

## Document created for FOI-3520

<b>Part of request</b>	<b>Number of AEFI</b>
<i>Number of serious adverse events reported following covid-19 vaccine injection correct up until 17 December 2021</i>	14,597
<i>Number of serious adverse events reported in persons under the age of 18 correct up until 17 December 2021</i>	346

Data extracted on 31 January 2022.

This document contains the number of cases included in the TGA database as 'serious' adverse events up to 31 January 2022. These include reports classified as serious by reporters (who may include health professionals, consumers, state and territory health departments and pharmaceutical companies) and reports classified by the TGA as serious against internationally accepted criteria.

Reports classified as serious by some reporters may not meet the TGA's serious criteria and may represent common and expected reactions, such as injection site pain, fever, headache and/or nausea. Not all serious adverse events have an ongoing impact on the patient, with many reports indicating full recovery.

The TGA classifies an adverse event as serious if it:

- results in death
- is life-threatening
- results in inpatient hospitalisation or prolonged hospitalisation
- results in persistent or significant disability or incapacity
- is associated with a congenital anomaly or birth defect
- is a medically important event or reaction.