COVID-19 vaccine weekly safety report - <date>

The national roll-out of COVID-19 vaccines began on 22 February 2021. The Therapeutic Goods Administration (TGA) has been closely monitoring any suspected side effects (also known as adverse events) from the use of the vaccines.

Current status

Our current assessment is that the COVID-19 vaccines used in Australia meet safety and effectiveness standards.

Learn about the TGA's COVID-19 vaccine safety monitoring and reporting activities or report a suspected side effect.

Total adverse event following immunisation (AEFI) reports received up to and including <date>

Gathering reports of suspected side effects following vaccination is just the first step in determining whether or not the effect is related to the vaccine and whether a significant safety issue is involved. Learn more about how the TGA identifies and responds to safety issues.

[A1]#.#	[A2]####	[A3]##,###
Reporting rate per 1000 doses	Total AEFI reports	Total doses administered

Reports per 1000 doses [A4]			
Australian Capital Territory	#.#	New South Wales	#.#
Northern Territory	#.#	Queensland	#.#
South Australia	#.#	Tasmania	#.#
Victoria	#.#	Western Australia	#.#

Total AEFI reports received in the week of <date – date *[Mon-Sun immediately prior]*>

In the last week, the TGA has received a total of **[A5]** ### AEFI reports for COVID-19 vaccines. Evaluation of these reports is ongoing and these reports will be included in the analysis that will be published in the following week. The most common reactions in this reporting period were:

- ####
- ####
- ####
- ####
- ####

The information in reports received by the TGA reflect the view of the reporter. As analysis of these reports is ongoing, the information may change as the data quality are reviewed or further information is provided. Total numbers may also change is duplicate reports are identified.

Analysis of adverse event reports by product received up to and including <date>

[add brief description of data analysis and lag]

Trade Name>

The most frequently reported adverse events for the <Trade Name> vaccine were:

- Diarrhoea
- Nausea
- Injection site reactions

This is consistent with what is already known about the <Trade Name> vaccine. Further information can be found in the Consumer Medicine Information for this product.

The total number of reports of adverse events of special interest for the <Trade Name> vaccine were:

- anaphylaxis ([B1] 1 report)
- facial paralysis ([B2]1 report)

These reports reflect the observations of individuals who suspect the events could be related to the vaccine. The relationship to the vaccine may be unclear. These events are being continuously monitored.

< Link to monthly safety summary reporting (PSUR) report date and review outcome content>

<TGA commentary>

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Active surveillance

AusVaxSafety is an active vaccine safety surveillance system that complements the TGA's enhanced safety surveillance activities. Active vaccine safety surveillance involves directly contacting people who have recently

administered or received a vaccine to collect information about adverse events. AusVaxSafety shares its findings with the TGA to assist our safety investigations and responses.

<TGA commentary if applicable>

Further information is available on the AusVaxSafety website.

Other TGA safety information

During the past week, the TGA has published the following COVID-19 vaccine safety-related information:

- **COVID-19 vaccine: Pfizer Australia - COMIRNATY BNT162b2 (mRNA) – 25 January 2021**
  The Therapeutic Goods Administration (TGA) has granted provisional approval to Pfizer Australia Pty Ltd for its COVID-19 vaccine, COMIRNATY, making it the first COVID-19 vaccine to receive regulatory approval in Australia.
- **ICMRA statement for healthcare professionals: How COVID-19 vaccines will be regulated for safety and effectiveness – 22 January 2021**
  Health professionals and public health authorities will have a central role in discussing vaccination against COVID-19 with their patients.
- **TGA grants additional provisional determination for a COVID-19 vaccine – 20 January 2021**
  The TGA has granted a provisional determination to Biocelect Pty Ltd (on behalf of Novavax Inc.) in relation to the COVID-19 Vaccine, NVX-CoV2373.

Useful links

Previous weekly reports

TGA COVID-19 vaccines hub

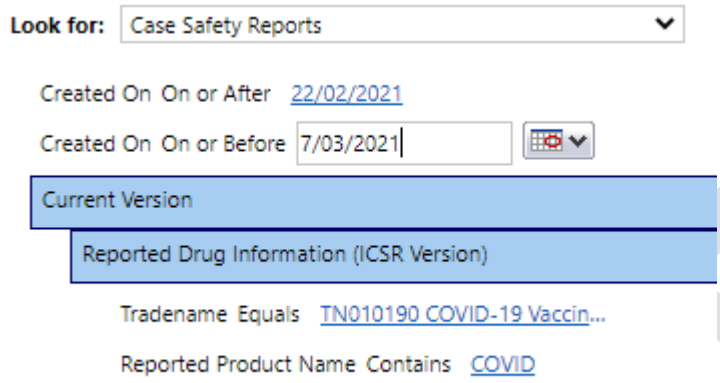
Australian Government Department of Health COVID-19 vaccines hub

Appendix A: calculating report figures

A1:

- All accepted reports for COVID vaccines with a created on date up to the most recent Sunday
- Search conducted Tuesday morning (1 day prior to publication)
- In AEMS Qlik app:
  - Default bookmark ON
    [case decision = 'accepted'; drug characterisation = 'suspect' or 'interacting'; study type = 'other' or 'unknown'; at least one coded reaction]
  - Date range = >=22/02/2021 <=[most recent Sunday]

If Qlik is down, search can be conducted in AEMS CRM with following search (adjusting dates as needed):



If unsure with search, get assistance from Warren.

A2:

Total AEFI reports*1000/total doses administered

A3

Total doses administered to be taken from SitRep [provide access details]

A4

State data searched with same strategy as in A1.
[provide access details on where state doses can be accessed]

A5:

- All accepted reports for COVID vaccines with a created on date up to the most recent Sunday
- Search conducted Tuesday morning (1 day prior to publication)
- In AEMS Qlik app:
  - Default bookmark ON
    [case decision = 'accepted'; drug characterisation = 'suspect' or 'interacting'; study type = 'other' or 'unknown'; at least one coded reaction]
  - Date range = Monday 8 days earlier to most recent Sunday

Appendix B: Calculating AESI figures

VSS to complete

Appendix C: Consumer appropriate terms for MedDRA preferred terms

MedDRA term	Consumer term
dizziness	dizziness
hyperhidrosis	sweating
oropharyngeal pain	sore throat
myalgia	muscle pain
presyncope	feeling faint
pyrexia	fever