



Australian Government
Repatriation Medical Authority

Statement of Principles
concerning
MYELODYSPLASTIC SYNDROME
(No. 73 of 2015)

The Repatriation Medical Authority determines the following Statement of Principles.

Dated 19 June 2015

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', written in a cursive style.

Professor Nicholas Saunders AO
Chairperson

Contents

| | | |
|--------------------------------------|--|----------|
| 1 | Name | 3 |
| 2 | Commencement | 3 |
| 3 | Authority | 3 |
| 4 | Revocation | 3 |
| 5 | Application..... | 3 |
| 6 | Definitions | 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 | 6 |
| 11 | Factors referring to an injury or disease covered by another Statement of Principles | 6 |
| Schedule 1 - Dictionary | | 7 |
| 1 | Definitions | 7 |

1 Name

This is the Statement of Principles concerning **myelodysplastic syndrome** (No. 73 of 2015).

2 Commencement

This instrument commences on **20 July 2015**.

3 Authority

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

4 Revocation

The Statement of Principles concerning myelodysplastic disorder No. 37 of 2006, as amended, made under subsections 196B(2) and (8) 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 myelodysplastic syndrome and death from myelodysplastic syndrome.

Meaning of myelodysplastic syndrome

- (2) For the purposes of this Statement of Principles, myelodysplastic syndrome:
- (a) means one of a group of clonal haematopoietic stem cell disorders characterised by ineffective haematopoiesis, resulting in peripheral cytopaenias, and disordered maturation of one or more myeloid cell lines, with fewer than 20 percent myeloblasts in bone marrow or peripheral blood, and which is characterised by progressive marrow failure, and that may progress to acute myeloid leukaemia; and
 - (b) includes refractory cytopaenia with unilineage dysplasia, refractory cytopaenia with multilineage dysplasia, refractory

anaemia with ring sideroblasts, and refractory anaemia with excess blasts.

Death from myelodysplastic syndrome

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

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 myelodysplastic syndrome and death from myelodysplastic syndrome 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 myelodysplastic syndrome or death from myelodysplastic syndrome with the circumstances of a person's relevant service:

- (1) smoking at least ten pack-years of cigarettes, or the equivalent thereof in other tobacco products, before the clinical onset of myelodysplastic syndrome, and:
- (a) smoking commenced at least five years before the clinical onset of myelodysplastic syndrome; and
 - (b) where smoking has ceased, the clinical onset of myelodysplastic syndrome has occurred within 15 years of cessation;

Note: *pack-years of cigarettes, or the equivalent thereof in other tobacco products* is defined in the Schedule 1 - Dictionary.

- (2) being treated with a drug or a drug from a class of drugs from the specified list of drugs before the clinical onset of myelodysplastic syndrome, where the first exposure occurred at least six months before the clinical onset of myelodysplastic syndrome, and where that therapy has ceased, the clinical onset of myelodysplastic syndrome occurred within 20 years of cessation;

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

- (3) having received a cumulative equivalent dose of at least 0.01 sievert of ionising radiation to the bone marrow at least one year before the clinical onset of myelodysplastic syndrome;

Note: *cumulative equivalent dose* is defined in the Schedule 1 - Dictionary.

- (4) undergoing treatment with radioactive iodine for cancer before the clinical onset of myelodysplastic syndrome, where the first exposure occurred at least one year before the clinical onset of myelodysplastic syndrome;
- (5) undergoing treatment with radioactive phosphorus for a myeloproliferative neoplasm before the clinical onset of myelodysplastic syndrome, where the first exposure occurred at least one year before the clinical onset of myelodysplastic syndrome;
- (6) being exposed to benzene:
 - (a) for a cumulative total of at least 1 250 hours within a continuous period of ten years before the clinical onset of myelodysplastic syndrome; and
 - (b) where the first exposure in that period occurred at least five years before the clinical onset of myelodysplastic syndrome;

Note: *being exposed to benzene* is defined in the Schedule 1 - Dictionary.
- (7) receiving greater than five ppm-years of cumulative exposure to benzene before the clinical onset of myelodysplastic syndrome, and where the first exposure occurred at least five years before the clinical onset of myelodysplastic syndrome;

Note: *ppm-years* is defined in the Schedule 1 - Dictionary.
- (8) having received a solid organ transplant before the clinical onset of myelodysplastic syndrome;
- (9) being infected with human immunodeficiency virus before the clinical onset of myelodysplastic syndrome;
- (10) being obese for at least five years within the 20 years before the clinical onset of myelodysplastic syndrome;

Note: *being obese* is defined in the Schedule 1 - Dictionary.
- (11) having a disease from the specified list of autoimmune diseases before the clinical onset of myelodysplastic syndrome;

Note: *specified list of autoimmune diseases* is defined in the Schedule 1 - Dictionary.
- (12) having aplastic anaemia at the time of the clinical onset of myelodysplastic syndrome;
- (13) inability to obtain appropriate clinical management for myelodysplastic syndrome.

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(13) applies only to material contribution to, or aggravation of, myelodysplastic syndrome where the person's myelodysplastic syndrome 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:

being exposed to benzene means:

- (a) having cutaneous contact with liquids containing benzene greater than 1% by volume;
- (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 benzene concentration exceeding five parts per million.

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

being obese means having a Body Mass Index (BMI) of 30 or greater.

The BMI = W/H^2 and where:

W is the person's weight in kilograms; and

H is the person's height in metres.

cumulative equivalent dose means the total dose of ionising radiation received by the particular organ or tissue. The formula used to calculate the cumulative equivalent dose allows doses from multiple types of ionising radiation to be combined, by accounting for their differing biological effect. The unit of equivalent dose is the sievert. For the purposes of this Statement of Principles, the calculation of cumulative equivalent dose excludes doses received from normal background radiation, but includes therapeutic radiation, diagnostic radiation, cosmic radiation at high altitude, radiation from occupation-related sources and radiation from nuclear explosions or accidents.

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

MRCAs means the *Military Rehabilitation and Compensation Act 2004*.

myelodysplastic syndrome—see subsection 7(2).

pack-years of cigarettes, or the equivalent thereof in other tobacco products means a calculation of consumption where one pack-year of cigarettes equals twenty tailor-made cigarettes per day for a period of one calendar year or 7 300 cigarettes. One tailor-made cigarette approximates one gram of tobacco or one gram of cigar or pipe tobacco by weight. One pack-year of tailor-made cigarettes equates to 7.3 kilograms of smoking tobacco by weight. Tobacco products mean either cigarettes, pipe tobacco or cigars, smoked alone or in any combination.

ppm-years means parts per million multiplied by years of exposure.

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.

specified list of autoimmune diseases means:

- (a) pernicious anaemia;
- (b) polymyalgia rheumatica; or
- (c) rheumatoid arthritis.

specified list of drugs means:

- (a) a topoisomerase II inhibitor;
- (b) an alkylating agent; or
- (c) azathioprine.

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*.