

Statement of Principles concerning GASTRO-OESOPHAGEAL REFLUX DISEASE (Reasonable Hypothesis) (No. 61 of 2021)

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

Dated 21 May 2021

The Common Seal of the Repatriation Medical Authority was affixed to this instrument at the direction of:

Professor Nicholas Saunders AO Chairperson

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1 Name

This is the Statement of Principles concerning *gastro-oesophageal reflux disease (Reasonable Hypothesis)* (No. 61 of 2021).

2 Commencement

This instrument commences on 21 June 2021.

3 Authority

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

4 Repeal

The Statement of Principles concerning gastro-oesophageal reflux disease No. 65 of 2013 (Federal Register of Legislation No. F2013L01653) made under subsection 196B(2) of the VEA is repealed.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 gastro-oesophageal reflux disease and death from gastro-oesophageal reflux disease.

Meaning of gastro-oesophageal reflux disease

- (2) For the purposes of this Statement of Principles, gastro-oesophageal reflux disease:
 - (a) means a chronic condition involving retrograde flow of gastroduodenal contents into the oesophagus, larynx or pharynx, resulting in:
 - (i) symptoms sufficient to warrant regular medical treatment;
 - (ii) histological evidence of oesophageal inflammation; and
 - (b) includes reflux oesophagitis and reflux with oesophageal ulceration; and

(c) excludes Barrett's oesophagus, non-reflux oesophageitis, non-reflux oesophageal ulceration, traumatic oesophageal perforation or tear and oesophageal varices.

Note: Symptoms of gastro-oesophageal reflux disease include heartburn, regurgitation with or without excess salivation, chest pain, difficulty with or pain when swallowing, chronic cough, hoarseness, wheezing and nausea.

- (3) While gastro-oesophageal reflux disease attracts ICD-10-AM code K21, in applying this Statement of Principles the meaning of gastro-oesophageal reflux 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 gastro-oesophageal reflux disease

(5) For the purposes of this Statement of Principles, gastro-oesophageal reflux disease, in relation to a person, includes death from a terminal event or condition that was contributed to by the person's gastro-oesophageal reflux 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 gastro-oesophageal reflux disease and death from gastro-oesophageal reflux 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 gastrooesophageal reflux disease or death from gastro-oesophageal reflux disease with the circumstances of a person's relevant service:

- (1) having a hiatus hernia at the time of the clinical onset of gastro-oesophageal reflux disease;
- (2) being overweight or obese at the time of the clinical onset of gastrooesophageal reflux disease;

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

- (3) having smoked tobacco products:
 - (a) in an amount of at least 1.5 pack-years before the clinical onset of gastro-oesophageal reflux disease; and
 - (b) commencing at least 5 years before the clinical onset of gastrooesophageal reflux disease; and

if smoking has ceased before the clinical onset of gastro-oesophageal reflux disease, then that onset occurred within 1 year of cessation;

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

(4) consuming an average of at least 300 grams of alcohol per week for at least the 1 year before the clinical onset of gastro-oesophageal reflux disease;

Note: Alcohol consumption is calculated utilising the Australian Standard of 10 grams of alcohol per standard alcoholic drink.

(5) undergoing surgery to the region of the oesophageal hiatus or surgery involving the fundus or body of the stomach, within the 6 months before the clinical onset of gastro-oesophageal reflux disease;

Note: Examples of surgery include oesophageal dilatation, bariatric surgery (such as laparoscopic adjustable gastric banding or laparoscopic sleeve gastrectomy) and per oral endoscopic myotomy (POEM).

(6) taking a drug from the Specified List 1 of drugs at the time of the clinical onset of gastro-oesophageal reflux disease;

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

(7) having a disease from the specified list of diseases at the time of the clinical onset of gastro-oesophageal reflux disease;

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

- (8) being pregnant at the time of the clinical onset of gastro-oesophageal reflux disease;
- (9) having diabetes mellitus at the time of the clinical onset of gastrooesophageal reflux disease;
- (10) performing or practising as a wind instrument musician:
 - (a) for an average of at least 25 hours per week; and
 - (b) for a cumulative period of at least 1 year before the clinical onset of gastro-oesophageal reflux disease; and

if those activities have ceased before the clinical onset of gastrooesophageal reflux disease, then that onset occurred within 30 days of cessation;

(11) having a hiatus hernia at the time of the clinical worsening of gastrooesophageal reflux disease; (12) being overweight or obese at the time of the clinical worsening of gastro-oesophageal reflux disease;

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

- (13) having smoked tobacco products:
 - (a) in an amount of at least 1.5 pack-years before the clinical worsening of gastro-oesophageal reflux disease; and
 - (b) commencing at least 5 years before the clinical worsening of gastro-oesophageal reflux disease; and

if smoking has ceased before the clinical worsening of gastrooesophageal reflux disease, then that worsening occurred within 1 year of cessation;

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

(14) consuming an average of at least 300 grams of alcohol per week for at least the 1 year before the clinical worsening of gastro-oesophageal reflux disease;

Note: Alcohol consumption is calculated utilising the Australian Standard of 10 grams of alcohol per standard alcoholic drink.

(15) undergoing surgery to the region of the oesophageal hiatus or surgery involving the fundus or body of the stomach, within the 6 months before the clinical worsening of gastro-oesophageal reflux disease;

Note: Examples of surgery include oesophageal dilatation, bariatric surgery (such as laparoscopic adjustable gastric banding or laparoscopic sleeve gastrectomy) and per oral endoscopic myotomy (POEM).

(16) taking a drug from the Specified List 1 of drugs at the time of the clinical worsening of gastro-oesophageal reflux disease;

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

(17) having a disease from the specified list of diseases at the time of the clinical worsening of gastro-oesophageal reflux disease;

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

- (18) being pregnant at the time of the clinical worsening of gastrooesophageal reflux disease;
- (19) having diabetes mellitus at the time of the clinical worsening of gastrooesophageal reflux disease;

- (20) performing or practising as a wind instrument musician:
 - (a) for an average of at least 25 hours per week; and
 - (b) for a cumulative period of at least 1 year before the clinical worsening of gastro-oesophageal reflux disease; and

if those activities have ceased before the clinical worsening of gastrooesophageal reflux disease, then that worsening occurred within 30 days of cessation;

(21) having a disorder of mental health from the specified list of disorders of mental health at the time of the clinical worsening of gastro-oesophageal reflux disease;

Note: specified list of disorders of mental health is defined in the Schedule 1 - Dictionary.

(22) taking orally a drug from the Specified List 2 of drugs at the time of the clinical worsening of gastro-oesophageal reflux disease;

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

- (23) taking orally a drug which is associated in the individual with the clinical worsening of gastro-oesophageal reflux disease during drug therapy and either:
 - (a) the improvement of gastro-oesophageal reflux disease within 3 months of discontinuing or tapering drug therapy; or
 - (b) the clinical worsening of gastro-oesophageal reflux disease on rechallenge with the same drug; and

where the drug was being taken at the time of the clinical worsening of gastro-oesophageal reflux disease;

(24) inability to obtain appropriate clinical management for gastrooesophageal reflux 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(11) to 9(24) apply only to material contribution to, or aggravation of, gastro-oesophageal reflux disease where the person's gastro-oesophageal reflux 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 Staten of Principles has been determined under subsection 196B(2) of the VEA;
then term	the factors in that Statement of Principles apply in accordance with ts 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 overweight or obese means:

- (a) having a Body Mass Index (BMI) of 25 or greater; or
- (b) having a waist circumference of greater than 80 centimetres in women or greater than 94 centimetres in men.

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

BMI means W/H² where:

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

gastro-oesophageal reflux disease—see subsection 7(2).

MRCA means the Military Rehabilitation and Compensation Act 2004.

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.

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.

Specified List 1 of drugs means:

- (a) aminophylline;
- (b) anti-cholinergic drugs;
- (c) benzodiazepines;
- (d) beta-adrenergic receptor agonists;
- (e) calcium channel blocker drugs;
- (f) nitrate drugs;
- (g) theophylline; or
- (h) tricyclic antidepressants.

Specified List 2 of drugs means:

- (a) anti-arrhythmic agents including quinidine and mexiletine;
- (b) antibiotics including amoxicillin, cefotiam, ciprofloxacin, clindamycin, erythromycin, metronidazole, rifampicin and tetracyclines (including doxycycline);
- (c) anti-convulsants including phenytoin and valproic acid;
- (d) anti-hypertensives including alprenolol and captopril;
- (e) ascorbic acid;
- (f) bisphosphonates including alendronate, ibandronate and risedronate;
- (g) chemotherapeutic agents including bevacizumab, bleomycin, cytarabine, dactinomycin, daunorubicin, doxorubicin, 5-fluorouracil, methotrexate, pemetrexed, sunitinib and vincristine;
- (h) cyproterone acetate;
- (i) dabigatran;
- (j) esomeprazole;
- (k) female hormones including estrogen, hormone replacement therapy and oral contraceptives;
- (1) ferrous sulphate;
- (m) glibenclamide (glyburide);
- (n) glucocorticoids;
- (o) incretins including exenatide, liraglutide and sitagliptin;
- (p) isotretinoin;
- (q) mycophenolate mofetil;
- (r) nonsteroidal anti-inflammatory agents including aspirin, diclofenac and naproxen;
- (s) paracetamol (acetaminophen);
- (t) phenothiazines;
- (u) potassium chloride;
- (v) selective serotonin re-uptake inhibitors including fluoxetine and paroxetine; or
- (w) warfarin.

specified list of diseases means:

- (a) dermatomyositis;
- (b) mixed connective tissue disease;
- (c) polymyositis;
- (d) Sjögren syndrome;
- (e) systemic lupus erythematosus;
- (f) systemic sclerosis (scleroderma); or
- (g) Zollinger-Ellison syndrome.

specified list of disorders of mental health means:

- (a) anxiety disorder;
- (b) depressive disorder; or
- (c) posttraumatic stress disorder.

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.