Australian Government
Repatriation Medical Authority

Statement of Principles
concerning
MYELODYSPLASTIC NEOPLASM (SYNDROME) (Reasonable Hypothesis)
(No. 76 of 2024)

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

Dated 18 October 2024.

Professor Terence Campbell AM
Chairperson
by and on behalf of
The Repatriation Medical Authority

Contents

1 Name

This is the Statement of Principles concerning *myelodysplastic neoplasm (syndrome) (Reasonable Hypothesis)* (No. 76 of 2024).

2 Commencement

This instrument commences on 19 November 2024.

3 Authority

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

4 Repeal

The Statement of Principles concerning myelodysplastic syndrome (No. 73 of 2015) (Federal Register of Legislation No. F2015L00905) made under subsections 196B(2) and (8) of the VEA is repealed.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 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 neoplasm (syndrome) and death from myelodysplastic neoplasm (syndrome).

*Meaning of **myelodysplastic neoplasm (syndrome)***

(2) For the purposes of this Statement of Principles, myelodysplastic neoplasm (syndrome):

(a) means a clonal haematopoietic stem cell neoplasm characterised by morphologic dysplasia ≥10% in at least one cell line of erythroid, granulocyte, or megakaryocyte lines; persistent cytopaenia; progressively ineffective haematopoiesis; and increased risk of acute myeloid leukaemia; and

(b) includes:

(i) morphologically defined myelodysplastic neoplasm including myelodysplastic neoplasm with low blasts;

hypoplastic myelodysplastic neoplasm; and myelodysplastic neoplasm with increased blasts; and

(ii) myelodysplastic neoplasms with defined genetic abnormalities including myelodysplastic neoplasm with low blasts and 5q deletion; myelodysplastic neoplasm with low blasts and SF3B1 mutation; myelodysplastic neoplasm with biallelic TP53 inactivation; and

(c) excludes:

(i) leukaemia including acute myeloid leukaemia;
(ii) myeloproliferative neoplasms including chronic myeloid leukaemia, chronic neutrophilic leukaemia, chronic eosinophilic leukaemia, polycythaemia vera, essential thromobocythaemia, primary myelofibrosis, and juvenile myelomonocytic leukaemia;
(iii) aplastic anaemia; and
(iv) Myelodysplastic/myeloproliferative neoplasms in the overlap category, including myelodysplastic/myeloproliferative neoplasm with neutrophilia; and myelodysplastic/myeloproliferative neoplasm with SF3B1 mutation and thrombocytosis; and myelodysplastic/myeloproliferative neoplasm not otherwise specified.

Note: Myelodysplastic neoplasms are also called myelodysplastic syndromes and myelodysplastic disorders

(3) While myelodysplastic neoplasm (syndrome) attracts ICD-10-AM codes D46 and C94.6, in applying this Statement of Principles the meaning of myelodysplastic neoplasm (syndrome) 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 ***myelodysplastic neoplasm (syndrome)***

(5) For the purposes of this Statement of Principles, myelodysplastic neoplasm (syndrome), in relation to a person, includes death from a terminal event or condition that was contributed to by the person's myelodysplastic neoplasm (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 neoplasm (syndrome) and death from myelodysplastic neoplasm (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: ***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 myelodysplastic neoplasm (syndrome) or death from myelodysplastic neoplasm (syndrome) with the circumstances of a person's relevant service:

(1) smoking at least 10 pack-years of cigarettes, or the equivalent thereof in other tobacco products, before clinical onset, and:

(a) smoking commenced at least 5 years before clinical onset; and
(b) where smoking has ceased, clinical onset has occurred within 15 years of cessation;

Note: ***one pack-year*** is defined in the Schedule 1 – Dictionary.

(2) being treated with one of the following drugs:

(a) a topoisomerase II inhibitor, including etoposide, and doxorubicin; or
(b) an alkylating agent including cyclophosphamide, chlorambucil, mechlorethamine, melphalan, nitrosoureas, cisplatin, carboplatin; or
(c) azathioprine;
(d) 5-fluorouracil;
(e) taxanes including paclitaxel, and docetaxel;
(f) granulocyte colony stimulating factor;

before clinical onset, where treatment commenced at least 6 months before clinical onset, and where the treatment has ceased, within 20 years of cessation;

(3) having received a cumulative equivalent dose of at least 0.01 sievert of ionising radiation to the bone marrow at least 1 year before clinical onset;

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

(4) undergoing ablative treatment with radioactive iodine for thyroid cancer between 6 months and 3 years before clinical onset.

(5) undergoing treatment with radioactive phosphorus for polycythaemia vera before clinical onset, where the first exposure occurred at least one year before clinical onset.

(6) being exposed to benzene:

(a) for a cumulative total of at least 1,250 hours within a continuous period of ten years before clinical onset; and
(b) where the first exposure in that period occurred at least five years before clinical onset;

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

(7) receiving greater than 5 ppm-years of cumulative exposure to benzene before clinical onset, where the first exposure occurred at least 5 years before clinical onset;

Note: ***ppm-years*** is defined in the Schedule 1 - Dictionary.

(8) having acquired immunodeficiency syndrome before clinical onset;

(9) being obese for at least 5 years within the 20 years before clinical onset;

Note: ***being obese*** is defined in the Schedule 1 - Dictionary.

(10) having one of the following autoimmune diseases before clinical onset;

(a) pernicious anaemia;
(b) polymyalgia rheumatica;
(c) rheumatoid arthritis;
(d) systemic lupus erythematosus; or
(e) Behcet's disease;

(11) completing a course of therapy for malignant neoplasm before clinical onset, where the first exposure occurred at least 6 months before clinical onset, and where that therapy has ceased, clinical onset occurred within 20 years of cessation;

(12) inability to obtain appropriate clinical management for myelodysplastic neoplasm (syndrome) before clinical worsening.

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

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

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

$BMI = W/H^2$ where:

(a) W is the person's weight in kilograms; and
(b) H is the person's height in metres.

***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 defined in the Schedule 1 - Dictionary.

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.

MRCA means the Military Rehabilitation and Compensation Act 2004.

myelodysplastic neoplasm (syndrome)—see subsection 7(2).

one pack-year means the amount of tobacco consumed in smoking 20 cigarettes per day for a period of 1 year, or an equivalent amount of tobacco products.

Note 1: An equivalent amount of tobacco products is 7,300 grams of smoking tobacco by weight, either in cigarettes, pipe tobacco or cigars, or a combination of same. For pipe tobacco, cigars or combinations of multiple tobacco types, 1 gram of tobacco is considered to be equal to one cigarette.

Note 2: Pack-years are calculated by dividing the number of cigarettes smoked per day by 20 and multiplying this number by the number of years the person has smoked. For example, smoking 10 cigarettes per day for 10 years is equal to 5 pack-years, and smoking 40 cigarettes per day for 10 years is equal to 20 pack-years.

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.

Note: ***MRCA*** and ***VEA*** are defined in the Schedule 1 - Dictionary.

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.