

Statement of Principles concerning DEEP VEIN THROMBOSIS (Reasonable Hypothesis) (No. 35 of 2021)

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

Dated 5 March 2021

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

Professor Nicholas Saunders AO Chairperson

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1 Name

This is the Statement of Principles concerning *deep vein thrombosis* (Reasonable Hypothesis) (No. 35 of 2021).

2 Commencement

This instrument commences on 5 April 2021.

3 Authority

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

4 Repeal

The Statement of Principles concerning deep vein thrombosis No. 54 of 2012 (Federal Register of Legislation No. F2012L01795) made under subsection 196B(2) of the VEA is repealed.

5 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.

6 Definitions

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

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

(1) This Statement of Principles is about deep vein thrombosis and death from deep vein thrombosis.

Meaning of deep vein thrombosis

- (2) For the purposes of this Statement of Principles, deep vein thrombosis:
 - (a) means formation of a blood clot within the deep venous system; and
 - (b) excludes thrombosis of the:
 - (i) retinal veins;
 - (ii) cerebral veins;
 - (iii) pulmonary veins;
 - (iv) hepatic vein;
 - (v) renal veins;
 - (vi) portal vein; and
 - (vii) mesenteric veins.

Death from deep vein thrombosis

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

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

8 Basis for determining the factors

The Repatriation Medical Authority is of the view that there is sound medical-scientific evidence that indicates that deep vein thrombosis and death from deep vein thrombosis 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.

9 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 deep vein thrombosis or death from deep vein thrombosis with the circumstances of a person's relevant service:

- (1) having superficial vein thrombosis within the twelve months before the clinical onset of deep vein thrombosis;
- (2) having external compression of the affected vein or a vein draining the affected vein at the time of the clinical onset of deep vein thrombosis;
 - Note: external compression of the affected vein or a vein draining the affected vein is defined in the Schedule 1 Dictionary.
- (3) having an infection involving the affected vein at the time of the clinical onset of deep vein thrombosis;
- (4) for deep vein thrombosis in an upper limb only, engagement in exercise of the affected upper limb within the seven days before the clinical onset of deep vein thrombosis;
 - Note: exercise of the affected upper limb is defined in the Schedule 1 Dictionary.
- (5) undergoing a course of therapeutic radiation for cancer, where the affected vein was in the field of radiation, within the three months before the clinical onset of deep vein thrombosis;
- (6) having acute myocardial infarction within the six months before the clinical onset of deep vein thrombosis;
- (7) having heart failure at the time of the clinical onset of deep vein thrombosis:
- (8) having a malignant neoplasm at the time of the clinical onset of deep vein thrombosis;

- (9) having an aneurysm of the affected vein at the time of the clinical onset of deep vein thrombosis;
- (10) being overweight or obese at the time of the clinical onset of deep vein thrombosis;
 - Note: being overweight or obese is defined in the Schedule 1 Dictionary.
- (11) having chronic obstructive pulmonary disease at the time of the clinical onset of deep vein thrombosis;
- (12) having sleep apnoea at the time of the clinical onset of deep vein thrombosis;
- (13) being pregnant within the three months before the clinical onset of deep vein thrombosis;
- (14) having cytomegalovirus infection of new onset within the 30 days before the clinical onset of deep vein thrombosis;
- (15) having infection with human immunodeficiency virus or hepatitis C virus at the time of the clinical onset of deep vein thrombosis;
- (16) having active tuberculosis disease within the 30 days before the clinical onset of deep vein thrombosis;
 - Note: active tuberculosis disease is defined in the Schedule 1 Dictionary.
- (17) having infection with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) within the three months before the clinical onset of deep vein thrombosis;
 - Note: SARS-CoV-2 is the virus which causes coronavirus disease 2019 (COVID-19).
- (18) having an autoimmune disease at the time of the clinical onset of deep vein thrombosis;
 - Note: Examples of autoimmune diseases that may cause deep vein thrombosis include rheumatoid arthritis, polymyositis and Sjögren syndrome.
- (19) having diabetes mellitus at the time of the clinical onset of deep vein thrombosis;
- (20) having a hypercoagulable state as specified at the time of the clinical onset of deep vein thrombosis;
 - Note: *hypercoagulable state as specified* is defined in the Schedule 1 Dictionary.
- (21) having a kidney disease from the specified list of kidney diseases at the time of the clinical onset of deep vein thrombosis;
 - Note: specified list of kidney diseases is defined in the Schedule 1 Dictionary.

(22) having a device implanted within the affected vein for a continuous period of at least 24 hours within the six months before the clinical onset of deep vein thrombosis;

Note: Examples of implanted devices include a central venous catheter, an indwelling cardiac pacemaker and defibrillator leads.

- (23) having surgery requiring a general, spinal or epidural anaesthetic within the six months before the clinical onset of deep vein thrombosis;
- (24) having an injury or illness as specified within the six months before the clinical onset of deep vein thrombosis;
 - Note: injury or illness as specified is defined in the Schedule 1 Dictionary.
- (25) having restricted mobility for a continuous period of at least four hours within the eight weeks before the clinical onset of deep vein thrombosis;

Note: Examples of situations in which restricted mobility can occur include travel by road, rail or air and physical restraint.

(26) having a neurological disease that causes loss or impairment of motor function of a limb within the three months before the clinical onset of deep vein thrombosis;

Note: Examples of neurological diseases that cause loss or impairment of motor function of a limb include cerebrovascular accident, multiple sclerosis and motor neurone disease.

(27) having a clinically significant disorder of mental health as specified at the time of the clinical onset of deep vein thrombosis;

Note: *clinically significant disorder of mental health as specified* is defined in the Schedule 1 - Dictionary.

(28) taking a drug from the specified list of drugs within the three months before the clinical onset of deep vein thrombosis;

Note: specified list of drugs is defined in the Schedule 1 - Dictionary.

(29) taking combined estrogen-progestogen contraception or taking menopausal hormone therapy as an oral estrogen, or a non-oral estrogen combined with a progestogen, for a continuous period of at least four weeks, within the three months before the clinical onset of deep vein thrombosis;

Note: *menopausal hormone therapy* is defined in the Schedule 1 - Dictionary.

- (30) having smoked tobacco products:
 - (a) in an amount of at least one pack-year before the clinical onset of deep vein thrombosis; or
 - (b) in an amount of at least 10 cigarettes per day, or the equivalent thereof in other tobacco products, for a period of at least three months before the clinical onset of deep vein thrombosis; and

if smoking has ceased before the clinical onset of deep vein thrombosis, then that onset occurred within six months of cessation;

Note: cigarettes per day, or the equivalent thereof in other tobacco products and pack-year are defined in the Schedule 1 - Dictionary.

- (31) being at an altitude of at least 3,000 metres for a continuous period of at least five days within the three months before the clinical onset of deep vein thrombosis;
- (32) inability to obtain appropriate clinical management for deep vein thrombosis.

10 Relationship to service

- (1) The existence in a person of any factor referred to in section 9, must be related to the relevant service rendered by the person.
- (2) The factor set out in subsection 9(32) applies only to material contribution to, or aggravation of, deep vein thrombosis where the person's deep vein thrombosis was suffered or contracted before or during (but did not arise out of) the person's relevant service.

11 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 9 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 6

1 Definitions

In this instrument:

abnormality of kidney structure or function means:

- (a) having a glomerular filtration rate of less than 60 mL/min/1.73 m²; or
- (b) having kidney damage, as evidenced by renal biopsy, imaging studies, albuminuria, urinary sediment abnormalities or other markers of abnormal renal function; or
- (c) having had a kidney transplant.

active tuberculosis disease means an illness in which tuberculosis bacteria are multiplying and inducing an inflammatory response.

acute kidney injury means:

- (a) having an increase in serum creatinine of at least 26.5 μmol/L within a period of 48 hours; or
- (b) having an increase in serum creatinine of at least 1.5 times baseline levels, which has occurred within the previous seven days; or
- (c) having a urine volume of less than 0.5 mL/kg/h for six hours.

being overweight or obese means having a Body Mass Index (BMI) of 25 or greater.

Note: **BMI** is also defined in the Schedule 1 - Dictionary.

BMI means W/H² where:

- (a) W is the person's weight in kilograms; and
- (b) H is the person's height in metres.

chronic kidney disease means an abnormality of kidney structure or function that has been present for at least three months.

Note: *abnormality of kidney structure or function* is also defined in the Schedule 1 - Dictionary.

cigarettes per day, or the equivalent thereof in other tobacco products means either:

- (a) cigarettes, pipe tobacco or cigars, alone or in any combination, where one tailor-made cigarette approximates one gram of tobacco; or
- (b) one gram of cigar, pipe or other smoking tobacco.

clinically significant disorder of mental health as specified means one of the following conditions, which is of sufficient severity to warrant ongoing management:

- (a) depressive disorder;
- (b) posttraumatic stress disorder; or
- (c) schizophrenia.

Note 1: Management of the condition may involve regular visits (for example, at least monthly) to a psychiatrist, counsellor or general practitioner.

Note 2: To warrant ongoing management does not require that any actual management was received or given for the condition.

deep vein thrombosis—see subsection 7(2).

exercise of the affected upper limb means strenuous, repetitive activity involving abduction of the shoulder or arm of the affected upper limb.

Note: Examples of activities that involve abduction of the shoulder or arm include weight lifting, swimming, rowing and wrestling.

external compression of the affected vein or a vein draining the affected vein means an endogenous or exogenous structure that compresses, occludes, displaces or infiltrates the affected vein or a vein draining the affected vein.

Note: Examples of structures that can cause external compression of a vein include an anatomical abnormality of the thoracic outlet, an arterial aneurysm and a pneumatic tourniquet.

hypercoagulable state as specified means:

- (a) antiphospholipid antibody syndrome;
- (b) cirrhosis of the liver;
- (c) Cushing syndrome;
- (d) disseminated intravascular coagulation;
- (e) heparin-induced thrombocytopaenia;
- (f) hyperhomocysteinaemia;
- (g) hyperthyroidism and thyrotoxicosis;
- (h) hypothyroidism;
- (i) inability to access anticoagulant treatment for an existing coagulation disorder;
- (j) paroxysmal nocturnal haemoglobinuria;
- (k) thrombocytosis; or
- (1) venom-induced thrombosis.

injury or illness as specified means:

- (a) a limb, pelvic, rib or spinal fracture;
- (b) a moderate to severe traumatic brain injury;
- (c) a physical injury or illness requiring mechanical ventilation support or admission to an intensive care unit;
- (d) a spinal cord injury;
- (e) a tear, rupture or avulsion of a muscle, tendon or ligament in the lower limb;
- (f) a traumatic upper or lower limb amputation;
- (g) an injury requiring immobilisation of an upper or lower limb in a plaster cast or similar restraining or bracing device; or
- (h) any other injury or illness that causes significantly reduced mobility.

Note: traumatic upper or lower limb amputation is also defined in the Schedule 1 - Dictionary.

menopausal hormone therapy means administration of estrogen preparations, often in combination with a progestogen, to offset a hormone deficiency following surgically induced or naturally occurring menopause.

MRCA means the *Military Rehabilitation and Compensation Act 2004*. *pack-year* means an amount of tobacco equivalent to:

(a) 20 cigarettes per day for a period of one calendar year; or

- (b) 7,300 cigarettes in a period of one calendar year; or
- (c) 7,300 grams of smoking tobacco by weight, either in cigarettes, pipe tobacco or cigars, or a combination of same.

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.

specified list of drugs means:

- (a) anti-psychotic drugs;
- (b) chemotherapy for a malignant disease;
- (c) erythropoiesis-stimulating agents (including erythropoietin and darbepoietin);
- (d) intravenous thrombin or fibrin sealant;
- (e) lenalidomide;
- (f) selective estrogen receptor modulators (including tamoxifen); or
- (g) thalidomide.

specified list of kidney diseases means:

- (a) acute kidney injury;
- (b) chronic kidney disease; or
- (c) nephrotic syndrome.

Note: acute kidney injury and chronic kidney disease 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.

traumatic upper or lower limb amputation means loss of an upper or lower limb as a result of an accidental injury, including blast injury.

VEA means the Veterans' Entitlements Act 1986.