

Statement of Principles concerning IMMUNE THROMBOCYTOPAENIA (Reasonable Hypothesis)

(No. 63 of 2017)

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

Dated 3 November 2017

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 *immune thrombocytopaenia* (*Reasonable Hypothesis*) (No. 63 of 2017).

2 Commencement

This instrument commences on 4 December 2017.

3 Authority

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

4 Revocation

The Statement of Principles concerning immune thrombocytopaenic purpura No. 72 of 2008, made under subsection 196B(2) of the VEA is revoked.

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 immune thrombocytopaenia and death from immune thrombocytopaenia.

Meaning of immune thrombocytopaenia

- (2) For the purposes of this Statement of Principles, immune thrombocytopaenia means:
 - (a) an autoimmune disorder characterised by an isolated thrombocytopaenia, and a peripheral platelet count of less than 100 000 per microlitre, together with either:
 - (i) the presence of bleeding symptoms; or
 - (ii) the need for treatment to increase the platelet count; and

Note: Bleeding symptoms can include bruising (purpura), mucocutaneous bleeding (petechiae), retinal haemorrhage, intracranial haemorrhage, nose bleeds (epistaxis), bleeding from the bowels (melaena) and vaginal bleeding (menorrhagia).

(b) excludes pseudothrombocytopaenia, thrombocytopaenia that is caused by non-immunological mechanisms, allergic and other

non-thrombocytopaenic purpura, purpura caused by qualitative platelet defects, thrombotic thrombocytopaenic purpura, Evan's syndrome, pancytopaenia, and thrombocytopaenia occurring in the presence of abnormal red or white blood cells.

Death from immune thrombocytopaenia

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

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 immune thrombocytopaenia and death from immune thrombocytopaenia 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.

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 immune thrombocytopaenia or death from immune thrombocytopaenia with the circumstances of a person's relevant service:

- (1) having a viral infection from the specified list of viral infections within the six weeks before the clinical onset of immune thrombocytopaenia;
 - Note: specified list of viral infections is defined in the Schedule 1 Dictionary.
- (2) having a bacterial or fungal infection from the specified list of bacterial and fungal infections, within the six weeks before the clinical onset of immune thrombocytopaenia;
 - Note: *specified list of bacterial and fungal infections* is defined in the Schedule 1 Dictionary.
- (3) being treated with a drug or a drug from a class of drugs from the specified list of drugs, within the six weeks before the clinical onset of immune thrombocytopaenia;
 - Note: $specified\ list\ of\ drugs$ is defined in the Schedule 1 Dictionary.
- (4) receiving a vaccine from the specified list of vaccines within the six weeks before the clinical onset of immune thrombocytopaenia;
 - Note: specified list of vaccines is defined in the Schedule 1 Dictionary.

- (5) being treated with a drug or receiving a dose of vaccine which is associated in the individual with the following:
 - (a) the development of immune thrombocytopaenia within six weeks of commencing drug therapy or receiving the dose of vaccine; and
 - (b) an absence of immune thrombocytopaenia prior to commencing drug therapy or vaccination; and
 - (c) sustained recovery from immune thrombocytopaenia on ceasing drug therapy or vaccination; and
 - (d) exclusion of other aetiologies for thrombocytopaenia (including other drugs or vaccines);
- (6) being pregnant within the six weeks before the clinical onset of immune thrombocytopaenia;
- (7) having a lymphoproliferative disorder from the specified list of lymphoproliferative disorders, at the time of the clinical onset of immune thrombocytopaenia;
 - Note: specified list of lymphoproliferative disorders is defined in the Schedule 1 Dictionary.
- (8) having an autoimmune or inflammatory disorder from the specified list of autoimmune and inflammatory disorders, at the time of the clinical onset of immune thrombocytopaenia;
 - Note: *specified list of autoimmune and inflammatory disorders* is defined in the Schedule 1 Dictionary.
- (9) consuming a food or beverage from the specified list of food and beverages, within the six weeks before the clinical onset of immune thrombocytopaenia;
 - Note: specified list of food and beverages is defined in the Schedule 1 Dictionary.
- (10) consuming a food or beverage which is associated in the individual with the following:
 - (a) the development of immune thrombocytopaenia within six weeks of consuming the food or beverage; and
 - (b) an absence of immune thrombocytopaenia prior to consuming the food or beverage; and
 - (c) sustained recovery from immune thrombocytopaenia on ceasing consumption of the food or beverage; and
 - (d) exclusion of other aetiologies for thrombocytopaenia; and
 - (e) recurrence of immune thrombocytopaenia on re-exposure to the food or beverage; or
 - (f) identification of platelet reactive antibodies specific to the food or beverage;

- (11) having a solid organ or stem cell transplant before the clinical onset of immune thrombocytopaenia;
- (12) having a solid organ cancer at the time of the clinical onset of immune thrombocytopaenia;
- (13) being treated with alemtuzumab in the two years before the clinical onset of immune thrombocytopaenia;
- (14) having a viral infection from the specified list of viral infections within the six weeks before the clinical worsening of immune thrombocytopaenia;
 - Note: specified list of viral infections is defined in the Schedule 1 Dictionary.
- (15) having a bacterial or fungal infection from the specified list of bacterial and fungal infections, within the six weeks before the clinical worsening of immune thrombocytopaenia;
 - Note: *specified list of bacterial and fungal infections* is defined in the Schedule 1 Dictionary.
- (16) being treated with a drug or a drug from a class of drugs from the specified list of drugs, within the six weeks before the clinical worsening of immune thrombocytopaenia;
 - Note: specified list of drugs is defined in the Schedule 1 Dictionary.
- (17) receiving a vaccine from the specified list of vaccines within the six weeks before the clinical worsening of immune thrombocytopaenia;

 Note: *specified list of vaccines* is defined in the Schedule 1 Dictionary.
- (18) being treated with a drug or receiving a dose of vaccine which is associated in the individual with the following:
 - (a) the worsening of immune thrombocytopaenia within six weeks of drug therapy or receiving the dose of vaccine; and
 - (b) recovery to the individual's baseline platelet level on ceasing drug therapy or vaccination; and
 - (c) exclusion of other aetiologies for thrombocytopaenia (including other drugs or vaccines);
- (19) being pregnant within the six weeks before the clinical worsening of immune thrombocytopaenia;
- (20) having a lymphoproliferative disorder from the specified list of lymphoproliferative disorders, at the time of the clinical worsening of immune thrombocytopaenia;
 - Note: specified list of lymphoproliferative disorders is defined in the Schedule 1 Dictionary.

- (21) having an autoimmune or inflammatory disorder from the specified list of autoimmune and inflammatory disorders, at the time of the clinical worsening of immune thrombocytopaenia;
 - Note: *specified list of autoimmune and inflammatory disorders* is defined in the Schedule 1 Dictionary.
- (22) consuming a food or beverage from the specified list of food and beverages, within the six weeks before the clinical worsening of immune thrombocytopaenia;
 - Note: specified list of food and beverages is defined in the Schedule 1 Dictionary.
- (23) consuming a food or beverage which is associated in the individual with the following:
 - (a) the worsening of immune thrombocytopaenia within six weeks of consuming the food or beverage; and
 - (b) recovery to the individual's baseline platelet level on ceasing consumption of the food or beverage; and
 - (c) exclusion of other aetiologies for thrombocytopaenia; and
 - (d) recurrence of the worsening of immune thrombocytopaenia on re-exposure to the food or beverage; or
 - (e) identification of platelet reactive antibodies specific to the food or beverage;
- (24) having a solid organ or stem cell transplant before the clinical worsening of immune thrombocytopaenia;
- (25) having a solid organ cancer at the time of the clinical worsening of immune thrombocytopaenia;
- (26) inability to obtain appropriate clinical management for immune thrombocytopaenia.

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 factors set out in subsections 9(14) to 9(26) apply only to material contribution to, or aggravation of, immune thrombocytopaenia where the person's immune thrombocytopaenia 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:

immune thrombocytopaenia—see subsection 7(2).

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.

specified list of autoimmune and inflammatory disorders means:

- (a) antiphospholipid syndrome;
- (b) autoimmune hepatitis;
- (c) coeliac disease;
- (d) dermatomyositis;
- (e) Graves' disease;
- (f) Hashimoto's thyroiditis;
- (g) inflammatory bowel disease;
- (h) rheumatoid arthritis;
- (i) sarcoidosis;
- (j) Sjögren's syndrome; or
- (k) systemic lupus erythematosus.

specified list of bacterial and fungal infections means:

- (a) Brucella species;
- (b) Candida albicans;
- (c) Helicobacter pylori; or
- (d) Mycobacterium tuberculosis.

specified list of drugs means:

- (a) abciximab;
- (b) aminosalicylic acid;
- (c) amiodarone;
- (d) amlodipine;
- (e) carbamazepine;
- (f) cephalosporins;
- (g) ciprofloxacin;
- (h) citalopram;

- (i) clopidogrel;
- (j) dactinomycin (actinomycin D);
- (k) diazoxide;
- (l) efalizumab;
- (m) eptifibatide;
- (n) ethambutol;
- (o) fludarabine;
- (p) furosemide (frusemide);
- (q) gentamicin;
- (r) glucagon;
- (s) haloperidol;
- (t) heparins;
- (u) hydrochlorothiazide;
- (v) imipramine;
- (w) infliximab;
- (x) interferon- α ;
- (y) interferon- β ;
- (z) irinotecan;
- (aa) isotretinoin;
- (bb) lamivudine;
- (cc) lamotrigine;
- (dd) levetiracetam;
- (ee) levofloxacin;
- (ff) lorazepam;
- (gg) melperone;
- (hh) methylphenidate;
- (ii) mirtazapine;
- (jj) nifedipine;
- (kk) nitrofurantoin;
- (ll) nivolumab;
- (mm) non-steroidal anti-inflammatory drugs, excluding aspirin;
- (nn) oxaliplatin;
- (oo) paracetamol;
- (pp) pembrolzumab;
- (qq) penicillin or penicillin derivatives;
- (rr) phenobarbital (phenobarbitone);
- (ss) phenytoin;
- (tt) quetiapine;
- (uu) quinidine;
- (vv) quinine;
- (ww) ranitidine;
- (xx) rifampicin;
- (yy) risperidone;
- (zz) sodium stibogluconate;
- (aaa) spironolactone;
- (bbb) sulfamethoxazole/trimethoprim;
- (ccc) sulfamethoxazole;
- (ddd) sulfasalazine;

- (eee) sulfonamides;
- (fff) suramin;
- (ggg) tamoxifen;
- (hhh) terazosin;
- (iii) tirofiban;
- (jjj) tolmetin;
- (kkk) tranilast;
- (lll) triamterene/hydrochlorothiazide;
- (mmm)triamterene;
- (nnn) trimethoprim; or
- (000) vancomycin.

specified list of food and beverages means:

- (a) cranberry juice;
- (b) Lupinus termis bean;
- (c) quinine-containing beverages;
- (d) tahini; or
- (e) walnuts.

specified list of lymphoproliferative disorders means:

- (a) acute lymphoblastic leukaemia;
- (b) chronic lymphocytic leukaemia/small lymphocytic lymphoma;
- (c) Hodgkin's lymphoma;
- (d) large granular lymphocytic leukaemia;
- (e) monoclonal gammopathy of unknown significance;
- (f) myeloma;
- (g) non-Hodgkin's lymphoma; or
- (h) Waldenstrom's macroglobulinaemia.

specified list of vaccines means:

- (a) diphtheria-tetanus-acellular pertussis vaccine;
- (b) hepatitis A vaccine;
- (c) hepatitis B vaccine;
- (d) influenza vaccine;
- (e) measles-mumps-rubella vaccine;
- (f) pneumococcal conjugate vaccine;
- (g) rabies vaccine; or
- (h) varicella vaccine.

specified list of viral infections means:

- (a) cytomegalovirus;
- (b) dengue virus;
- (c) Epstein-Barr virus;
- (d) hepatitis A virus;
- (e) hepatitis B virus;
- (f) hepatitis C virus;
- (g) hepatitis E virus;
- (h) human immunodeficiency virus;
- (i) human T-cell lymphotropic virus type-1;

- (j) influenza virus;
- (k) measles virus;
- (l) mumps virus;
- (m) parvovirus B19;
- (n) rotavirus;
- (o) rubella virus;
- (p) varicella-zoster virus (chickenpox); or
- (q) Zika virus.

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.

VEA means the Veterans' Entitlements Act 1986.