



Australian Government
Repatriation Medical Authority

Statement of Principles
concerning
APLASTIC ANAEMIA
(Balance of Probabilities)
(No. 59 of 2020)

The Repatriation Medical Authority determines the following Statement of Principles under subsection 196B(3) 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:

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

Professor Nicholas Saunders AO
Chairperson

Contents

1	Name	3
2	Commencement	3
3	Authority	3
4	Repeal	3
5	Application.....	3
6	Schedules	3
7	Kind of injury, disease or death to which this Statement of Principles relates	3
8	Basis for determining the factors	4
9	Factors that must exist.....	4
10	Relationship to service.....	5
11	Factors referring to an injury or disease covered by another Statement of Principles.....	5
Schedule 1 - Dictionary		7
1	Definitions.....	7
Schedule 2 - Drugs.....		8
1	Specified Drugs.....	8

1 Name

This is the Statement of Principles concerning *aplastic anaemia (Balance of Probabilities)* (No. 59 of 2020).

2 Commencement

This instrument commences on 28 September 2020.

3 Authority

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

4 Repeal

The Statement of Principles concerning aplastic anaemia No. 51 of 2012 (Federal Register of Legislation No. F2012L01793) made under subsections 196B(3) and (8) of the VEA is repealed.

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 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 cytopenia; 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 thrombocytopenia;
 - (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

On the sound medical-scientific evidence available, the Repatriation Medical Authority is of the view that it is more probable than not that aplastic anaemia and death from aplastic anaemia can be related to relevant service rendered by veterans 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 exist before it can be said that, on the balance of probabilities, aplastic anaemia or death from aplastic anaemia is connected 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 six months 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) being exposed to benzene as specified on at least 45 days within the six months before the clinical onset of aplastic anaemia;

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

- (5) inhaling, ingesting or having cutaneous contact with an organophosphate insecticide on at least 45 days within the six months before the clinical onset of aplastic anaemia;
- (6) having acute hepatitis within the one year before the clinical onset of aplastic anaemia;
- (7) having a liver transplant within the three months before the clinical onset of aplastic anaemia;
- (8) 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.

- (9) having chronic lymphocytic leukaemia/small lymphocytic lymphoma or T-cell large granular lymphocytic leukaemia within the six months before the clinical onset of aplastic anaemia;
- (10) having a thymoma or thymic carcinoma before the clinical onset of aplastic anaemia;
- (11) being pregnant at the time of the clinical worsening of aplastic anaemia;
- (12) 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(11) and 9(12) 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(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:

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) 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 diseases means:

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

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)

1 Specified Drugs

1. alkylating agents (including temozolomide, busulfan, dacarbazine, cyclophosphamide, melphalan hydrochloride and nitrogen mustard)	2. allopurinol	3. antimetabolite agents (including 6-mercaptopurine, fludarabine, fluouracil, methotrexate and pemetrexed)
4. arsenic	5. azathioprine	6. bismuth
7. carbamazepine	8. carbimazole	9. carbonic anhydrase inhibitors (including acetazolamide and methazolamide)
10. chloramphenicol	11. chlordiazepoxide	12. chloroquine
13. chlorpheniramine	14. chlorthalidone	15. cimetidine
16. dapsone	17. daunorubicin	18. d-penicillamine
19. ethosuximide	20. felbamate	21. fluoxetine
22. ganoderma	23. gold	24. hydantoins
25. imatinib	26. immune checkpoint inhibitors (including nivolumab and pembrolizumab)	27. indapamide
28. lamivudine	29. leflunomide	30. lenalidomide
31. linezolid	32. mepacrine	33. mercury
34. mesalamine	35. methimazole,	36. mycophenolate
37. nifedipine	38. nizatidine	39. osimertinib
40. phenytoin	41. procainamide	42. proguanil
43. propylthiouracil	44. quinacrine	45. sulphonamide antibiotics (including trimethoprim and sulfamethoxazole) and drugs containing sulphonamide antibiotics (including sulfasalazine)
46. sulphonylureas (including chlorpropamide and tolbutamide)	47. thiazide diuretics	48. ticlopidine

Schedule 2 - Drugs

49. tocainide	50. valganciclovir	51. valproic acid
52. zidovudine		