverse event reports are included in analyses to identify and investigate signals. The TGA does not remove any reports of death from the Database of Adverse Event Notifications (DAEN).
- I also note the following SQoNs that we've answered previously on this topic include:
  - SQ25-003155 - Covid VSIG
  - SQ25-003215 - Paediatric vaccines causing death
  - SQ24-003070 - Autopsy reports
  - SQ24-003119 - Reported deaths and autopsy reports
  - SQ24-000230 - COVID-19 Vaccine autopsies
  - SQ24-000234 - COVID-19 Vaccines – TGA FOI 4263 – Determinations on Cause of Death

**IF ASKED****TGA review of fatal cases**

- Every death following a COVID-19 vaccination that is reported to the TGA is reviewed to determine whether a regulatory response is necessary, based on the weight of evidence.
- The TGA considers the evidence for a causal link between the vaccine and the diagnosis.
- **Cause of death** is determined by coroners and treating doctors, not the TGA. The TGA does not 'overrule' the cause of death included on the death certificate.
- Regardless of the outcome of the individual causality assessment, all fatal adverse event reports are included in analyses to identify and investigate signals. The TGA does not remove any reports of death from the DAEN.

**Reported death vs causal link to vaccine**

- Reporting of a death to the TGA does not mean the vaccine has caused the death, or the reporting doctor or individual considers the death was caused by a vaccine.
- The TGA strongly encourages consumers and health professionals to have a very low threshold for reporting suspected adverse events, even if there is only a very small chance a vaccine was the cause.
- Under state and territory regulations in NSW, WA, QLD, NT and the ACT, it is mandatory for health professionals to report certain adverse events following immunisation.

**Australian Bureau of Statistics mortality data and excess deaths**

- **There is no credible evidence to suggest COVID-19 vaccines have contributed to excess deaths in Australia or overseas.** See 'AMPS Campaign' brief for details ([D25-5659012](#)).
- Independent analysis of Australian death data by the Actuaries Institute found that the timing, shape and age pattern of excess mortality does not support a link to vaccination.
- The Australian Institute of Health and Welfare (AIHW) report on 'Health system spending on the response to COVID-19 in Australia 2019-20 to 2021-22', demonstrated that Australia had one of the lowest global excess death rates (published November 2023):
  - Australia's excess mortality rate (2020-22) ranked 5<sup>th</sup> lowest of 31 studied countries.
  - Excess mortality in Australia was 4.4% in this period, compared to an average excess mortality of 14% across 30 countries, including the USA and UK.
  - Global excess mortality data do not correlate with high vaccination rates - in general, countries with high vaccination rates had lower rates of excess mortality.
    - Noting a further study published by Lin et al. on 16 April 2024 found that Australia achieved one of the highest vaccination rates in the world, with more than 85% of its eligible population fully vaccinated with at least 2 doses.<sup>1</sup>
- *[only if asked about discrepancy in number of reported deaths]* The Australian Bureau of Statistics' (ABS') underlying cause of death data include 16 deaths reported by a health professional or coroner as being a COVID-19 vaccine-related death: 0 in 2023; 15 in the 2021 report; and 1 in 2022. The TGA has confirmed all the COVID-19 vaccine-related deaths included in the ABS report are known to the TGA and have been included in the TGA's safety monitoring, even where no causal link has been found.
  - The difference in numbers is due to how the 2 agencies categorise deaths as being related to a COVID-19 vaccine.
  - The ABS uses the International Classification of Diseases (ICD) to code information on the cause of death identified by health professionals or coroner. There is an ICD code for COVID-19 vaccine-related deaths. Questions on how the cause of death is coded should be directed to the ABS.
  - The information in the ABS report does not change the known safety profile of the COVID-19 vaccines.

**Reports in children**

- There are 9 adverse event reports with a fatal outcome following COVID-19 vaccination in children under 18 years of age in the TGA's DAEN – medicines.
- Of the 9 reports, none have been determined by the TGA to indicate a causal relationship between the vaccine and the adverse event.

**Batch safety**

- There is no evidence to suggest that any of the deaths reported to the TGA for a COVID-19 vaccine were related to a vaccine quality issue.

---

<sup>1</sup>Lin L et al. (2024) Assessing the impact of Australia's mass vaccination campaigns over the Delta and Omicron outbreaks. *PloS One*, 19(4):e0299844. Available at: <https://pubmed.ncbi.nlm.nih.gov/38626045/>

**DATA**

- Since the beginning of the vaccine rollout in early 2021 to 31 December 2025, over **74 million doses** of COVID-19 vaccine have been given in Australia. As at 31 December 2025, the TGA has received 1,052 adverse event reports with a fatal outcome. Of these, the number of **deaths in adults where the cause of death was** determined by the TGA to be related to COVID-19 vaccine-associated causes is **incredibly small**.
- These deaths were associated with rare but serious adverse events and have occurred at a rate far lower than the risks associated with COVID-19 itself.
- Assessment by the TGA has determined 14 deaths associated with COVID-19 vaccinations:
  - 13 deaths were identified to have occurred after the first dose of Vaxzevria (AstraZeneca) as follows:
    - 8 thrombosis with thrombocytopenia syndrome (TTS)
    - 2 cases Guillain-Barré syndrome (GBS)
    - 2 rare neurological conditions
    - 1 case of immune thrombocytopenia.
- One death was identified as related to myocarditis after a booster dose of Spikevax (Moderna).
- A further 3 historic reports of possible vaccine-associated death have been identified from the published literature<sup>2</sup>. All 3 cases are reported as deaths related to TTS following administration of Vaxzevria in 2022. One case has been assessed by the TGA as having an alternative non-vaccine-related cause of death. There is insufficient information on the other 2 cases to determine whether they are duplicates of reports already provided to the TGA, so these have been included as cases in the TGA's adverse events management system.

**Important background for this data**

- Causality assessment undertaken by the TGA is primarily concerned with the relationship between the COVID-19 vaccine and the adverse event that led to death, undertaken with the intention of appraising risk-benefit balance for the specific vaccine under Australia's regulatory framework for therapeutic goods.
- The TGA can convene the Vaccine Safety Investigation Group (VSIG), a time-limited group of independent experts, to conduct formal causality assessments between a vaccine and a single adverse event, where a single adverse event report has the potential to change the entire positive benefit-risk balance of the vaccine.
- A VSIG may be convened to provide specialist immunisation expertise to assist the TGA in investigating and/or managing adverse events following immunisation (AEFIs) or vaccine safety signals if certain criteria are met, namely: when an AEFI of concern or a safety signal of concern is identified, that the AEFI has the potential to change the favourable risk-benefit profile of the vaccine in a National or State immunisation program, or could threaten public confidence in vaccine safety, AND the case/s is/are considered eligible for assessment/investigation.
- The investigation of a single case report of a serious AEFI, including cases where death is reported as the outcome, is just one part of a broad and comprehensive system of pharmacovigilance for vaccines registered in Australia.

<sup>2</sup> Clarke L et al. (2023) Vaccine-induced immune thrombotic thrombocytopenia post dose 2 ChAdOx1 nCoV19 vaccination: Less severe but remains a problem. *Vaccine*, 41(20): 3285-3291. Available at: <https://pubmed.ncbi.nlm.nih.gov/37085453/>

**HPRG - Senate Estimates Brief**

- Critical appraisal of the causal relationship between a vaccine and adverse event may also involve application of clinical and scientific expertise internally within the TGA without progressing to formal causality assessment via a VSIG.
- During the early years of the rollout of COVID-19 vaccines in Australia, the TGA convened the VSIG several times for conditions such as TTS and myocarditis. This was because the risk-benefit profile of COVID-19 vaccines were still being characterised, and therefore the potential impact of these conditions on that balance was unknown. Now that the safety profile of COVID-19 vaccines is well-established, and conditions such as myocarditis are well described in the Product Information (PI) documents and the risk mitigated in certain population groups who are most susceptible to these conditions, there is no regulatory purpose for confirming the relationship between the vaccine and the adverse event.
- It is extremely rare for a formal causality assessment process via the VSIG to identify a new safety signal from a single adverse event report, and to confirm beyond doubt that the vaccine caused the adverse event. The purpose of pharmacovigilance is to look for patterns in large numbers of adverse event reports to find new safety signals, and to confirm these signals using population level evidence, comparing rates of the adverse event following vaccination to background rates of the condition in the community (occurring separate to vaccination).

**RECENT SQoNs**

TGA has answered numerous SQoNs on this topic, including:

- SQ25-003155 - Covid VSIG
- SQ25-003215 - Paediatric vaccines causing death
- SQ24-003070 - Autopsy reports
- SQ24-003120 - Reported death from COVID vaccine
- SQ24-003119 - Reported deaths and autopsy reports
- SQ24-000218 – Does the TGA track reported deaths and adverse events by batch number?
- SQ24-000230 – COVID-19 Vaccines autopsies
- SQ24-000234 – COVID-19 Vaccines – TGA FOI 4263 – Determinations on Cause of Death
- SQ24-000233 – COVID-19 Vaccines – TGA FOI 4205 – Database of Adverse Event Notifications (DAEN)
- SQ23-002226 – Reporting of COVID vaccine deaths
- SQ23-001134 – Deaths of children following covid vaccine
- SQ23-001086 – FOI 4217 – Deaths of children under 18
- SQ23-001101 – Follow up of reported death in the Australian
- SQ23-001074 – Temporal association between the rollout of the vaccine and excess deaths
- SQ23-000139 – Causality assessments of the death of a 7 and 9 years old
- SQ23-000140 – Causality assessment of the 973 reports of deaths
- SQ22-000529 – COVID-19 Vaccine deaths
- SQ21-001218 – Autopsies performed on deaths of patients recently vaccinated

Division:	Medicines Regulation Division
Cleared by:	Nick Henderson <span style="background-color: #cccccc;">s22</span>
Contact Officer:	Tahli Fenner/Daniel Dascombe
Date:	14 January 2026

---

**From:** s22 [redacted]@health.gov.au>  
**Sent:** Tuesday, 6 January 2026 3:33 PM  
**To:** s22 [redacted]@Health.gov.au>  
**Cc:** s22 [redacted]@health.gov.au>; s22 [redacted]  
[redacted]@health.gov.au>; s22 [redacted]@health.gov.au>;  
s22 [redacted]@Health.gov.au>; s22 [redacted]  
[redacted]@health.gov.au>  
**Subject:** RE: FOR ACTION: Due COB Tuesday 13 January - Senate Estimates - Additional  
Estimates 2025-2026 - Back Pocket Briefs (BPBs) [SEC=OFFICIAL]

OFFICIAL

Hi s22 [redacted],

I have updated/confirmed the AE report numbers for the COVID-19 vaccine s22 [redacted]  
s22 [redacted] briefs highlighted for AEMDS inputs.

s22

s22

s22

MRD	Title	TRIM	Lead area	Other input	AEMDS Comments/actions
8.	COVID-19 Vaccine Deaths	<a href="#">D25-5659081</a>	PB - Dan	<ul style="list-style-type: none"><li>AEMDS usually provides input as to AE numbers (noting unlikely to have changed but will need confirmation)</li></ul>	<ul style="list-style-type: none"><li>AEMDS has updated/confirmed the data on number of fatal AE reports up to 31 Dec 2025-based Qlik-AEMS app search conducted on 06 Jan 2026.</li><li>Data on doses and causal relationship etc, to be confirmed by VSS.</li></ul>

s22



OFFICIAL

**From:** s22 [redacted]@health.gov.au>  
**Sent:** Monday, 5 January 2026 2:55 PM  
**To:** s22 [redacted]@health.gov.au>; s22 [redacted]@health.gov.au>  
**Cc:** s22 [redacted]@health.gov.au>; s22 [redacted]@health.gov.au>; s22 [redacted]@health.gov.au>; s22 [redacted]@health.gov.au>; s22 [redacted]@Health.gov.au>; s22 [redacted]@health.gov.au>  
**Subject:** FOR ACTION: Due COB Tuesday 13 January - Senate Estimates - Additional Estimates 2025-2026 - Back Pocket Briefs (BPBs) [SEC=OFFICIAL]

OFFICIAL

Happy New Year!

In preparation for the upcoming **Additional Estimates**, commencing on **9<sup>th</sup> February 2026**, it is time to update the Dep Sec-confirmed HPRG Back Pocket Briefs (BPBs).

**BPB drafting requirements:**

- MRD's BPBs are listed in the table below: this includes links to each BPB copied from the cleared version drafted in December.
- We have one **NEW** BPB, which is an amalgamation of 2 BPBs from the last Senate Estimates session. Content Manager links to the 2 old BPBs are in the table below.
- Update the BPBs in TRIM **using Track Changes** – please ensure the date is updated in the bottom of the document
  - **NOTE: It is the responsibility of the lead area to seek cleared input from other areas. The lead area is to collate all cleared information from other areas before sending to the FAS office.**
- The data cut-off date for BPBs is as of **31 December 2025**
- Previously cleared wording from briefs and Questions on Notice (QoNs) are available in the previous **OneNote - December 2025** and TRIM **E25-578516**

[redacted]

All text must be **black, size 11 and in Calibri.**

**BPB deadline:**

- AS clearance is due to @22 by **COB Tuesday 13 January 2026** to allow time for FAS and Dep Sec clearance.

**Please note:**

- HIBs and QTBs are being handled separately and updates to the BPB Index will be actioned by HPRG Parli as required
- MRD's Additional Information and FAS-level briefs will be circulated tomorrow.

Kind regards,

s22

MRD	Title	TRIM	Lead area	Other input
8.	COVID-19 Vaccine Deaths	<a href="#">D25-5659081</a>	PB - Dan	<ul style="list-style-type: none"> <li>• AEMDS usually provides input as to AE numbers (noting unlikely to have changed but will need confirmation)</li> </ul>

s22





**From:** [LAWLER, Tony](#)  
**To:** [s22](#)  
**Cc:** [s22](#)  
**Subject:** RE: For clearance 23/1: Senate Estimates DS Briefs [SEC=OFFICIAL:Sensitive]  
**Date:** Thursday, 22 January 2026 11:47:58 AM

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OFFICIAL:Sensitive

Thank [s22](#) - all cleared now I think!

Additional Estimates – February 2026 – INDEX: All HPRG Briefs				
Back Pocket Briefs (BPBs) Question Time Briefs (QTBs) and Hot Issues Briefs (HIBs)	Link	Comments / cleared	TL Comments	
MRD				
<a href="#">s22</a>				
8.	COVID-19 Vaccine Deaths	<a href="#">D25-5659081</a>	Ready for clearance	Cleared, there were no changes

[s22](#)









**From:** [Trim Admin](#)  
**To:** [DASCOMBE, Daniel](#)  
**Subject:** TRIM Content Manager Notification - Action Made Current. Approval / Authorisation [SEC=OFFICIAL]  
**Date:** Thursday, 8 January 2026 12:31:49 PM  
**Attachments:** [HPRG BACK POCKET BRIEFS - MRD - COVID-19 Vaccines Deaths.tr5](#)

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OFFICIAL

Record number: D25-5659081  
Record title: HPRG BACK POCKET BRIEFS - MRD - COVID-19 Vaccines Deaths  
Action: Approval / Authorisation  
Responsible location: Dascombe, Daniel  
Due date: 12/01/2026 at 1:31 PM

File Notes:

This Action has been recently created and assigned to you and is due to be started on 08/01/2026 at 1:31 PM. Could you please ensure that it is completed by 12/01/2026 at 1:31 PM.

When you are ready to record in TRIM Content Manager that you have completed the action, right click on the record and select Workflow > Complete Current Action.

--

This email message has been automatically generated by Content Manager (DOHA PRODUCTION).

OFFICIAL

OFFICIAL:Sensitive

**From:** s22  
**Sent:** Monday, 19 January 2026 3:55 PM  
**To:** LAWLER, Tony s22 @Health.gov.au>  
**Cc:** s22 @Health.gov.au>  
**Subject:** For clearance 23/1: Senate Estimates DS Briefs

Hi Tony

First batch of SE Briefs for your review and clearance please.

Thanks

s22

**Additional Estimates – February 2026 – INDEX: All HPRG Briefs**

Back Pocket Briefs (BPs) Question Time Briefs (QTBs) and Hot Issues Briefs (HIBs)	Link	Comments / cleared
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MRD

s22

8.	COVID-19 Vaccine Deaths	<a href="#">D25-5659081</a>	Ready for clearance
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s22





OFFICIAL:Sensitive

**From:** LAWLER, Tony [s22 \[redacted\]@Health.gov.au](#)>  
**Sent:** Tuesday, 20 January 2026 10:09 PM  
**To:** [s22 \[redacted\]@health.gov.au](#)>  
**Cc:** [s22 \[redacted\]@Health.gov.au](#)>  
**Subject:** RE: For clearance 23/1: Senate Estimates DS Briefs [SEC=OFFICIAL:Sensitive]

OFFICIAL:Sensitive

Thanks

Update of progress on full list as below- I have reviewed all the ones with me.

<b>Additional Estimates – February 2026 – INDEX: All HPRG Briefs</b>	
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Back Pocket Briefs (BPBs) Question Time Briefs (QTBs) and Hot Issues Briefs (HIBs)	Link	Comments / cleared	TL Comments	
MRD				
<div data-bbox="194 353 272 396" data-label="Text">s22</div>				
8.	COVID-19 Vaccine Deaths	<a href="#">D25-5659081</a>	Ready for clearance	Cleared, there were no changes

s22











From: s22  
 To: s22 ; s22 ; s22 ; s22 ; s22 ; s22 ; s22 ;  
 s22 ; s22 ; s22 ; s22 ; s22 ; s22 ;  
 Subject: Cleared DS SE briefs! [SEC=OFFICIAL:Sensitive]  
 Date: Thursday, 22 January 2026 7:14:37 PM  
 Attachments: s22

OFFICIAL:Sensitive

Team, we are all done! A whole day early

Thank you all for all your assistance with this estimates process. Big shout out to our parli team for keeping us all organised and informed, and for the huge effort to coordinate this process. I know there is still lots of work to come in preparing the folders and getting ready for the day, thank you!!

Also to our new and acting crew, s22, well done! Estimates is a bit of a trial by fire and you all nailed it.

I really enjoyed reading your briefs and learning more about what our group does.

s22

Additional Estimates – February 2026 – INDEX: All HPRG Briefs			
Back Pocket Briefs (BPBs) Question Time Briefs (QTBs) and Hot Issues Briefs (HIBs)	Link	Comments / cleared	
<b>MRD</b>			
s22			
8.	COVID-19 Vaccine Deaths	<a href="#">D25-5659081</a>	Cleared

s22







**From:** s22  
**To:** s22  
**Cc:** s22 ; s22  
**Subject:** RE: CMO prep for ASE [SEC=OFFICIAL]  
**Date:** Monday, 9 February 2026 9:04:51 AM  
**Attachments:** [Additional Budget Estimates – February 2026 – INDEX - All HPRG Briefs.DOCX](#)  
[image001.png](#)  
[image002.png](#)  
[image003.png](#)

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Hi s22 ,

Pretty much all our briefs have been updated, and they've all been Dep Sec cleared. I've attached our index which contains the CM links for our briefs so you can just pop into that and print out the ones you would like.

Please let me know if you would like any of the HIBs/ QTBs and I can send those to you.

Cheers,

s22

s22

s22

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Health Products Regulation Group

Australian Government, Department of Health, Disability and Ageing

: s22 | : s22 @health.gov.au

This email comes to you from Ngunnawal Country

Location: 27 Scherger Drive Fairbairn, Level 2

*I may send emails out of hours at a time that suits me. I look forward to receiving your response during your normal working hours.*

*The Department of Health, Disability and Ageing acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.*



s22

# Additional Budget Estimates – February 2026

## INDEX: All HPRG Briefs

s22

Back Pocket Briefs (BPBs) Question Time Briefs (QTBs) and Hot Issues Briefs (HIBs)

s22

8.	COVID-19 Vaccine Deaths	<a href="#">D25-5659081</a>
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s22





s22



OFFICIAL

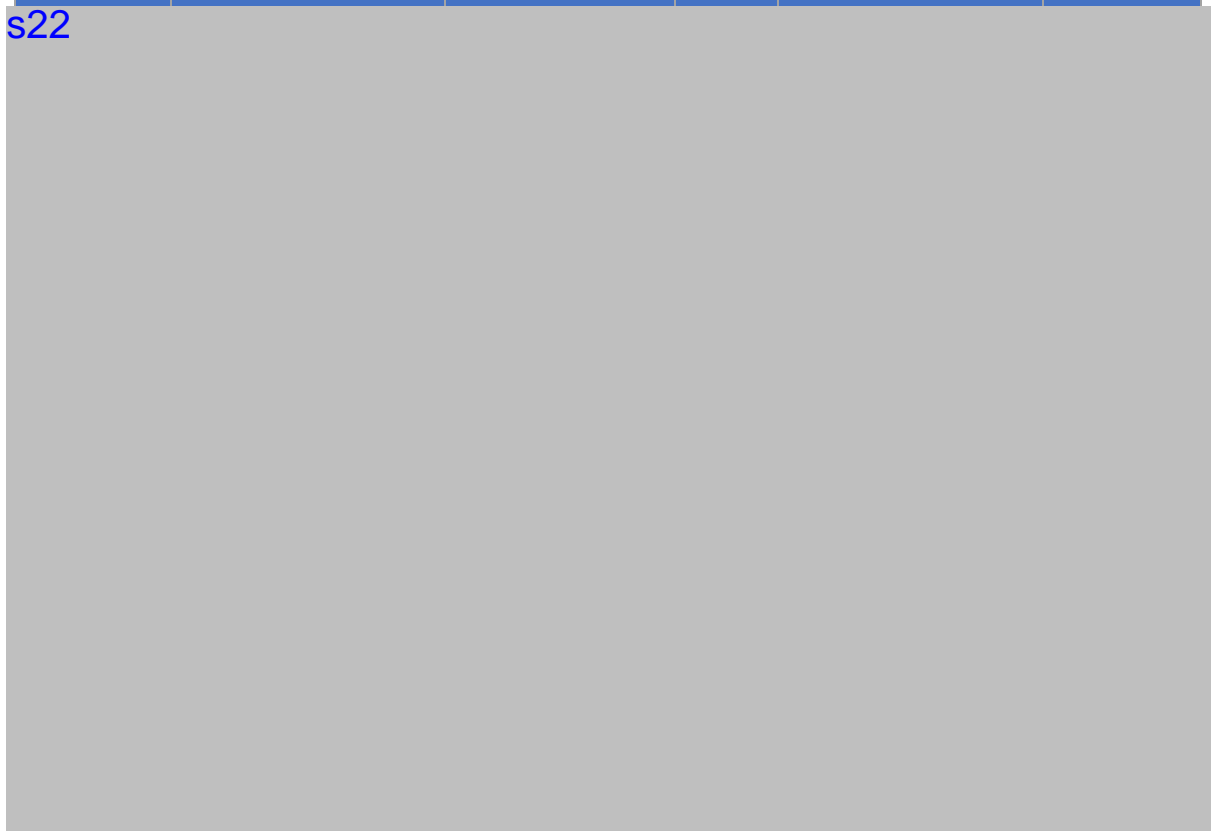
**From:** s22  
**Sent:** Friday, 30 January 2026 3:34 PM  
**To:** HENDERSON, Nick  
**Cc:** s22  
**Subject:** Current state of SE briefs [SEC=OFFICIAL]

OFFICIAL

Hi Nick,  
Please see an updated table of SE briefs.

	Back Pocket Briefs (BPs), Question Time Briefs (QTBs) and Hot Issue Briefs (HIBs)				
MRD		Content Manager	Lead area	Other input	Status

s22



s22



8.	COVID-19 Vaccine Deaths	<a href="#">D25-5659081</a>	PB - Dan	AEMDS - usually provides input as to AE numbers (noting unlikely to have changed but will need confirmation) Labs (batch info)	With Dep Sec EO
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s22











Kind regards,

s22  
s22  
s22  
Medicines Regulation Division

Medicines Regulation Division | Health Products Regulation Group  
Australian Government, Department of Health, Disability and Ageing  
T: s22 | E: s22@health.gov.au  
This email comes to you from Ngunnawal Country  
Location: s22

PO Box 100, Woden ACT 2606, Australia



*The Department of Health, Disability and Ageing acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.*

OFFICIAL

**From:** s22  
**To:** s22 ; s22  
**Cc:** s22 ; s22 ; s22 ; s22 ; s22  
**Subject:** FOR ACTION: Due COB Tuesday 13 January - Senate Estimates - Additional Estimates 2025-2026 - Back Pocket Briefs (BPBs) [SEC=OFFICIAL]  
**Date:** Monday, 5 January 2026 3:54:52 PM  
**Attachments:** [image001.png](#)  
[image002.jpg](#)  
[image003.jpg](#)  
[image006.jpg](#)  
[image007.jpg](#)

OFFICIAL

Happy New Year!

In preparation for the upcoming **Additional Estimates**, commencing on **9<sup>th</sup> February 2026**, it is time to update the Dep Sec-confirmed HPRG Back Pocket Briefs (BPBs).

**BPB drafting requirements:**

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- We have one **NEW** BPB, which is an amalgamation of 2 BPBs from the last Senate Estimates session. Content Manager links to the 2 old BPBs are in the table below.
- Update the BPBs in TRIM **using Track Changes** – please ensure the date is updated in the bottom of the document
  - **NOTE: It is the responsibility of the lead area to seek cleared input from other areas. The lead area is to collate all cleared information from other areas before sending to the FAS office.**
- The data cut-off date for BPBs is as of **31 December 2025**
- Previously cleared wording from briefs and Questions on Notice (QoNs) are available in the previous [OneNote - December 2025](#) and TRIM [E25-578516](#)
- All text must be **black, size 11 and in Calibri.**

**BPB deadline:**

- AS clearance is due to @s22 by **COB Tuesday 13 January 2026** to allow time for FAS and Dep Sec clearance.

**Please note:**

- HIBs and QTBs are being handled separately and updates to the BPB Index will be actioned by HPRG Parli as required
- MRD's Additional Information and FAS-level briefs will be circulated tomorrow.

Kind regards,

s22

MRD	Title	TRIM	Lead area	Other input
8.	COVID-19 Vaccine Deaths	<a href="#">D25-</a>	<b>PB</b> - Dan	<ul style="list-style-type: none"> <li>● AEMDS usually provides</li> </ul>

		5659081		input as to AE numbers (noting unlikely to have changed but will need confirmation)
--	--	---------	--	--

s22









**From:** [DASCOMBE, Daniel](#)  
**To:** [s22](#)  
**Cc:** [s22](#); [s22](#); [s22](#); [s22](#); [s22](#)  
**Subject:** For FAS review/Clearance: BPBs for February Estimates [SEC=OFFICIAL]  
**Date:** Monday, 12 January 2026 4:28:46 PM  
**Attachments:** [image001.png](#)

---

OFFICIAL

Dear [s22](#),

With many thanks to VSS, the following BPBs are now ready for FAS review/clearance, ahead of the February Estimates hearing:

- COVID-19 vaccine deaths: [D25-5659081](#).
- [s22](#).
- [s22](#)
- [s22](#)

[s22](#)

Thanks a lot for your assistance, and let us know if you'd like to discuss further,

Dan

**Dr Daniel Dascombe** BPharm MChD MPHTM DCH FRACGP  
**A/g Principal Medical Adviser**  
**Pharmacovigilance Branch**

Medicines Regulation Division | Health Products Regulation Group  
Australian Government Department of Health, Disability and Ageing  
T: [s22](#) | E: [s22](#)@health.gov.au

This email comes to you from Ngunnawal Country

Location: [s22](#)

PO Box 9848, Canberra ACT 2601, Australia

*The Department of Health, Disability and Ageing acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.*

OFFICIAL

s22

OFFICIAL

**From:** s22  
**Sent:** Wednesday, 14 January 2026 1:14 PM  
**To:** HENDERSON, Nick  
**Cc:** s22  
**Subject:** UPDATED - For review and clearance - SE briefs [SEC=OFFICIAL]

OFFICIAL

Hi Nick,  
Updated table of briefs for your review and clearance are below.

s22

Title	Content Manager	Lead area	Comments
COVID-19 Vaccine Deaths	<a href="#">D25-5659081</a>	PB - Dan	Ok, I'm also all good with the proposed deletions

s22



OFFICIAL

**From:** s22 [redacted] <[redacted]@health.gov.au>  
**Sent:** Monday, 12 January 2026 4:17 PM  
**To:** HENDERSON, Nick s22 [redacted] <[redacted]@health.gov.au>  
**Cc:** s22 [redacted] <[redacted]@health.gov.au>  
**Subject:** For review and clearance - SE briefs [SEC=OFFICIAL]

OFFICIAL

Hi Nick,  
Updated lists below, for review and clearance, please.  
Thanks,  
s22 [redacted]

Back Pocket Briefs	Content Manager	Lead area	Comments
COVID-19 Vaccine Deaths	<a href="#">D25-5659081</a>	PB - Dan	



**From:** s22  
**To:** s22  
**Cc:** s22, s22  
**Subject:** For Dep Sec review and clearance - Senate Estimates - Additional Estimates 2025-2026 - Back Pocket Briefs (BPBs)  
**Date:** Wednesday, 14 January 2026 5:27:00 PM

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Hi s22

Please find MRD's first 4 FAS-cleared BPBs in the table below for Dep Sec review and clearance, please.

Thanks

s22

Title	Content Manager
COVID-19 Vaccine Deaths	<a href="#">D25-5659081</a>

s22



OFFICIAL

**From:** s22 [redacted]  
**Sent:** Friday, 16 January 2026 11:07 AM  
**To:** s22 [redacted]  
**Cc:** s22 [redacted]  
**Subject:** RE: FOR ADVICE: February Senate Estimates - vaccine safety briefing request  
 [SEC=OFFICIAL]

OFFICIAL

Morning,  
 Sorry it has taken a while to get back to you about this.  
 The BPBs in the table below could be of use to ATAGI – they aren’t Dep Sec cleared yet  
 though (but are FAS cleared), s22 [redacted]

Assuming we don’t need to get permission to share these?

Kind regards,

s22 [redacted]

COVID-19 Vaccine Deaths	<a href="#">D25-5659081</a>
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s22

