

Statement of Principles concerning ERECTILE DYSFUNCTION (Reasonable Hypothesis) (No. 72 of 2022)

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

Dated 24 June 2022

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

Professor Terence Campbell AM Chairperson

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1 Name

This is the Statement of Principles concerning *erectile dysfunction* (*Reasonable Hypothesis*) (No. 72 of 2022).

2 Commencement

This instrument commences on 25 July 2022.

3 Authority

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

4 Repeal

The Statement of Principles concerning erectile dysfunction No. 43 of 2013 (Federal Register of Legislation No. F2013L01136) made under subsections 196B(2) and (8) of the VEA is repealed.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 Schedules

Any item in a Schedule to this Instrument has effect according to its terms.

7 Kind of injury, disease or death to which this Statement of Principles relates

(1) This Statement of Principles is about erectile dysfunction and death from erectile dysfunction.

Meaning of erectile dysfunction

- (2) For the purposes of this Statement of Principles, erectile dysfunction:
 - (a) means persistent or recurrent inability to develop or maintain an erection adequate for sexual intercourse; and
 - (b) includes psychogenic and organic impotence; and
 - (c) excludes transient failure of erection due to fatigue, situational anxiety, alcohol or drugs.
- (3) While erectile dysfunction attracts ICD-10-AM code F52.2 or N48.4, in applying this Statement of Principles the meaning of erectile dysfunction 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 erectile dysfunction

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

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 erectile dysfunction and death from erectile dysfunction 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 erectile dysfunction or death from erectile dysfunction with the circumstances of a person's relevant service:

- (1) having a clinically significant disorder of mental health as specified at the time of the clinical onset of erectile dysfunction;
 - Note: *clinically significant disorder of mental health as specified* is defined in the Schedule 1 Dictionary.
- (2) having a cardiovascular disease from the specified list of cardiovascular diseases at the time of the clinical onset of erectile dysfunction;
 - Note: specified list of cardiovascular diseases is defined in the Schedule 1 Dictionary.
- (3) having a medical condition from the specified list of medical conditions at the time of the clinical onset of erectile dysfunction;
 - Note: *specified list of medical conditions* is defined in the Schedule 1 Dictionary.
- (4) having an autoimmune disease from the specified list of autoimmune diseases at the time of the clinical onset of erectile dysfunction;
 - Note: specified list of autoimmune diseases is defined in the Schedule 1 Dictionary.
- (5) having an endocrine disorder from the specified list of endocrine disorders at the time of the clinical onset of erectile dysfunction;
 - Note: specified list of endocrine disorders is defined in the Schedule 1 Dictionary.

- (6) having a neurological disorder from the specified list of neurological disorders at the time of the clinical onset of erectile dysfunction;
 - Note: *specified list of neurological disorders* is defined in the Schedule 1 Dictionary.
- (7) having a urological condition from the specified list of urological conditions, where that condition causes lower urinary tract symptoms, for at least the 3 months before the clinical onset of erectile dysfunction;
 - Note: *specified list of urological conditions* is defined in the Schedule 1 Dictionary.
- (8) having an infection from the specified list of infections at the time of the clinical onset of erectile dysfunction;
 - Note: *specified list of infections* is defined in the Schedule 1 Dictionary.
- (9) having herpes zoster affecting a sacral dermatome at the time of the clinical onset of erectile dysfunction;
- (10) having hypertension at the time of the clinical onset of erectile dysfunction;
- (11) having chronic renal failure at the time of the clinical onset of erectile dysfunction;
 - Note: *chronic renal failure* is defined in the Schedule 1 Dictionary.
- (12) having Peyronie disease before the clinical onset of erectile dysfunction;
 - Note: *Peyronie disease* is defined in the Schedule 1 Dictionary.
- (13) having hidradenitis suppurativa at the time of the clinical onset of erectile dysfunction;
- (14) having ischaemic priapism for a continuous period of at least the 4 hours before the clinical onset of erectile dysfunction;
 - Note: *ischaemic priapism* is defined in the Schedule 1 Dictionary.
- (15) having a surgical operation from the specified list of surgical operations within the 3 months before the clinical onset of erectile dysfunction;
 - Note: *specified list of surgical operations* is defined in the Schedule 1 Dictionary.
- (16) having a trauma or surgery involving the brain, spinal cord, thoracolumbosacral nerve roots, cauda equina or the nerve supply to the penis, where the trauma or surgery results in permanent neurological impairment, within the 3 months before the clinical onset of erectile dysfunction;
- (17) having blunt trauma, penetrating trauma including surgical trauma, explosive blast injury or gunshot injury to the external genitals,

perineum or pelvis, within the 3 months before the clinical onset of erectile dysfunction;

Note: *blunt trauma* is defined in the Schedule 1 – Dictionary.

(18) having internal burns, substantial external burns, or electrical injury to the external genitals, perineum or pelvic region within the 3 months before the clinical onset of erectile dysfunction;

Note: *substantial external burns* is defined in the Schedule 1 – Dictionary.

- (19) having smoked tobacco products:
 - (a) in an amount of at least 10 pack-years before the clinical onset of erectile dysfunction; and
 - (b) if smoking has ceased before the clinical onset of erectile dysfunction, then that onset occurred within 20 years of cessation;

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

- (20) undergoing a course of therapeutic radiation for cancer, where the penis, pelvis or perineal region was in the field of radiation, within the 10 years before the clinical onset of erectile dysfunction;
- (21) being obese at the time of the clinical onset of erectile dysfunction; Note: *being obese* is defined in the Schedule 1 - Dictionary.
- (22) taking a drug specified in the Schedule 2 Drugs of this Instrument at the time of the clinical onset of erectile dysfunction;
- (23) inhaling, ingesting or having cutaneous contact with carbon disulphide, where inhalation occurred in an unventilated and confined space, on more days than not for a consecutive period of at least 5 years before the clinical onset of erectile dysfunction, and if exposure has ceased before the clinical onset of erectile dysfunction, then that onset occurred within 1 year of cessation;
- (24) inability to undertake any physical activity greater than 3 METs for at least the 5 years before the clinical onset of erectile dysfunction;

 Note: *MET* is defined in the Schedule 1 Dictionary.
- (25) experiencing childhood sexual abuse before the clinical onset of erectile dysfunction;
- (26) having a clinically significant disorder of mental health as specified at the time of the clinical worsening of erectile dysfunction;

Note: *clinically significant disorder of mental health as specified* is defined in the Schedule 1 - Dictionary.

- (27) having a cardiovascular disease from the specified list of cardiovascular diseases at the time of the clinical worsening of erectile dysfunction;
 - Note: specified list of cardiovascular diseases is defined in the Schedule 1 Dictionary.
- (28) having a medical condition from the specified list of medical conditions at the time of the clinical worsening of erectile dysfunction;

 Note: *specified list of medical conditions* is defined in the Schedule 1 Dictionary.
- (29) having an autoimmune disease from the specified list of autoimmune diseases at the time of the clinical worsening of erectile dysfunction;

 Note: specified list of autoimmune diseases is defined in the Schedule 1 Dictionary.
- (30) having an endocrine disorder from the specified list of endocrine disorders at the time of the clinical worsening of erectile dysfunction;

 Note: *specified list of endocrine disorders* is defined in the Schedule 1 Dictionary.
- (31) having a neurological disorder from the specified list of neurological disorders at the time of the clinical worsening of erectile dysfunction;

 Note: *specified list of neurological disorders* is defined in the Schedule 1 Dictionary.
- (32) having a urological condition from the specified list of urological conditions, where that condition causes lower urinary tract symptoms, for at least the 3 months before the clinical worsening of erectile dysfunction;
 - Note: *specified list of urological conditions* is defined in the Schedule 1 Dictionary.
- (33) having an infection from the specified list of infections at the time of the clinical worsening of erectile dysfunction;
 - Note: *specified list of infections* is defined in the Schedule 1 Dictionary.
- (34) having herpes zoster affecting a sacral dermatome at the time of the clinical worsening of erectile dysfunction;
- (35) having hypertension at the time of the clinical worsening of erectile dysfunction;
- (36) having chronic renal failure at the time of the clinical worsening of erectile dysfunction;
 - Note: *chronic renal failure* is defined in the Schedule 1 Dictionary.
- (37) having Peyronie disease before the clinical worsening of erectile dysfunction;
 - Note: *Peyronie disease* is defined in the Schedule 1 Dictionary.
- (38) having hidradenitis suppurativa at the time of the clinical worsening of erectile dysfunction;

- (39) having ischaemic priapism for a continuous period of at least the 4 hours before the clinical worsening of erectile dysfunction;
 - Note: *ischaemic priapism* is defined in the Schedule 1 Dictionary.
- (40) having a surgical operation from the specified list of surgical operations within the 3 months before the clinical worsening of erectile dysfunction;
 - Note: *specified list of surgical operations* is defined in the Schedule 1 Dictionary.
- (41) having a trauma or surgery involving the brain, spinal cord, thoracolumbosacral nerve roots, cauda equina or the nerve supply to the penis, where the trauma or surgery results in permanent neurological impairment, within the 3 months before the clinical worsening of erectile dysfunction;
- (42) having blunt trauma, penetrating trauma including surgical trauma, explosive blast injury or gunshot injury to the external genitals, perineum or pelvis, within the 3 months before the clinical worsening of erectile dysfunction;
 - Note: *blunt trauma* is defined in the Schedule 1 Dictionary.
- (43) having internal burns, substantial external burns, or electrical injury to the external genitals, perineum or pelvic region within the 3 months before the clinical worsening of erectile dysfunction;
 - Note: *substantial external burns* is defined in the Schedule 1 Dictionary.
- (44) having smoked tobacco products:
 - (a) in an amount of at least 10 pack-years before the clinical worsening of erectile dysfunction; and
 - (b) if smoking has ceased before the clinical worsening of erectile dysfunction, then that worsening occurred within 20 years of cessation;
 - Note: *one pack-year* is defined in the Schedule 1 Dictionary.
- (45) undergoing a course of therapeutic radiation for cancer, where the penis, pelvis or perineal region was in the field of radiation, within the 10 years before the clinical worsening of erectile dysfunction;
- (46) being obese at the time of the clinical worsening of erectile dysfunction;
 - Note: *being obese* is defined in the Schedule 1 Dictionary.
- (47) taking a drug specified in the Schedule 2 Drugs of this Instrument at the time of the clinical worsening of erectile dysfunction;
- (48) inhaling, ingesting or having cutaneous contact with carbon disulphide, where inhalation occurred in an unventilated and confined space, on more days than not for a consecutive period of at least 5 years before

- the clinical worsening of erectile dysfunction, and if exposure has ceased before the clinical worsening of erectile dysfunction, then that worsening occurred within 1 year of cessation;
- (49) inability to undertake any physical activity greater than 3 METs for at least the 5 years before the clinical worsening of erectile dysfunction;

 Note: *MET* is defined in the Schedule 1 Dictionary.
- (50) inability to obtain appropriate clinical management for erectile dysfunction.

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(26) to 9(50) apply only to material contribution to, or aggravation of, erectile dysfunction where the person's erectile dysfunction 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:

acromegaly means a chronic disease of adults resulting from excessive production of growth hormone after closure of the epiphyses.

active migraine means having at least three migraine headaches per year.

being obese means:

- (a) having a Body Mass Index (BMI) of 30 or greater; or
- (b) for males, having a waist circumference exceeding 102 centimetres; or
- (c) for females, having a waist circumference exceeding 88 centimetres.

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

blunt trauma means an injury that results in pain and swelling or tenderness for at least 48 hours and which is of sufficient severity to warrant medical attention.

BMI means W/H² where:

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

chronic renal failure means:

- (a) having a glomerular filtration rate of less than 15 mL/min/1.73 m² for a period of at least 3 months; or
- (b) a need for renal replacement therapy (dialysis or transplantation) for treatment of complications of decreased glomerular filtration rate which would otherwise increase the risk of morbidity and mortality; or
- (c) undergoing chronic dialysis.

clinically significant disorder of mental health as specified means one of the following conditions, which is of sufficient severity to warrant ongoing management:

- (a) severe alcohol use disorder;
- (b) anxiety disorder;
- (c) bipolar disorder;
- (d) cannabis use disorder;
- (e) depressive disorder;
- (f) opioid use disorder;
- (g) panic disorder;
- (h) posttraumatic stress disorder; or
- (i) schizophrenia and other persistent psychoses.
- Note 1: Management of the condition may involve regular visits (for example, at least monthly) to a psychiatrist, counsellor or general practitioner.
- Note 2: To warrant ongoing management does not require that any actual management was received or given for the condition.

Note 3: severe alcohol use disorder is also defined in the Schedule 1 – Dictionary.

DSM-5-TR means the American Psychiatric Association: Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, Text Revision. Washington, DC, American Psychiatric Association, 2022.

erectile dysfunction—see subsection 7(2).

iron overload means an accumulation of excess iron in tissues and organs which has been confirmed by elevated ferritin or transferrin saturation levels. Causes include haemochromatosis and blood transfusions.

ischaemic priapism means a persistent erection marked by rigidity of the corpora cavernosa, and little or no cavernous arterial inflow.

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, or 1.0 kcal/kg of body weight per hour, or resting metabolic rate.

MRCA means the Military Rehabilitation and Compensation Act 2004.

obstructive sleep apnoea means a type of sleep apnoea characterised on sleep study by repetitive cessation or decrease of airflow during sleep, despite respiratory effort.

Note: Obstructive sleep apnoea includes upper airway resistance syndrome, which involves prolonged, partial obstruction of the upper airway during sleep.

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.

Peyronie disease means fibrosis of the corpora cavernosa of the penis, characterised by a circumscribed, firm, painless plaque or band, usually situated on the dorsum of the penis.

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.

severe alcohol use disorder means a mental disorder that meets the following diagnostic criteria (derived from DSM-5-TR):

A problematic pattern of alcohol use leading to clinically significant impairment or distress, as manifested by at least six of the following, occurring within a 12-month period:

- A. Alcohol is often taken in larger amounts or over a longer period than was intended.
- B. There is a persistent desire or unsuccessful efforts to cut down or control alcohol use.
- C. A great deal of time is spent in activities necessary to obtain alcohol, use alcohol, or recover from its effects.
- D. Craving, or a strong desire or urge to use alcohol.
- E. Recurrent alcohol use resulting in a failure to fulfill major role obligations at work, school, or home.
- F. Continued alcohol use despite having persistent or recurrent social or interpersonal problems caused or exacerbated by the effects of alcohol.
- G. Important social, occupational, or recreational activities are given up or reduced because of alcohol use.
- H. Recurrent alcohol use in situations in which it is physically hazardous.
- I. Alcohol use is continued despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by alcohol.
- J. Tolerance, as defined by either of the following:
 - (i) a need for markedly increased amounts of alcohol to achieve intoxication or desired effect; or
 - (ii) a markedly diminished effect with continued use of the same amount of alcohol.
- K. Withdrawal, as manifested by either of the following:
 - (i) the characteristic withdrawal syndrome for alcohol; or
 - (ii) alcohol (or a closely related substance, such as a benzodiazepine) is taken to relieve or avoid withdrawal symptoms.

The definition of alcohol use disorder excludes acute alcohol intoxication in the absence of alcohol use disorder.

Note; **DSM-5-TR** is also defined in the Schedule 1 – Dictionary.

specified list of autoimmune diseases means:

- (a) Behcet syndrome;
- (b) psoriasis;
- (c) systemic lupus erythematosus; or
- (d) systemic sclerosis (scleroderma).

specified list of cardiovascular diseases means:

- (a) aortic aneurysm and aortic wall disorders;
- (b) atrial fibrillation;
- (c) non-aneurysmal aortic atherosclerotic disease; or
- (d) peripheral artery disease.

specified list of endocrine disorders means:

- (a) acromegaly;
- (b) Cushing syndrome;
- (c) hyperprolactinaemia;
- (d) hyperthyroidism, including goitre and Graves disease that has resulted in hyperthyroidism;
- (e) hypogonadism;
- (f) hypothyroidism, including Hashimoto thyroiditis that has resulted in hypothyroidism;
- (g) hypopituitarism; or
- (h) thyrotoxicosis.

Note: *acromegaly* is also defined in the Schedule 1 – Dictionary.

specified list of infections means:

- (a) chronic hepatitis B virus infection;
- (b) human immunodeficiency virus infection;
- (c) human T-cell lymphotropic virus type 1 infection; or
- (d) tuberculosis of the penis.

specified list of medical conditions means:

- (a) cirrhosis of the liver;
- (b) diabetes mellitus;
- (c) iron overload;
- (d) malignant neoplasm of the penis, seminal vesicles, prostate, or testis and paratesticular tissues; or
- (e) obstructive sleep apnoea.

Note: *iron overload* and *obstructive sleep apnoea* are also defined in the Schedule 1 – Dictionary.

specified list of neurological disorders means:

- (a) active migraine;
- (b) cerebrovascular accident;
- (c) epilepsy;
- (d) Guillain-Barre syndrome;
- (e) multiple sclerosis;
- (f) multiple system atrophy;
- (g) neuromyelitis optica spectrum disorder;
- (h) Parkinson's disease or secondary parkinsonism;
- (i) peripheral autonomic neuropathy;
- (j) transverse myelitis; or
- (k) compression, neoplasm, infection, degeneration or inflammation of the brain, spinal cord, thoracolumbosacral nerve roots, cauda equina or the somatic or autonomic nerve supply to the penis.

Note 1: An example of degeneration of the spinal cord and autonomic nerve supply to the penis is vitamin B12 deficiency.

Note 2: *active migraine* is also defined in the Schedule 1 – Dictionary.

specified list of surgical operations means:

- (a) cystectomy;
- (b) prostate surgery excluding biopsy;
- (c) resection of malignant neoplasm of the lung;

- (d) resection of malignant neoplasm of the prostate; or
- (e) resection of malignant neoplasm of the rectum.

specified list of urological conditions means:

- (a) benign prostatic hyperplasia;
- (b) bladder outlet obstruction;
- (c) prostatitis; or
- (d) a condition which presents with urinary storage, voiding or post-micturition symptoms.

substantial external burns means an injury to a least 20 percent of the surface area of the skin, where that injury results in pain and swelling or tenderness for at least 48 hours and which is of sufficient severity to warrant medical attention.

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.

Schedule 2 - Drugs Note: See Section 6, Subsections 9(22) and 9(47)

Specified Drugs 1

1. 5-alpha-reductase inhibitors for the treatment of benign prostatic hyperplasia, including finasteride and dutasteride	2. anabolic steroids
3. androgen deprivation therapy for prostate cancer	4. antiandrogens
5. amiloride	6. antidepressants
7. antipsychotics	8. beta-blockers
9. carbamazepine	10. chlortalidone or chlorthalidone
11. cimetidine	12. clonidine
13. degarelix	14. gabapentin
15. gemfibrozil	16. hydrochlorothiazide
17. indapamide	18. methyldopa
19. metoclopramide	20. methadone
21. oral itraconazole or ketoconazole	22. oral retinoids including isotretinoin and acitretin
23. phentermine	24. phenytoin
25. phenobarbital	26. pregabalin
27. primidone	28. sotalol
29. spironolactone	30. tamoxifen
31. testosterone	32. valproate