

Statement of Principles concerning APLASTIC ANAEMIA (Reasonable Hypothesis) (No. 58 of 2020)

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

Dated 28 August 2020

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

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Professor Nicholas Saunders AO Chairperson

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1 Name

This is the Statement of Principles concerning *aplastic anaemia (Reasonable Hypothesis)* (No. 58 of 2020).

2 Commencement

This instrument commences on 28 September 2020.

3 Authority

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

4 Repeal

The Statement of Principles concerning aplastic anaemia No. 50 of 2012 (Federal Register of Legislation No. F2012L01791) made under subsections 196B(2) and (8) of the VEA is repealed.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 Schedules

Any item in a Schedule to this Instrument has effect according to its terms.

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

(1) This Statement of Principles is about aplastic anaemia and death from aplastic anaemia.

Meaning of aplastic anaemia

- (2) For the purposes of this Statement of Principles, aplastic anaemia:
 - (a) means bone marrow failure, characterised by:
 - (i) destruction of haematopoietic stem cells with peripheral blood cytopaenia; and
 - (ii) hypocellular bone marrow in which normal haematopoietic tissue is replaced by fatty marrow; and
 - (b) excludes:
 - (i) inherited bone marrow failure syndromes, including Fanconi anaemia, dyskeratosis congenita, Shwachman-Diamond syndrome and inherited amegakaryocytic thrombocytopaenia;

- (ii) isolated leukopaenia and isolated thrombocytopaenia;
- (iii) myelodysplastic syndrome;
- (iv) paroxysmal nocturnal haemoglobinuria; and
- (v) replacement of bone marrow due to fibrosis or an infiltrative neoplastic process.
- (3) While aplastic anaemia attracts ICD-10-AM code D61.1, D61.2, D61.3 or D61.8, in applying this Statement of Principles the meaning of aplastic anaemia is that given in subsection (2).
- (4) For subsection (3), a reference to an ICD-10-AM code is a reference to the code assigned to a particular kind of injury or disease in *The International Statistical Classification of Diseases and Related Health Problems, Tenth Revision, Australian Modification* (ICD-10-AM), Tenth Edition, effective date of 1 July 2017, copyrighted by the Independent Hospital Pricing Authority, ISBN 978-1-76007-296-4.

Death from aplastic anaemia

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

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 aplastic anaemia and death from aplastic anaemia 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 aplastic anaemia or death from aplastic anaemia with the circumstances of a person's relevant service:

- (1) being pregnant at the time of the clinical onset of aplastic anaemia;
- (2) being treated with a drug specified in the Schedule 2 Drugs of this Instrument within the one year before the clinical onset of aplastic anaemia;

- (3) being treated with a drug which is associated in the individual with:
 - (a) the development of aplastic anaemia within six months of drug therapy; and
 - (b) the improvement of aplastic anaemia within six months of discontinuing or tapering drug therapy;
- (4) taking a non-aspirin, nonsteroidal, anti-inflammatory drug on at least four days per week for a continuous period of at least four weeks, within the one year before the clinical onset of aplastic anaemia;
- (5) using 3,4-methylenedioxymethamphetamine (ecstasy) within the three months before the clinical onset of aplastic anaemia;
- (6) being exposed to benzene as specified on at least 30 days within the one year before the clinical onset of aplastic anaemia;

Note: *being exposed to benzene as specified* is defined in the Schedule 1 - Dictionary.

(7) inhaling, ingesting or having cutaneous contact with a herbicide or insecticide from the specified list of herbicides and insecticides, on at least 30 days within the six months before the clinical onset of aplastic anaemia;

Note: *specified list of herbicides and insecticides* is defined in the Schedule 1 - Dictionary.

- (8) having acute hepatitis within the one year before the clinical onset of aplastic anaemia;
- (9) having a liver transplant within the six months before the clinical onset of aplastic anaemia;
- (10) having an autoimmune disease from the specified list of autoimmune diseases within the two years before the clinical onset of aplastic anaemia;

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

 (11) having a haematological malignancy from the specified list of haematological malignancies within the six months before the clinical onset of aplastic anaemia;

Note: *specified list of haematological malignancies* is defined in the Schedule 1 - Dictionary.

- (12) having a thymoma or thymic carcinoma before the clinical onset of aplastic anaemia;
- (13) having an infection with parvovirus B19 or acute infectious mononucleosis within the six months before the clinical onset of aplastic anaemia;
- (14) being pregnant at the time of the clinical worsening of aplastic anaemia;

(15) inability to obtain appropriate clinical management for aplastic anaemia.

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) and 9(15) apply only to material contribution to, or aggravation of, aplastic anaemia where the person's aplastic anaemia 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:

8-hour time-weighted average (TWA) means the averaging of different exposure levels to benzene during an average exposure period equivalent to eight hours.

aplastic anaemia—see subsection 7(2).

being exposed to benzene as specified means:

- (a) having cutaneous contact with liquids containing benzene greater than 1% by volume; or
- (b) ingesting liquids containing benzene greater than 1% by volume; or
- (c) inhaling benzene vapour where such exposure occurs at an ambient 8-hour time-weighted average (TWA) benzene concentration exceeding five parts per million.

Note: 8-hour time-weighted average (TWA) is also defined in the Schedule 1 - Dictionary.

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 diseases means:

- (a) ABO mismatched haematopoietic stem cell transplant;
- (b) coeliac disease;
- (c) eosinophilic fasciitis;
- (d) graft versus host disease;
- (e) hyperimmunoglobulinaemia;
- (f) hypoimmunoglobulinaemia; or
- (g) systemic lupus erythematosus.

specified list of haematological malignancies means:

- (a) chronic lymphocytic leukaemia/small lymphocytic lymphoma;
- (b) Hodgkin's lymphoma;
- (c) non-Hodgkin lymphoma; or
- (d) T-cell large granular lymphocytic leukaemia.

specified list of herbicides and insecticides means:

- (a) a carbamate insecticide;
- (b) an organochlorine insecticide;
- (c) an organophosphate insecticide; or
- (d) paraquat.

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.

Schedule 2 - Drugs Note: See Section 6, Subsection 9(2)

Specified Drugs 1

1	11 1 1	•	11 1		11 • •
1.	albendazole	2.	alkylating agents (including temozolomide, busulfan, dacarbazine, cyclophosphamide, melphalan hydrochloride, nitrogen mustard)		allopurinol
4.	aminoglutethimide	5.	antimetabolite agents (including 6- mercaptopurine, fludarabine, fluouracil, methotrexate, pemetrexed)	6.	arsenic
7.	azathioprine	8.	azithromycin	9.	bismuth
10.	captopril	11.	carbamazepine	12.	carbimazole
13.	carbonic anhydrase inhibitors (including acetazolamide, methazolamide)	14.	cephalosporins		chloramphenicol
16.	chlordiazepoxide	17.	chloroquine	18.	chlorpheniramine
19.	chlorthalidone	20.	cimetidine		clopidogrel
22.	clozapine	23.	colchicine		dapsone
25.		26.	doxycycline		d-penicillamine
28.	erythromycin	29.	etanercept		ethosuximide
	felbamate		flucloxacillin	33.	flucytosine
34.	fluoxetine	35.	furosemide	36.	ganoderma
37.	gold	38.	golimumab		guanidine
	hydantoins	41.	imatinib	42.	immune checkpoint inhibitors (including nivolumab, pembrolizumab)
43.	indapamide	44.	infliximab		interferon alfa-2 and peg-interferon alfa-2
46.	lamivudine	47.	lamotrigine	48.	leflunomide
49.	lenalidomide	50.	linezolid	51.	lisinopril

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		1
52. lithium	53. mebendazole	54. mepacrine
55. meprobamate	56. mercury	57. mesalamine
58. methicillin	59. methimazole	60. methyldopa
61. methyprylon	62. mycophenolate	63. nifedipine
64. nizatidine	65. non-topical corticosteroids	66. osimertinib
67. pentoxifylline	68. phenothiazines	69. phenytoin
70. procainamide	71. proguanil	72. propylthiouracil
73. protease inhibitors for chronic hepatitis C	74. quinacrine	75. quinidine
76. quinine	77. quinolones	78. ribavirin
79. rituximab	80. streptomycin	 81. sulphonamide antibiotics (including trimethoprim, sulfamethoxazole) and drugs containing sulphonamide antibiotics (including sulfasalazine)
82. sulphonylureas (including chlorpropamide, tolbutamide)	83. tetracycline	84. thiazide diuretics
85. thiocyanate	86. ticlopidine	87. tocainide
88. valganciclovir	89. valproic acid	90. zidovudine
91. zonisamide	-	