



## AEFI Causality Assessment AU-TGA-0000s 47F

### Patient Details

RG	s22
Date of birth/age	77
Sex	F
Sources of information	s22
Quality of information	

### Vaccine and AEFI diagnosis details

Vaccine involved	ChAdOx1-S
Vaccine brand name	Vaxzevria; formerly COVID-19 vaccine AstraZeneca
Vaccine batch number	Unknown
Date administered	s22
Event/Diagnosis	s22 – Guillain Barre Syndrome
Case definition	TGA has assessed this illness as meeting Level 1 Brighton Collaboration criteria for the diagnosis of Guillain Barre Syndrome

### Assessment details

Assessors	s22
Others present	
Date of assessment	07/12/2021

This template has been developed in line with the World Health Organization Causality Assessment of an Adverse Event Following Immunization (AEFI): user manual for the revised WHO classification (Second Edition), 2018. The template should be used in conjunction with the WHO document.

The AEFI causality assessment process is guided by the following three steps:

1. **Checklist:** the checklist is designed to assemble key information on the AEFI.
2. **Algorithm:** information from the checklist is applied to the algorithm to assist in the decision-making of the reviewers. The algorithm helps to determine if the AEFI could be consistent or inconsistent with an association to immunisation, an indeterminate outcome or unclassifiable.
3. **Classification:** the final classification of the AEFI is determined based on the findings from step 1 and 2.











Review each of the four steps in the algorithm and select the relevant conclusion for each step in Table 1. Summarise the responses in the checklist next to the corresponding conclusion in the Table 1 or as a summary note (see headings after table).

**Table 1: Steps and conclusions from the algorithm**

Step	Conclusion
I. Is there strong evidence for other causes?	<input checked="" type="checkbox"/> No
II. Is there a known causal association with the vaccine/vaccination?	<input checked="" type="checkbox"/> YES
III. Is there strong evidence against a causal association?	<input checked="" type="checkbox"/> No
IV. Review other qualifying factors.	<input checked="" type="checkbox"/> Consistent causal association to immunization <input type="checkbox"/> Indeterminate <input type="checkbox"/> Inconsistent causal association to immunisation <input type="checkbox"/> Unclassifiable

A. Summary of factors suggesting consistent causal association to immunisation

B. Summary of factors suggesting indeterminate causal association to immunisation

C. Summary of factors suggesting inconsistent causal association to immunisation

Other Considerations



### **Step 3 – Classification**

Select the relevant classification(s) in the Table 2 based on the conclusions from step 2.

Table 2: Adapted from page 25 of the World Health Organization Causality assessment of an adverse event following immunization (AEFI): user manual for the revised WHO classification (Second edition)

<b>A. Consistent with causal association to immunisation</b>  <input checked="" type="checkbox"/> A1. Vaccine product-related reaction (As per published literature) <input type="checkbox"/> A2. Vaccine quality defect-related reaction <input type="checkbox"/> A3. Immunization error-related reaction <input type="checkbox"/> A4. Immunisation anxiety-related reaction	<b>B. Indeterminate</b>  <input type="checkbox"/> B1. Temporal relationship is consistent but there is insufficient definitive evidence for vaccine causing event (may be a new vaccine-linked event)  <input type="checkbox"/> B2. Reviewing factors result in conflicting trends of consistency and inconsistency with causal association to immunisation	<b>C. Inconsistent with causal association to immunisation</b>  <input type="checkbox"/> C. Coincidental Underlying or emerging condition(s), or conditions caused by exposure to something other than vaccine.
<input type="checkbox"/> <b>Unclassifiable</b> Specify the additional information required for classification:		

### **Summarise the classification logic in order of priority**

*With the available evidence, we could conclude that the most likely classification is:* [select the relevant final classification]

#### **A. Consistent causal association to immunisation**

- ☒ A1. Vaccine product-related reaction; or
- ☐ A2. Vaccine quality defect-related reaction; or
- ☐ A3. Immunisation error-related reaction; or
- ☐ A4. Immunisation anxiety-related reaction

#### **B. Indeterminate**

- ☐ B1. Consistent temporal relationship but insufficient evidence for causality
- ☐ B2. Conflicting trends of consistency and inconsistency with causality

#### **C. Inconsistent causal association to immunisation**

- ☐ C. Coincidental

**Reasons:**

- Likely causal association between AZ vaccination and GBS, based on post-licensure, surveillance observational studies.
- Onset of symptoms occurred within a plausible time window
- No alternate explanation/trigger evident

s22

