



Australian Government
Repatriation Medical Authority

Statement of Principles
concerning
VACCINE-INDUCED THROMBOTIC
THROMBOCYTOPAENIA
(Reasonable Hypothesis)
(No. 33 of 2022)

The Repatriation Medical Authority determines the following Statement of Principles under subsection 196B(2) of the *Veterans' Entitlements Act 1986*.

Dated 4 March 2022

The Common Seal of the
Repatriation Medical Authority
was affixed to this instrument
at the direction of:

Professor Terence Campbell AM
Chairperson

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1 Name

This is the Statement of Principles concerning *vaccine-induced thrombotic thrombocytopaenia (Reasonable Hypothesis)* (No. 33 of 2022).

2 Commencement

This instrument commences on 4 April 2022.

3 Authority

This instrument is made under subsection 196B(2) of the *Veterans' Entitlements Act 1986*.

4 Application

This instrument applies to a claim to which section 120A of the VEA or section 338 of the *Military Rehabilitation and Compensation Act 2004* applies.

5 Definitions

The terms defined in the Schedule 1 - Dictionary have the meaning given when used in this instrument.

6 Kind of injury, disease or death to which this Statement of Principles relates

- (1) This Statement of Principles is about vaccine-induced thrombotic thrombocytopaenia and death from vaccine-induced thrombotic thrombocytopaenia.

Meaning of vaccine-induced thrombotic thrombocytopaenia

- (2) For the purposes of this Statement of Principles, vaccine-induced thrombotic thrombocytopaenia means a disorder of coagulation in which there is formation of blood clots in the vascular system in association with a low platelet count, in a person with no exposure to heparin within the previous 30 days.

Note 1: Vaccine-induced thrombotic thrombocytopaenia (VITT) is also known as vaccine-induced immune thrombotic thrombocytopaenia and thrombosis with thrombocytopaenia syndrome.

Note 2: Platelet counts are typically below 150,000 per microlitre, but some patients with platelet levels within the normal range may have had, or later will have, a significant drop in platelet levels, or may have the diagnosis confirmed by the presence of other clinical features that are typical of vaccine-induced thrombotic thrombocytopaenia.

Note 3: Thrombosis often occurs in locations which are unusual for other kinds of thrombotic disorders, including the cerebral venous sinuses, the portal vein and the splenic vein. Patients may concurrently or separately have thrombosis or embolism in more common locations, including venous thromboembolism (for example, deep vein thrombosis and pulmonary thromboembolism) and arterial thromboembolism (for example, acute myocardial infarction and ischaemic cerebrovascular accident).

Note 4: The diagnosis of vaccine-induced thrombotic thrombocytopenia is supported by evidence of thrombosis on imaging, elevated D-dimer levels, low fibrinogen levels, detection of antibodies against platelet factor 4–polyanion complexes or detection of platelet-activating antibodies on functional testing.

Death from vaccine-induced thrombotic thrombocytopenia

- (3) For the purposes of this Statement of Principles, vaccine-induced thrombotic thrombocytopenia, in relation to a person, includes death from a terminal event or condition that was contributed to by the person's vaccine-induced thrombotic thrombocytopenia.

Note: *terminal event* is defined in the Schedule 1 – Dictionary.

7 Basis for determining the factors

The Repatriation Medical Authority is of the view that there is sound medical-scientific evidence that indicates that vaccine-induced thrombotic thrombocytopenia and death from vaccine-induced thrombotic thrombocytopenia can be related to relevant service rendered by veterans, members of Peacekeeping Forces, or members of the Forces under the VEA, or members under the MRCA.

Note: *MRCA*, *relevant service* and *VEA* are defined in the Schedule 1 – Dictionary.

8 Factors that must exist

At least one of the following factors must as a minimum exist before it can be said that a reasonable hypothesis has been raised connecting vaccine-induced thrombotic thrombocytopenia or death from vaccine-induced thrombotic thrombocytopenia with the circumstances of a person's relevant service:

- (1) having received an adenovirus vector coronavirus disease 2019 (COVID-19) vaccine within the 100 days before the clinical onset of vaccine-induced thrombotic thrombocytopenia;

Note: Examples of adenovirus vector COVID-19 vaccines include:

- (a) Ad26.COV2.S (Janssen COVID-19 Vaccine);
- (b) ChAdOx1 nCoV-19 (Vaxevria, Oxford/Astra-Zeneca);
- (c) Gam-COVID-Vac (Sputnik V, Sputnik Light); and
- (d) AD5-nCOV (Convidecia).

- (2) inability to obtain appropriate clinical management for vaccine-induced thrombotic thrombocytopenia.

9 Relationship to service

- (1) The existence in a person of any factor referred to in section 8, must be related to the relevant service rendered by the person.
- (2) The factor set out in subsection 8(2) applies only to material contribution to, or aggravation of, vaccine-induced thrombotic thrombocytopenia where the person's vaccine-induced thrombotic

thrombocytopaenia was suffered or contracted before or during (but did not arise out of) the person's relevant service.

10 Factors referring to an injury or disease covered by another Statement of Principles

In this Statement of Principles:

- (1) if a factor referred to in section 8 applies in relation to a person; and
- (2) that factor refers to an injury or disease in respect of which a Statement of Principles has been determined under subsection 196B(2) of the VEA;

then the factors in that Statement of Principles apply in accordance with the terms of that Statement of Principles as in force from time to time.

Schedule 1 - Dictionary

Note: See Section 5

1 Definitions

In this instrument:

MRCA means the *Military Rehabilitation and Compensation Act 2004*.

relevant service means:

- (a) operational service under the VEA;
- (b) peacekeeping service under the VEA;
- (c) hazardous service under the VEA;
- (d) British nuclear test defence service under the VEA;
- (e) warlike service under the MRCA; or
- (f) non-warlike service under the MRCA.

Note: **MRCA** and **VEA** are also defined in the Schedule 1 - Dictionary.

terminal event means the proximate or ultimate cause of death and includes the following:

- (a) pneumonia;
- (b) respiratory failure;
- (c) cardiac arrest;
- (d) circulatory failure; or
- (e) cessation of brain function.

vaccine-induced thrombotic thrombocytopenia—see subsection 6(2).

VEA means the *Veterans' Entitlements Act 1986*.