



Australian Government
Repatriation Medical Authority

Statement of Principles
concerning
MULTIPLE SCLEROSIS
(Reasonable Hypothesis)
(No. 11 of 2020)

The Repatriation Medical Authority determines the following Statement of Principles under subsection 196B(2) 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 (Reasonable Hypothesis)* (No. 11 of 2020).

2 Commencement

This instrument commences on 23 March 2020.

3 Authority

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

4 Repeal

The Statement of Principles concerning multiple sclerosis No. 100 of 2011 (Federal Register of Legislation No. F2011L01736) made under subsections 196B(2) and (8) of the VEA is repealed.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 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

The Repatriation Medical Authority is of the view that there is sound medical-scientific evidence that indicates that multiple sclerosis and death from multiple sclerosis 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 multiple sclerosis or death from multiple sclerosis 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 five 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) inhaling an organic solvent or having cutaneous contact with an organic solvent on more days than not for a continuous period of at least one year before the clinical onset of multiple sclerosis;

Note: *organic solvent* is defined in the Schedule 1 - Dictionary.

- (5) undergoing a course of treatment with a tumour necrosis factor alpha antagonist within the two years before the clinical onset of multiple sclerosis;

- (6) in the absence of supplemental ultraviolet light exposure, having an inability to meet the specified sunlight exposure levels for at least one year before the clinical onset of multiple sclerosis, and where this inability to meet the specified sunlight exposure levels occurred more than two years before the clinical onset of multiple sclerosis;

Note: *specified sunlight exposure levels* is defined in the Schedule 1 - Dictionary.

- (7) 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;

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

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

- (9) being overweight 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 overweight* is defined in the Schedule 1 - Dictionary.

- (10) having type 1 diabetes mellitus before the clinical onset of multiple sclerosis;

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

- (12) smoking at least five 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.

- (13) 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.

- (14) undergoing a course of treatment with a tumour necrosis factor alpha antagonist within the two years before the clinical worsening of multiple sclerosis;

- (15) undergoing a course of treatment with granulocyte colony-stimulating factor or interferon within the one year before the clinical worsening of multiple sclerosis;

- (16) 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.

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

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

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

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

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

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

- (20) experiencing a category 2 stressor within the six 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.

- (21) 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 six months before the clinical worsening of multiple sclerosis;

- (22) 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.
- (23) 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;
- (24) having received a cumulative equivalent dose of at least 10 sieverts of ionising radiation to the affected site before the clinical worsening of multiple sclerosis;
Note: *cumulative equivalent dose* is defined in the Schedule 1 - Dictionary.
- (25) having dyslipidaemia at the time of the clinical worsening of multiple sclerosis;
Note: *dyslipidaemia* is defined in the Schedule 1 - Dictionary.
- (26) 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(11) to 9(26) 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(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 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 overweight means having a Body Mass Index (BMI) of 25 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.

cumulative equivalent dose means the total dose of ionising radiation received by the particular organ or tissue from external exposure, internal exposure or both, apart from normal background radiation exposure in Australia, calculated in accordance with the methodology set out in the *Guide to calculation of 'cumulative equivalent dose' for the purpose of applying ionising radiation factors contained in Statements of Principles determined under Part XIA of the Veterans' Entitlements Act 1986 (Cth)*, Australian Radiation Protection and Nuclear Safety Agency, as in force on 2 August 2017.

Note 1: Examples of circumstances that might lead to exposure to ionising radiation include being present during or subsequent to the testing or use of nuclear weapons, undergoing diagnostic or therapeutic medical procedures involving ionising radiation, and being a member of an aircrew, leading to increased levels of exposure to cosmic radiation.

Note 2: For the purpose of dose reconstruction, dose is calculated as an average over the mass of a specific tissue or organ. If a tissue is exposed to multiple sources of ionising radiation, the various dose estimates for each type of radiation must be combined.

dyslipidaemia means persistently abnormal blood lipid levels, diagnosed by a medical practitioner and evidenced by:

- (a) a total serum cholesterol level greater than 5.5 mmol/L; or
- (b) a serum low density lipoprotein level greater than 4.0 mmol/L; or
- (c) a serum high density lipoprotein cholesterol level less than 1.0 mmol/L; or
- (d) the regular administration of drug therapy to normalise blood lipid levels.

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.

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

multiple sclerosis—see subsection 7(2).

organic solvent means:

- (a) aliphatic hydrocarbon solvent;
- (b) aromatic hydrocarbon solvent;
- (c) chlorinated organic solvent; or
- (d) oxygenated organic solvent.

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) 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.

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.

specified sunlight exposure levels means sunlight exposure four times a week on exposed arms and legs, or an equivalent body surface for the following amount of time:

- (a) 5 to 15 minutes, excluding winter exposure; or
- (b) 9 to 15 minutes between 0° and 23° latitude in winter; or
- (c) 20 to 30 minutes between 23° and 34° latitude in winter; or
- (d) 30 to 50 minutes between 34° and 60° latitude in winter.

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*.