



COVID-19 Vaccine Claims Scheme

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General

1. What is the COVID-19 Vaccine Claims Scheme?

The COVID-19 Vaccine Claims Scheme (the Scheme) will enable eligible claimants who have received a TGA approved COVID-19 vaccine to obtain compensation for a number of recognised moderate to severe vaccine-related adverse effects (clinical conditions, including deaths from these conditions) or vaccine administration injuries. The Government is establishing a fit for purpose, time limited claims Scheme to respond to the unprecedented circumstances of the COVID-19 pandemic. The time limited Scheme, specific for TGA approved COVID-19 vaccines will provide eligible claimants with an administrative option to seek compensation rather than a complex and costly court process. The Scheme has been established through an authority via the *Financial Framework* (Supplementary Powers) Regulations 1997 which will be supported by publicly available guidelines setting out the Scheme policy.

2. Will this be expanded to all vaccinations?

No. The Scheme relates only to TGA approved COVID-19 vaccinations.

It is part of a range of specific Government responses to assist Australia on the pathway out of the COVID-19 pandemic.

The Scheme is intended to be a time-limited, targeted measure that will only cover moderate to severe TGA approved COVID-19 vaccine related adverse effects (clinical conditions) or vaccine administration injuries, not conditions or injuries resulting from having other vaccines such as seasonal influenza vaccines. The Scheme will apply to TGA approved COVID-19 vaccines received by an eligible person from an approved healthcare practitioner since the start of the vaccine rollout (22 February 2021). Vaccinations and claims for compensation will be accepted up to two years after the end of the Human Biosecurity Emergency period under the *Biosecurity Act 2015*.

3. How will the Scheme work?

The Scheme will provide compensation to eligible claimants who meet the threshold of \$1,000 out of pocket costs and/or lost earnings and carer costs (both past and future). The list of recognised adverse effects for claims purposes under the Scheme includes:

- clinical conditions that are diagnosed by a treating doctor and are included in the <u>Product</u> <u>Information</u> document for the specific vaccine as listed in Table 1 below; and
- administration related injuries which are a clinically diagnosed:
 - o shoulder injury; or
 - other moderate to significant physical injury giving rise to permanent impairment or the need for an extended period of medical treatment but excluding the injuries in Table 2

Table 1 - Adverse effects covered by the Scheme - Clinical conditions

Clinical Condition	Applicable Vaccine(s)
Anaphylactic reaction	AstraZeneca Pfizer Moderna
Thrombosis with Thrombocytopenia Syndrome	AstraZeneca
Myocarditis	Pfizer Moderna
Pericarditis	Pfizer Moderna
Capillary leak syndrome	AstraZeneca
Demyelinating disorders including Guillain Barre Syndrome (GBS)	AstraZeneca
Thrombocytopenia, including immune Thrombocytopenia, identified as a final diagnosis	AstraZeneca

Notes:

- 1. The first four rows in this table comprise conditions that are included in the product information for which a causal link to vaccination with a COVID-19 vaccine has been established.
- 2. The final three rows comprise conditions that are included in the product information for which causality has not been established at a population level, but that could potentially be caused by the vaccine and are recognised in the Australian approved Product Information document.

Table 2 – adverse effects and Injuries NOT covered by the Scheme

- a) COVID-19;
- b) psychological and psychiatric conditions (e.g. shock);
- c) secondary injuries (e.g. injury suffered when fainting, or a haematoma at the injection site that becomes infected); and
- d) the following other symptoms unless they form part of the symptom complex of a clinical condition listed in Table 1: headache; fatigue; injection site reaction; muscle or joint pain; dizziness; diarrhoea; pain in extremity; fever; insomnia; nausea; vomiting; lethargy; hyperhidrosis; chills; decreased appetite; malaise; lymphadenopathy; somnolence; abdominal pain; puritus; urticaria/rash; influenza-like illness; angioedema; anxiety-related reactions such as hyperventilation and fainting.

Claimants will need to provide information and evidence about the nature and cause of their clinical condition, injury, or the person's death, and the amount of their loss, in support of their application.

4. My claim relates to a clinical condition in Table 1. Is this automatically covered by the Scheme?

The Scheme is specific to a list of adverse effects and injuries relating to medically diagnosed clinical conditions considered likely to be related to a TGA-approved COVID-19 vaccination. The treating doctor will need to provide an opinion that the condition is most likely caused by the COVID-19 vaccine as part of the patient's diagnosis.

5. My claim relates to an injury received when the vaccine was administered. Is this covered by the Scheme?

If the harm relates to the administration of the vaccine, the same evidence requirements would apply from the patient's treating doctor (rather than the vaccine administrator). The claim would be referred to a panel of independent legal experts for assessment, who will make a recommendation regarding whether compensation should be paid, and if so the amount.

6. Who is eligible under the Scheme?

The Scheme is open to those vaccinated in Australia and individuals vaccinated overseas under the Australian Government Overseas Network (AGON) COVID-19 vaccination rollout managed by DFAT and Defence who:

- received a TGA approved COVID-19 vaccine;
- suffered moderate to significant harm or death caused by the vaccine or the administration of the vaccine:
- meet the minimum threshold of \$1,000 in out of pocket costs or lost income and carers costs (both past and future); and
- was hospitalised.

The hospitalisation requirement may be waived if outpatient treatment was received and the COVID-19 Vaccine Recipient was not admitted to hospital, when they otherwise would have been, because:

- of the nature of their clinical condition or harm; or
- the recipient was in a rural or remote area making it difficult to access a hospital.

The hospitalisation requirement does not apply in the case of death.

7. Are there different levels of eligibility for compensation under the Scheme?

The Scheme eligibility is broken up into three tiers.

Eligible Claimant for a Tier 1 claim, is a person who:

- received a COVID-19 Vaccine
- suffered a recognised clinical condition or injury covered by the scheme

- suffered Loss totalling between \$1,000 and \$19,999
- was hospitalised.
- Meets the evidence requirements including their treating doctor's statement confirming the diagnosis and link to vaccination.

Eligible Claimant for a Tier 2 claim, is a person who:

- received a COVID-19 Vaccine
- suffered a recognised clinical condition or injury covered by the scheme
- was hospitalised
- suffered Loss totalling \$20,000 or more.
- Meets the evidence requirements including their treating doctor's statement confirming the diagnosis and link to vaccination.

Eligible Claimant for a Tier 3 claim, is the Executor or an Administrator of the Estate of the Deceased. Eligibility requirements

- Presents the death certificate of the deceased listing the cause(s) of death.
- received a COVID-19 Vaccine
- suffered a recognised clinical condition or injury covered by the scheme
- Meets the evidence requirements including a statement from a treating doctor of the deceased confirming the condition(s) that led to death and link to vaccination.

Where a claimant is a minor or suffers from some incapacity, a claim may be made by a guardian on that person's behalf.

8. Is the Scheme only available to Australian citizens?

No, Australian citizenship is not an eligibility requirement. The Scheme is open to those vaccinated with a TGA approved COVID-19 vaccine, by an authorised healthcare practitioner under the national COVID-19 vaccine rollout program or those vaccinated under the AGON vaccine rollout program.

9. Which COVID-19 vaccinations does the Scheme cover?

The Scheme covers all COVID-19 vaccinations that have been provisionally approved by the Therapeutic Goods Administration. This includes Vaxzevria (AstraZenecca Pty Limited), Comirnaty (Pfizer Australia Pty Limited) and Spikevax (Moderna Pty Limited) that are currently supplied in Australia.

10. Am I eligible if I have already had my vaccination?

Yes. To ensure no person who has already been vaccinated is disadvantaged, the Scheme will apply to all TGA approved COVID-19 vaccinations delivered by authorised healthcare practitioners to eligible persons from the start of the vaccine rollout which commenced on 22 February 2021.

11. How long does the Scheme run for?

The Scheme will remain open for two years after the human biosecurity emergency period under the *Biosecurity Act 2015* ends. You will be able to receive your vaccination and submit a claim for compensation within two years after the official end of the emergency period.

12. Do I need to identify who caused the harm?

A person making the claim does not need to establish that anyone in particular was at fault. However, the claimant must provide evidence detailed in the Scheme Policy to establish that the harm (or a person's death) was likely caused by a TGA approved COVID-19 vaccine or its administration.

13. When can a claim be made?

Since 6 September 2021, potential claimants have been able to register their interest in claiming through a link located on the Department of Health website at COVID-19 vaccine claims scheme | Australian Government Department of Health.

It is anticipated that eligible claimants will be able to submit a claim for compensation to Services Australia from mid-December 2021.

All those who have registered an interest in claiming with the Department of Health will be notified when the online portal opens. Individuals who have registered their interest must also submit a claim in order to be eligible to receive compensation.

It is not necessary to register your intent to claim before submitting a claim.

14. What compensation will be paid?

Compensation will be determined based on the circumstances of the individual, which may include an amount for lost earnings, care services, out of pocket costs and pain and suffering.

The compensation arrangements where death has been caused by a clinical condition most likely linked to a TGA approved COVID-19 vaccine or its administration will be assessed by the Independent Expert Panel.

15. What sort of evidence will be required?

The Scheme will require eligible claimants to submit three types of evidence to Services Australia in support of their claim. In addition, the claimant will need to provide authorisation to Services Australia to access relevant internal Government records in order to verify the accuracy of the information provided. The evidence that will need to be submitted includes:

- Information to confirm that the claimant received a COVID-19 vaccine e.g. COVID-19
 digital certificate or approval for Services Australia to access their vaccination information on
 the Australian Immunisation Record (AIR).
- A medical report from their treating doctor or hospital physician with the treating doctor's opinion on the diagnosed condition or injury and likely link to vaccination. This medical report will also include information about the healthcare needs, the duration of hospitalisation

and any ongoing medical care requirements. This will enable the decision maker to be satisfied that the claim is for a clinical condition or injury covered by the Scheme and that the treating doctor confirms that the vaccination is the most likely cause.

 Documents verifying any financial losses the claimant alleges were caused or suffered because of the harm – e.g. a schedule of treatment expenses, details of salary or income foregone or other costs incurred, including care costs. This must also include evidence of other financial support already received, e.g. workers' compensation payments, Medicare rebates, income support payments, paid leave entitlements or a statement that any such payments have been deducted from the amount of compensation sought.

In order to assess the claimant's entitlement in relation to pain and suffering, and/or future loss, additional information will also be required, including:

- the duration and severity of symptoms and extent of recovery to enable the decision maker to determine an amount of compensation for pain and suffering; and
- if applicable, information as to the:
 - o nature and expected cost of future medical treatments and the period such treatment is expected to be required; and
 - o the period that the claimant will be restricted in their ability to work.

If the person who received the vaccine has died, the Executor or Administrator of the estate is entitled to lodge a claim under the Scheme (however, a family member may commence the process).

Additional evidence will also be required to establish that the claimant is the Executor or Administrator and a copy of the deceased death certificate establishing the cause(s) of death as one of the claimable clinical conditions.

16. How is my claim assessed?

Where the claim is for an amount from \$1,000 up to \$19,999.99, Services Australia will assess the claim against the eligibility criteria and evidence and make a recommendation to an authorised delegate within Services Australia, as the administrator of the Scheme.

Claims for \$20,000 and above will be assessed by a panel of independent legal experts, and complex claims below this amount may also be referred to the panel. A member of the panel will review the claim and may seek additional evidence or advice, including from the claimant, the Department of Health or a medical expert, before making a recommendation to an authorised delegate within Services Australia regarding whether compensation should be paid and if so, the amount.

Claimants will need to agree to authorise Services Australia to access relevant information in order to verify and assess the claim. This may include patient data held in the Australian Immunisation Register, and other relevant bodies such as the Department of Health, including the TGA, as well as the health practitioner or organisation who administered the vaccine and the hospital where the claimant was hospitalised.

17. What if some or all of my time off work was paid as sick leave? Am I still eligible for reimbursement?

The Scheme will provide compensation for expenses and losses actually incurred by the claimant. It does not cover amounts paid by third parties (such as Medicare, private health insurers, etc.) nor does it cover leave for which you have been paid leave entitlements (such as sick leave) or have received other Government payments (such as COVID emergency payments).

18. Is compensation capped?

No, the Scheme does not have an overall cap on the compensation that may be paid to an eligible claimant, however guidance will be provided to the panel consistent with compensation payments under the *Civil Liability Act* (NSW). The intention is to ensure consistency in compensation payments awarded by specifying guidance for the different categories of loss (lost earnings, care services, out of pocket expenses, pain and suffering). The panel may make a determination outside of the guidance if they feel it is appropriate in their professional opinion.

19. What is the tax treatment?

The taxation treatment of any compensation paid under the Scheme is a matter to be determined in accordance with applicable taxation laws. Claimants should consider obtaining professional or legal advice on the appropriate tax treatment of any payments they receive under the Scheme.

20. Will there be any conditions placed on me if I accept a payment under the Scheme?

Yes. If you agree to accept compensation under the Scheme, you will need to agree in writing to repay any further compensation received (up to the amount of that compensation) for the same clinical condition or harm from someone else (e.g. from a workers' compensation insurer). A principle of the Scheme is that a person is not compensated twice for the same harm.

21. Will decisions be made public?

No, privacy provisions will protect claimants' information, including the outcomes from being made public. Claimants are encouraged to also report their experience to the TGA to help with ongoing safety monitoring of the vaccine.

22. Who pays?

The Commonwealth will make all payments to claimants and for the administration of the Scheme.

23. Will the Scheme reimburse costs to individuals who choose to pursue a claim through the courts?

No. The Scheme will not cover the costs to individuals who choose to pursue a claim through the courts.

Although people won't be prevented from taking action through the courts, the Scheme has been designed as a faster and simpler alternative to legal proceedings.

24. What happens if a person pursues a claim through a court process. Are they able to claim through the Scheme?

The intent of this Scheme is to provide patients with quicker access to compensation that would be similar to what is awarded through a court process. If a person has received payment under the Scheme and subsequently received a payment through a court process in relation to the same injury, they will be required to pay money back to the Scheme.

25. What happens if there has been harm caused in the administration of the vaccine?

In the event an Assessor considers, as a result of the information available in relation to a Claim, that there may have been harm caused by a registered health practitioner in the administration of the COVID-19 Vaccine received by the COVID-19 Vaccine Recipient, they may recommend a referral to the Australian Health Practitioner Regulation Agency (AHPRA) for a review of the practitioner's conduct or performance by the relevant professional board.

Unsatisfactory conduct or performance is relatively rare however these steps are in keeping with the Commonwealth's intention that health practitioners continue to practise with skill and diligence and to promote confidence in the population being vaccinated. These measures will support the integrity of the COVID-19 vaccination program and the Scheme itself.

26. Can I apply for compensation under the Scheme if I am also obtaining benefits under the National Disability Insurance Scheme (NDIS)?

The Scheme will not prevent an individual who receives compensation from accessing the NDIS but the amount received through the NDIS might be affected.

Business Focused

27. How do state based workers compensation arrangements interact with the COVID-19 Vaccine Claims Scheme? For example, can you only claim for vaccination injuries under the Scheme?

The intent of the Scheme is not to replace existing workers compensation arrangements. It also does not remove an individual's right to pursue workers compensation if eligible or seek to litigate in relation to an adverse outcome from vaccination. However, the Scheme will provide claimants with a more efficient administrative option to seek compensation and an outcome similar to a court process, rather than having to undertake a complex and costly court process.

Should a patient seek and receive workers' compensation payments related to an adverse reaction to a TGA approved vaccine, any payments received by way of workers' compensation would be taken into account so that the claimant is not compensated twice. Where compensation is also paid under the Scheme for the same injury, the claimant may be required to repay either the Commonwealth or the relevant workers' compensation scheme.

28. What happens if an employee suffers an adverse effect following the vaccine as part of our workplace vaccine program?

If your employee has suffered an adverse effect related to a TGA approved COVID-19 vaccine received in the course of employment, they may be eligible to make a claim under the Scheme.

The employee will need to meet the eligibility criteria for claims under the Scheme, including providing medical evidence from a healthcare practitioner confirming that they suffered harm as a result of receiving a TGA approved COVID-19 vaccine.

29. Will employers be responsible for an adverse event that occurred as part of our employee vaccination program?

The Scheme does not replace workers compensation arrangements. However, the Scheme will provide claimants with an administrative option to seek compensation rather than a complex and costly court process. In assessing claims under the Scheme, the Commonwealth will not consider responsibility of employers in relation to harm suffered by a claimant, or death of an employee, that is directly a result of a workplace COVID-19 vaccination. However, employers' broader responsibilities are not being indemnified through this Scheme.

30. Could an employee pursue legal proceedings against an employer?

Claimants are not prevented from taking action through the courts. However, the Scheme has been designed as a streamlined alternative to legal proceedings. If a claimant pursues subsequent legal proceedings after receiving compensation under the Scheme, they will be required to repay back to the Commonwealth, the lesser compensation amount received.

31. Will business interruption costs \$1,000 and over be claimable under the Scheme?

The Scheme is designed to only provide compensation to eligible individual claimants who have suffered harm as a result of receiving a TGA approved COVID-19 vaccine. The Scheme will not provide compensation for business interruption costs or any other lost profits or other amounts, including indirect or consequential loss.

If an eligible claimant is a sole trader or business owner, a loss of their personal income may be claimed as lost earnings under the Scheme.

32. What advice should employers provide employees who want to know what compensation cover is in place if they have an adverse effect related to a vaccine sanctioned via the employer?

The employer should refer the employee (patient) to the Department of Health website COVID-19 vaccine claims scheme | Australian Government Department of Health.

While side effects from COVID-19 vaccinations can occur, most are mild and last no longer than a couple of days. Serious and life-threatening clinical conditions caused by vaccination are very rare. The Scheme provides a safety net to support those affected, by providing eligible claimants with access to compensation where they suffer a moderate to severe harm or death caused by a TGA approved COVID-19 vaccination.

33. Will employers have rehabilitation and return to work obligations for someone who successfully makes a claim under the COVID-19 Vaccine Claims Scheme? With respect to compensation being paid, will this cover income lost by person/s that need to take time off work to care for someone impacted as a result of the COVID-19 Vaccine Claim Scheme?

Employers should obtain their own legal advice on this issue specific to an individual's circumstances.

The Scheme is intended to provide a one-off compensation payment to those who have suffered moderate to severe harm or death caused by a TGA approved COVID-19 vaccine. This claim should take into account any other compensation amounts the claimant may have received as a result of the harm. It may include an amount for additional domestic care, if required by the claimant.

The Scheme does not apply to third parties, such as family members of the eligible claimant.

34. Will workers compensation claims still be an option if a claim is successfully pursued under the vaccine scheme and vice versa (will there in effect be dual insurance)?

See #27 above.

35. What happens if there is a long-term side effect from the vaccination?

The Scheme is structured to cover harm that occurs within 2 years after the *Biosecurity (Human Biosecurity Emergency) (Human Coronavirus with Pandemic Potential) Declaration 2020* expiring. Claims will be settled having regard to the both past and future costs associated with the harm.

36. Should employers encourage employees to have a vaccine under the federal scheme, rather than under a formal employer sanctioned vaccine program, to eliminate the risk of a workers' compensation claim?

The consistent message to all people in Australia is to get vaccinated. The Scheme applies to all vaccinations carried out by approved healthcare practitioners as part of the Commonwealth Government's rollout, including vaccines administered in the context of an employer sanctioned vaccine program.

Employers should seek their own legal advice in relation to whether an employee could make a workers' compensation claim in respect of a COVID-19 vaccination received in an employer sanctioned vaccination program.

37. What is the interaction between the vaccine claims scheme and workers compensation? See #27 above.

38. Can workers compensation schemes recover from the Scheme for vaccine harm claims?

The Scheme is only open to eligible claimants. The Scheme does not enable third parties such as workers' compensation bodies to make claims for compensation.

39. What is the interaction between the vaccine claims scheme and businesses?

If an eligible claimant is injured as a result of a TGA approved COVID-19 vaccination received in the workplace, the individual can submit a claim under the Scheme where the minimum threshold is \$1,000.

If a claimant is a sole trader or business owner, the impact on their income as a result of the harm suffered as a result of receiving a TGA approved COVID-19 vaccine will likely be relevant to assessing any compensation amounts for lost earnings by that individual.

40. Will the COVID-19 Vaccine Claims Scheme apply to people vaccinated through mandatory vaccination programs?

Yes. The Commonwealth is funding the Scheme. It is open to all eligible claimants who receive a TGA approved COVID-19 vaccination from an approved healthcare practitioner as part of the Commonwealth Government's COVID-19 vaccine rollout.

Practitioner

41. I am a nurse working in a private clinic administering COVID-19 vaccinations, what does the Scheme mean for me?

The Scheme is universally available to eligible claimants who suffer harm as a result of receiving a TGA approved COVID-19 vaccine from an approved healthcare practitioner.

42. My patient has suffered an adverse effect to a TGA approved COVID-19 Vaccine, what steps should I take?

While side effects from COVID-19 vaccinations can occur, most are mild and last no longer than a couple of days. Serious and life-threatening side effects are very rare. The Scheme provides a safety net to support those affected by providing eligible claimants with access to compensation where they suffer a moderate to severe harm or death caused by a TGA approved COVID-19 vaccination.

If your patient has suffered a moderate to significant harm or death caused by a TGA approved COVID-19 vaccine, you can refer them (or the executor or administrator of their estate, in the event of death) to register their interest in making a compensation claim through a link located on the Department of Health website at COVID-19 vaccine claims scheme | Australian Government Department of Health

As part of the claims process the patient will need to provide evidence in support of their claim that their harm has been caused by the vaccine. This evidence will include a medical report from their treating doctor or a hospital physician indicating the nature of the harm suffered by the patient post-vaccination, the duration of that condition and the causative link to the TGA approved COVID-19 vaccination. Current information regarding the required evidence is at #15.

It is also important that any adverse reaction to a TGA approved COVID-19 is reported to the TGA as part of their usual surveillance program.

43. Would I be subjected to any legal proceedings?

A key aim of the Scheme is to reduce the risk of a legal action against a healthcare practitioner who is involved in the COVID-19 vaccination program.

The Scheme does not prevent someone from taking action through the courts, however, the Scheme has been designed as a streamlined alternative to court proceedings.

In the event an Assessor considers, as a result of the information available in relation to a Claim, that there may have been harm caused by a registered health practitioner in the administration of the COVID-19 Vaccine received by the COVID-19 Vaccine Recipient, they may recommend a referral to AHPRA for a review of the practitioner's conduct or performance by the relevant professional board.

Unsatisfactory conduct or performance is relatively rare however these steps are in keeping with the Commonwealth's intention that health practitioners continue to practise with skill and diligence and to promote confidence in the population being vaccinated. These measures will support the integrity of the COVID-19 vaccination program and the Scheme itself.