



Australian Government
Repatriation Medical Authority

Statement of Principles
concerning
ANTIPHOSPHOLIPID SYNDROME
(Reasonable Hypothesis)
(No. 69 of 2016)

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

Dated 26 August 2016

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

A handwritten signature in black ink, appearing to read 'N. Saunders'.

Professor Nicholas Saunders AO
Chairperson

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1 Name

This is the Statement of Principles concerning *antiphospholipid syndrome (Reasonable Hypothesis)* (No. 69 of 2016).

2 Commencement

This instrument commences on 26 September 2016.

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 antiphospholipid syndrome and death from antiphospholipid syndrome.

Meaning of antiphospholipid syndrome

- (2) For the purposes of this Statement of Principles, antiphospholipid syndrome means:
 - (a) an autoimmune disorder characterised by vascular thrombosis or pregnancy morbidity in association with the presence of antiphospholipid antibodies; and
 - (b) includes catastrophic antiphospholipid syndrome and antiphospholipid syndrome occurring in association with another autoimmune disorder.

Note: *antiphospholipid antibodies*, *catastrophic antiphospholipid syndrome*, *pregnancy morbidity* and *vascular thrombosis* are defined in the Schedule 1 – Dictionary.

Death from antiphospholipid syndrome

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

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 antiphospholipid syndrome and death from antiphospholipid syndrome 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: *relevant service* is 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 antiphospholipid syndrome or death from antiphospholipid syndrome with the circumstances of a person's relevant service:

- (1) having a systemic viral or bacterial infection within the 30 days before the clinical onset of antiphospholipid syndrome;
- (2) for catastrophic antiphospholipid syndrome only, having surgery requiring a general, spinal or epidural anaesthetic within the 30 days before the clinical onset of antiphospholipid syndrome;

Note: *catastrophic antiphospholipid syndrome* is defined in the Schedule 1 - Dictionary.

- (3) being pregnant within the six weeks before the clinical onset of antiphospholipid syndrome;
- (4) having a haematological or solid organ cancer at the time of the clinical onset of antiphospholipid syndrome;
- (5) having ceased or reduced anticoagulant therapy within the 30 days before the clinical onset of antiphospholipid syndrome;
- (6) being treated with a tumour necrosis factor- α inhibitor for at least the four weeks before the clinical onset of antiphospholipid syndrome;
- (7) having a systemic viral or bacterial infection within the 30 days before the clinical worsening of antiphospholipid syndrome;
- (8) having surgery requiring a general, spinal or epidural anaesthetic within the 30 days before the clinical worsening of antiphospholipid syndrome;
- (9) being pregnant within the six weeks before the clinical worsening of antiphospholipid syndrome;
- (10) having a haematological or solid organ cancer at the time of the clinical worsening of antiphospholipid syndrome;
- (11) having ceased or reduced anticoagulant therapy within the 30 days before the clinical worsening of antiphospholipid syndrome;

- (12) being treated with a tumour necrosis factor- α inhibitor for at least the four weeks before the clinical worsening of antiphospholipid syndrome;
- (13) inability to obtain appropriate clinical management for antiphospholipid syndrome.

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 factors set out in subsections 8(7) to 8(13) apply only to material contribution to, or aggravation of, antiphospholipid syndrome where the person's antiphospholipid syndrome 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:

antiphospholipid antibodies means one of the following antibodies which have been detected on two or more occasions at least 12 weeks apart (or in the case of catastrophic antiphospholipid syndrome, at least six weeks apart):

- (a) immunoglobulin G or immunoglobulin M anticardiolipin antibodies;
- (b) immunoglobulin G or immunoglobulin M anti- β 2-glycoprotein-I antibodies; or
- (c) lupus anticoagulant.

antiphospholipid syndrome—see subsection 6(2).

catastrophic antiphospholipid syndrome means a severe form of antiphospholipid syndrome involving generalised thrombosis and rapid organ failure, which has the following features:

- (a) evidence of vascular thrombosis in more than one organ, system or tissue; and
- (b) development of at least two thrombotic manifestations in less than a week, or development of at least three thrombotic manifestations in less than 30 days; and
- (c) laboratory confirmation of the presence of antiphospholipid antibodies at least six weeks apart, except when repeat testing is not possible due to the death of the patient.

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

pregnancy morbidity means:

- (a) an unexplained death of a morphologically normal foetus at or beyond the tenth week of gestation, with normal foetal morphology documented by ultrasound or by direct examination of the foetus; or
- (b) the premature birth of a morphologically normal neonate before the 34th week of gestation because of eclampsia, severe preeclampsia or placental insufficiency; or
- (c) three or more unexplained consecutive spontaneous abortions before the tenth week of gestation, where maternal anatomic or hormonal abnormalities, and paternal and maternal chromosomal causes have been excluded.

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.

vascular thrombosis means one or more clinical episodes of arterial, venous or small vessel thrombosis, in any tissue or organ.

VEA means the *Veterans' Entitlements Act 1986*.