



Australian Government
Repatriation Medical Authority

Statement of Principles
concerning
MULTIPLE SCLEROSIS
(Balance of Probabilities)
(No. 12 of 2020)

The Repatriation Medical Authority determines the following Statement of Principles under subsection 196B(3) of the *Veterans' Entitlements Act 1986*.

Dated 28 February 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

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1 Name

This is the Statement of Principles concerning *multiple sclerosis (Balance of Probabilities)* (No. 12 of 2020).

2 Commencement

This instrument commences on 23 March 2020.

3 Authority

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

4 Repeal

The Statement of Principles concerning multiple sclerosis No. 101 of 2011 (Federal Register of Legislation No. F2011L01738) made under subsections 196B(3) and (8) of the VEA is repealed.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 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 multiple sclerosis and death from multiple sclerosis.

Meaning of multiple sclerosis

- (2) For the purposes of this Statement of Principles, multiple sclerosis:
- (a) means a chronic relapsing-remitting or progressive disorder affecting the motor and sensory systems of the central nervous system and characterised by multiple focal regions of demyelination of neuronal axons, inflammation and gliosis occurring on multiple occasions; and
 - (b) includes relapsing-remitting multiple sclerosis, primary progressive multiple sclerosis and secondary progressive multiple sclerosis; and
 - (c) excludes:
 - (i) clinically isolated syndrome;

- (ii) radiologically isolated syndrome;
 - (iii) neuromyelitis optica;
 - (iv) acute disseminated encephalomyelitis;
 - (v) Marburg disease;
 - (vi) Balo concentric sclerosis; and
 - (vii) Schilder disease.
- (3) While multiple sclerosis attracts ICD-10-AM code G35, in applying this Statement of Principles the meaning of multiple sclerosis 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 multiple sclerosis

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

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 multiple sclerosis and death from multiple sclerosis 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, multiple sclerosis or death from multiple sclerosis is connected with the circumstances of a person's relevant service:

- (1) having acute infectious mononucleosis before the clinical onset of multiple sclerosis;
- (2) smoking at least ten pack-years of cigarettes, or the equivalent thereof in other tobacco products, before the clinical onset of multiple sclerosis, and where smoking has ceased, the clinical onset of multiple sclerosis has occurred within five years of cessation;

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

- (3) being exposed to second-hand smoke for at least 10 000 hours before the clinical onset of multiple sclerosis;

Note: *being exposed to second-hand smoke* is defined in the Schedule 1 - Dictionary.

- (4) having vitamin D deficiency, with a serum 25-hydroxyvitamin D level of less than 50 nanomoles per litre for a continuous period of at least one year before the clinical onset of multiple sclerosis, and where this vitamin D deficiency occurred more than two years before the clinical onset of multiple sclerosis;

- (5) being obese for at least five years when aged less than 30 years before the clinical onset of multiple sclerosis, and where this five year period occurred within the 15 years before the clinical onset of multiple sclerosis;

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

- (6) having onset of a viral or bacterial infection within the five weeks before, or the two weeks after, the clinical worsening of multiple sclerosis;

- (7) smoking at least ten pack-years of cigarettes, or the equivalent thereof in other tobacco products, before the clinical worsening of multiple sclerosis, and where smoking has ceased, the clinical worsening of multiple sclerosis has occurred within five years of cessation;

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

- (8) being exposed to second-hand smoke for at least 10 000 hours before the clinical worsening of multiple sclerosis;

Note: *being exposed to second-hand smoke* is defined in the Schedule 1 - Dictionary.

- (9) undergoing a course of treatment with a tumour necrosis factor alpha antagonist within the one year before the clinical worsening of multiple sclerosis;

- (10) undergoing a course of treatment with granulocyte colony-stimulating factor or interferon within the six months before the clinical worsening of multiple sclerosis;

- (11) undergoing a course of treatment with an immune checkpoint inhibitor within the four months before the clinical worsening of multiple sclerosis;

Note: Immune checkpoint inhibitors include, but are not limited to, ipilimumab, nivolumab, atezolizumab and pembrolizumab.

- (12) experiencing the death of a significant other within the three months before the clinical worsening of multiple sclerosis;

Note: *significant other* is defined in the Schedule 1 - Dictionary.

- (13) experiencing a category 1A stressor within the three months before the clinical worsening of multiple sclerosis;

Note: *category 1A stressor* is defined in the Schedule 1 - Dictionary.

- (14) experiencing a category 1B stressor within the three months before the clinical worsening of multiple sclerosis;

Note: *category 1B stressor* is defined in the Schedule 1 - Dictionary.

- (15) experiencing a category 2 stressor within the three months before the clinical worsening of multiple sclerosis;

Note 1: A category 2 stressor can arise in a variety of circumstances connected with service. Such circumstances can arise during the course of service, as a result of separation from service and the conditions associated with that separation, and in the transition to civilian life in the years following separation.

Note 2: *category 2 stressor* is defined in the Schedule 1 - Dictionary.

- (16) having a medical illness or injury, other than multiple sclerosis, which is life-threatening or which results in serious physical or cognitive disability, within the three months before the clinical worsening of multiple sclerosis;

- (17) for women only, using hormonal assisted reproductive therapy within the three months before the clinical worsening of multiple sclerosis;

Note: *hormonal assisted reproductive therapy* is defined in the Schedule 1 - Dictionary.

- (18) undergoing a course of therapeutic radiation for cancer, where the affected site was in the field of radiation, before the clinical worsening of multiple sclerosis;

- (19) inability to obtain appropriate clinical management for multiple sclerosis.

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(6) to 9(19) apply only to material contribution to, or aggravation of, multiple sclerosis where the person's multiple sclerosis 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:

being exposed to second-hand smoke means being in an enclosed space and inhaling smoke from burning tobacco products or smoke that has been exhaled by a person who is smoking.

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

Note: ***BMI*** is also defined in the Schedule 1 - Dictionary.

BMI means W/H^2 where:

W is the person's weight in kilograms; and

H is the person's height in metres.

category 1A stressor means one of the following severe traumatic events:

- (a) experiencing a life-threatening event;
- (b) being subject to a serious physical attack or assault including rape and sexual molestation; or
- (c) being threatened with a weapon, being held captive, being kidnapped or being tortured.

category 1B stressor means one of the following severe traumatic events:

- (a) killing or maiming a person;
- (b) being an eyewitness to a person being killed or critically injured;
- (c) being an eyewitness to atrocities inflicted on another person;
- (d) participating in the clearance of a corpse or a critically injured casualty;
or
- (e) viewing a corpse or a critically injured casualty as an eyewitness.

Note: ***corpse*** and ***eyewitness*** are also defined in the Schedule 1 - Dictionary.

category 2 stressor means one of the following negative life events, the effects of which are chronic in nature and cause the person to feel ongoing distress, concern or worry:

- (a) being socially isolated and unable to maintain friendships or family relationships, due to physical location, language barriers, disability, or medical or psychiatric illness;
- (b) experiencing a problem with a long-term relationship including the break-up of a close personal relationship, the need for marital or relationship counselling, marital separation or divorce;
- (c) having concerns in the work or school environment including ongoing disharmony with fellow work or school colleagues, perceived lack of social support within the work or school environment, perceived lack of control over tasks performed and stressful workloads, or experiencing bullying in the workplace or school environment;

- (d) experiencing serious legal issues including being detained or held in custody, ongoing involvement with the police concerning violations of the law, or court appearances associated with personal legal problems;
- (e) having severe financial hardship including loss of employment, long periods of unemployment, foreclosure on a property or bankruptcy;
- (f) having a family member or significant other experience a major deterioration in their health; or
- (g) being a full-time caregiver to a family member or significant other with a severe physical, mental or developmental disability.

Note: *significant other* is also defined in the Schedule 1 - Dictionary.

corpse means the human remains or body parts of one or more persons who have met a violent or horrific death.

Note: Examples of a violent or horrific death may include death due to suicide, gunshot, improvised explosive devices, natural and technological disasters, terrorist attacks or motor vehicle accidents. Seeing a closed body bag or viewing a body in an open-casket coffin are excluded from this definition.

eyewitness means a person who observes an incident first hand and can give direct evidence of it. This excludes persons exposed only to public broadcasting or mass media coverage of the incident.

hormonal assisted reproductive therapy means administration of a sequence of hormone treatments to achieve pregnancy, including gonadotrophin-releasing hormone agonists or antagonists, follicle stimulating hormone, human menopausal gonadotrophin, and chorionic gonadotrophin.

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

multiple sclerosis—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 20 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.

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.

significant other means a person who has a close family bond or a close personal relationship and is important or influential in one's life.

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*.