



Australian Government
Repatriation Medical Authority

Statement of Principles
concerning
INFLAMMATORY BOWEL DISEASE
(Reasonable Hypothesis)
(No. 90 of 2020)

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

Dated 30 October 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 'Nicholas Saunders'.

Professor Nicholas Saunders AO
Chairperson

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1 Name

This is the Statement of Principles concerning *inflammatory bowel disease (Reasonable Hypothesis)* (No. 90 of 2020).

2 Commencement

This instrument commences on 30 November 2020.

3 Authority

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

4 Repeal

The Statement of Principles concerning inflammatory bowel disease No. 19 of 2012 (Federal Register of Legislation No. F2012L00449) made under subsections 196B(2) and (8) of the VEA is repealed.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 inflammatory bowel disease and death from inflammatory bowel disease.

Meaning of inflammatory bowel disease

- (2) For the purposes of this Statement of Principles, inflammatory bowel disease:
- (a) means a chronic, relapsing and remitting inflammatory autoimmune disorder of the gastrointestinal tract; and
 - (b) includes:
 - (i) Crohn disease;
 - (ii) ulcerative colitis; and
 - (iii) inflammatory bowel disease of unspecified type; and

- (c) excludes bowel inflammation that is unrelated to autoimmunity.

Note 1: Symptoms of inflammatory bowel disease typically include abdominal pain, diarrhoea and weight loss.

Note 2: Inflammatory bowel disease may be associated with extra-intestinal manifestations, including episcleritis, erythema nodosum, peripheral arthritis and pyoderma gangrenosum.

Note 3: *Crohn disease* and *ulcerative colitis* are defined in the Schedule 1 - Dictionary.

- (3) While inflammatory bowel disease attracts ICD-10-AM code K50 or K51, in applying this Statement of Principles the meaning of inflammatory bowel disease 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 inflammatory bowel disease

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

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 inflammatory bowel disease and death from inflammatory bowel disease 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 inflammatory bowel disease or death from inflammatory bowel disease with the circumstances of a person's relevant service:

- (1) taking a drug from the Specified List 1 of drugs for at least the seven days before the clinical onset of inflammatory bowel disease;

Note: *Specified List 1 of drugs* is defined in the Schedule 1 - Dictionary.

- (2) taking a nonsteroidal anti-inflammatory drug on at least ten days per month, for a continuous period of at least two months before the clinical onset of inflammatory bowel disease and the last dose of the drug was taken within the 14 days before the clinical onset of inflammatory bowel disease;
- (3) taking an immune checkpoint inhibitor within the one year before the clinical onset of inflammatory bowel disease;
- (4) taking a combined oral contraceptive pill for a continuous period of at least six months before the clinical onset of inflammatory bowel disease and where taking the combined oral contraceptive pill has ceased, the clinical onset of inflammatory bowel disease has occurred within one year of cessation;
- (5) undergoing organ or tissue transplantation, excluding corneal transplant, before the clinical onset of inflammatory bowel disease;
Note: *organ or tissue transplantation* is defined in the Schedule 1 - Dictionary.
- (6) experiencing a category 1A stressor within the three months before the clinical onset of inflammatory bowel disease;
Note: *category 1A stressor* is defined in the Schedule 1 - Dictionary.
- (7) experiencing a category 1B stressor within the three months before the clinical onset of inflammatory bowel disease;
Note: *category 1B stressor* is defined in the Schedule 1 - Dictionary.
- (8) experiencing a category 2 stressor within the 30 days before the clinical onset of inflammatory bowel disease;
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.
- (9) having a clinically significant depressive disorder or a clinically significant anxiety disorder for at least the one year before the clinical onset of inflammatory bowel disease;
Note: *clinically significant* is defined in the Schedule 1 - Dictionary.
- (10) for Crohn disease only:
 - (a) having smoked at least one pack-year of tobacco products before the clinical onset of Crohn disease, and where smoking has permanently ceased, the clinical onset of Crohn disease has occurred within four years of cessation;
Note: *pack-year of tobacco products* is defined in the Schedule 1 - Dictionary.

- (b) where exposure to second-hand smoke has not permanently ceased:
- (i) being exposed to second-hand smoke for at least 5,000 hours before the clinical onset of Crohn disease; and
 - (ii) the first exposure to second-hand smoke commenced at least one year before the clinical onset of Crohn disease;

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

- (c) where exposure to second-hand smoke has permanently ceased before the clinical onset of Crohn disease:
- (i) being exposed to second-hand smoke for at least 5,000 hours; and
 - (ii) the first exposure to second-hand smoke commenced at least one year before the clinical onset of Crohn disease; and
 - (iii) the clinical onset of Crohn disease has occurred within four years of the last exposure to second-hand smoke;

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

- (d) taking at least three courses of antibiotics within the five years before the clinical onset of Crohn disease, and the last course of antibiotics was completed at least six months before the clinical onset of Crohn disease;
- (e) inability to consume an average daily intake of at least ten grams of fibre in food for a period of at least five consecutive years within the ten years before the clinical onset of Crohn disease;
- (f) consuming an average of at least 100 grams per day of sucrose, for at least two consecutive years within the five years before the clinical onset of Crohn disease;

Note: The consumption of sucrose includes sucrose in soft drinks.

- (g) inability to undertake any physical activity greater than three METs for at least the five years before the clinical onset of Crohn disease;

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

- (h) being obese for at least five years within the 20 years before the clinical onset of Crohn disease;

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

- (11) for ulcerative colitis only, in a person with a prior history of a regular smoking habit as specified, permanently ceasing to smoke between one and 20 years before the clinical onset of ulcerative colitis;

Note: *regular smoking habit as specified* is defined in the Schedule 1 - Dictionary.

- (12) taking a drug from the Specified List 2 of drugs for at least the seven days before the clinical worsening of inflammatory bowel disease;

Note: *Specified List 2 of drugs* is defined in the Schedule 1 - Dictionary.

- (13) taking an immune checkpoint inhibitor within the one year before the clinical worsening of inflammatory bowel disease;

- (14) taking a combined oral contraceptive pill for a continuous period of at least six months before the clinical worsening of inflammatory bowel disease and where taking the combined oral contraceptive pill has ceased, the clinical worsening of inflammatory bowel disease has occurred within one year of cessation;

- (15) undergoing organ or tissue transplantation, excluding corneal transplant, before the clinical worsening of inflammatory bowel disease;

Note: *organ or tissue transplantation* is defined in the Schedule 1 - Dictionary.

- (16) having a bowel infection within the 30 days before the clinical worsening of inflammatory bowel disease;

- (17) experiencing a category 1A stressor within the three months before the clinical worsening of inflammatory bowel disease;

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

- (18) experiencing a category 1B stressor within the three months before the clinical worsening of inflammatory bowel disease;

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

- (19) experiencing a category 2 stressor within the 30 days before the clinical worsening of inflammatory bowel disease;

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.

- (20) having a clinically significant depressive disorder or a clinically significant anxiety disorder for at least the one year before the clinical worsening of inflammatory bowel disease;

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

(21) for Crohn disease only:

- (a) having smoked at least one pack-year of tobacco products before the clinical worsening of Crohn disease, and where smoking has permanently ceased, the clinical worsening of Crohn disease has occurred within four years of cessation;

Note: *pack-year of tobacco products* is defined in the Schedule 1 - Dictionary.

- (b) where exposure to second-hand smoke has not permanently ceased:
 - (i) being exposed to second-hand smoke for at least 5,000 hours before the clinical worsening of Crohn disease; and
 - (ii) the first exposure to second-hand smoke commenced at least one year before the clinical worsening of Crohn disease;

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

- (c) where exposure to second-hand smoke has permanently ceased before the clinical worsening of Crohn disease:
 - (i) being exposed to second-hand smoke for at least 5,000 hours; and
 - (ii) the first exposure to second-hand smoke commenced at least one year before the clinical worsening of Crohn disease; and
 - (iii) the clinical worsening of Crohn disease occurs within four years of the last exposure to second-hand smoke;

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

- (d) an inability to undertake any physical activity greater than three METs for at least the five years before the clinical worsening of Crohn disease;

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

(22) for ulcerative colitis only, in a person with a prior history of a regular smoking habit as specified, permanently ceasing to smoke between one and 20 years before the clinical worsening of ulcerative colitis;

Note: *regular smoking habit as specified* is defined in the Schedule 1 - Dictionary.

(23) inability to obtain appropriate clinical management for inflammatory bowel disease.

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(12) to 9(23) apply only to material contribution to, or aggravation of, inflammatory bowel disease where the person's inflammatory bowel disease 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 another 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:

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

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

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

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

- (a) being an eyewitness to a person being killed or critically injured;
- (b) being an eyewitness to atrocities inflicted on another person;
- (c) killing or maiming a 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 a full-time caregiver to a family member or significant other with a severe physical, mental or developmental disability;
- (b) being socially isolated and unable to maintain friendships or family relationships, due to physical location, language barriers, disability, or medical or psychiatric illness;
- (c) 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;
- (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 a family member or significant other experience a major deterioration in their health;
- (f) 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; or
- (g) having severe financial hardship including loss of employment, long periods of unemployment, foreclosure on a property or bankruptcy.

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

clinically significant means sufficient to warrant ongoing management. Management of the condition may involve regular visits (for example, at least monthly) to a psychiatrist, counsellor or general practitioner.

Note: To warrant ongoing management does not require that any actual management was received or given for the condition.

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.

Crohn disease means a form of inflammatory bowel disease characterised by transmural inflammation and discontinuous areas of involvement along the bowel. The inflammation may lead to any of the following:

- (a) fibrosis;
- (b) fistulas;
- (c) obstructive clinical presentations;
- (d) sinus tracts; or
- (e) strictures.

eyewitness means a person who experiences 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.

inflammatory bowel disease—see subsection 7(2).

MET means a unit of measurement of the level of physical exertion. 1 MET = 3.5 ml of oxygen/kg of body weight per minute, 1.0 kcal/kg of body weight per hour or resting metabolic rate.

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

organ or tissue transplantation means the transplantation of:

- (a) all or part of an organ or tissue; or
- (b) a substance obtained from an organ or tissue.

pack-year of tobacco products means:

- (a) 20 cigarettes per day for a period of one calendar year; or
- (b) 7,300 cigarettes in a period of one calendar year; or

- (c) 7,300 grams of smoking tobacco by weight, either in cigarettes, pipe tobacco or cigars, or a combination of same, in a period of one calendar year.

regular smoking habit as specified means having smoked at least five pack-years of tobacco products, within a continuous five year period.

Note: *pack-year of tobacco products* is also defined in the Schedule 1 - Dictionary.

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 List 1 of drugs means:

- (a) interferons;
- (b) isotretinoin; or
- (c) tumour necrosis factor antagonists.

Specified List 2 of drugs means:

- (a) interferons;
- (b) isotretinoin;
- (c) nonsteroidal anti-inflammatory drugs; or
- (d) tumour necrosis factor antagonists.

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.

ulcerative colitis means a form of inflammatory bowel disease characterised by relapsing and remitting episodes of inflammation limited to the mucosal layer of the colon. It almost invariably involves the rectum, and often involves more proximal portions of the colon in a continuous fashion.

VEA means the *Veterans' Entitlements Act 1986*.