# COVID-19 vaccine weekly safety report #1 – 3 March 2021

The national roll-out of COVID-19 vaccines commenced on 22 February 2021. The vaccine currently being supplied is [redacted]

The Therapeutic Goods Administration (TGA) is closely monitoring suspected side effects (also known as adverse events) from the use of the vaccine.

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

**Commented [PM1]:** Hover text - Unintended and sometimes harmful occurrences associated with a vaccine. Importantly, an adverse event is not always caused by the vaccine itself.

## Total adverse event following immunisation (AEFI) reports received up to 28 February 2021

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.

| 2.3 | 79 | 33,702 |
|---|---|---|
| Reporting rate per 1000 doses | Total AEFI reports received | Total doses administered |

**Commented [LC2]:** Hover text: This is the number of reports received and entered into the TGA adverse event database.

| Reports by jurisdiction | | | |
|---|---|---|---|
| Australian Capital Territory | 2 | New South Wales | 34 |
| Northern Territory | 3 | Queensland | 4 |
| South Australia | 5 | Tasmania | 2 |
| Victoria | 28 | Western Australia | 0 |
| Not reported | 1 | | |

The most common reactions reported in the first week were:

- Feeling faint
- Dizziness
- Headache
- Nausea
- Sweating

Evaluation of these reports is ongoing.

Adverse events reported to the TGA may not be caused by the vaccine. Learn more about causality.

Not all adverse events are reported, especially for minor and well-known side effects. Learn more about reporting levels.

The information the TGA receives in reports reflects 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.

## Active surveillance

AusVaxSafety is an active vaccine safety surveillance system that complements the TGA's enhanced safety surveillance activities. Active vaccine safety surveillance uses SMS and a short survey to collect reports of AEFI directly from a subset of people receiving the vaccines. AusVaxSafety is an Australian Government-funded system that shares its findings with the TGA to assist our safety investigations and responses.

AusVaxSafety surveillance data to 28 February 2021:

There were 11,079 surveys sent in six of the eight states and territories, with 7397 people responding (67% response rate).

Of those who responded:

- 64% reported no adverse event
- 36% reported one or more adverse events
- 0.7% reported visiting a doctor or emergency department as a result of their adverse event.

The most commonly reported reactions were:

- injection site pain
- fatigue
- headache.

**Commented [PM3]:** Web Team - Please present in a box or in another way that effectively links this information.

## Useful links

TGA COVID-19 vaccines hub

Australian Government Department of Health COVID-19 vaccines hub

AusVaxSafety