



Australian Government
Repatriation Medical Authority

**Statement of Principles
concerning
IMMUNE THROMBOCYTOPAENIA
(Balance of Probabilities)
(No. 64 of 2017)**

The Repatriation Medical Authority determines the following Statement of Principles under subsection 196B(3) 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 (Balance of Probabilities)* (No. 64 of 2017).

2 Commencement

This instrument commences on 4 December 2017.

3 Authority

This instrument is made under subsection 196B(3) of the *Veterans' Entitlements Act 1986*.

4 Revocation

The Statement of Principles concerning immune thrombocytopaenic purpura No. 73 of 2008, made under subsection 196B(3) of the VEA is revoked.

5 Application

This instrument applies to a claim to which section 120B of the VEA or section 339 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, pancytopenia, 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**

On the sound medical-scientific evidence available, the Repatriation Medical Authority is of the view that it is more probable than not that immune thrombocytopaenia and death from immune thrombocytopaenia can be related to relevant service rendered by veterans 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 exist before it can be said that, on the balance of probabilities, immune thrombocytopaenia or death from immune thrombocytopaenia is connected 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 thrombocytopenia;
- (12) having a solid organ cancer at the time of the clinical onset of immune thrombocytopenia;
- (13) being treated with alemtuzumab in the two years before the clinical onset of immune thrombocytopenia;
- (14) having a viral infection from the specified list of viral infections within the six weeks before the clinical worsening of immune thrombocytopenia;

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 thrombocytopenia;

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 thrombocytopenia;

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 thrombocytopenia;

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 thrombocytopenia 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 thrombocytopenia (including other drugs or vaccines);
- (19) being pregnant within the six weeks before the clinical worsening of immune thrombocytopenia;

- (20) having a lymphoproliferative disorder from the specified list of lymphoproliferative disorders, at the time of the clinical worsening of immune thrombocytopenia;

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 thrombocytopenia;

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 thrombocytopenia;

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 thrombocytopenia 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 thrombocytopenia; and
 - (d) recurrence of the worsening of immune thrombocytopenia 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 thrombocytopenia;
- (25) having a solid organ cancer at the time of the clinical worsening of immune thrombocytopenia;
- (26) inability to obtain appropriate clinical management for immune thrombocytopenia.

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 thrombocytopenia where the person's immune thrombocytopenia 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(3) 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) eligible war service (other than operational service) under the VEA;
- (b) defence service (other than hazardous service and British nuclear test defence service) under the VEA; or
- (c) peacetime 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) aminosalicyclic 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) pembrolizumab;
- (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
- (ooo) 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) hepatitis A vaccine;
- (b) hepatitis B vaccine;
- (c) influenza vaccine; or
- (d) measles-mumps-rubella vaccine.

specified list of viral infections means:

- (a) cytomegalovirus;
- (b) Epstein-Barr virus;
- (c) hepatitis A virus;
- (d) hepatitis B virus;
- (e) hepatitis C virus;
- (f) hepatitis E virus;
- (g) human immunodeficiency virus;
- (h) influenza virus;
- (i) measles virus;
- (j) mumps virus;
- (k) parvovirus B19;
- (l) rotavirus;
- (m) rubella virus;
- (n) varicella-zoster virus (chickenpox); or
- (o) 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*.