

## Statement of Principles concerning

# No. 44 of 2013

for the purposes of the

#### Veterans' Entitlements Act 1986 and Military Rehabilitation and Compensation Act 2004

#### Title

1. This Instrument may be cited as Statement of Principles concerning erectile dysfunction No. 44 of 2013.

#### Determination

- 2. The Repatriation Medical Authority under subsection **196B(3)** and **(8)** of the *Veterans' Entitlements Act 1986* (the VEA):
  - (a) revokes Instrument No. 18 of 2005 concerning erectile dysfunction; and
  - (b) determines in its place this Statement of Principles.

#### Kind of injury, disease or death

- 3. (a) This Statement of Principles is about **erectile dysfunction** and **death from erectile dysfunction**.
  - (b) For the purposes of this Statement of Principles, "erectile dysfunction" means persistent or recurrent inability to develop or maintain an erection adequate for sexual intercourse. This definition excludes transient failure of erection due to fatigue, situational anxiety, alcohol or drugs.

#### **Basis for determining the factors**

4. On the sound medical-scientific evidence available, the Repatriation Medical Authority is of the view that it is more probable than not that **erectile dysfunction** and **death from erectile dysfunction** can be related to relevant

service rendered by veterans or members of the Forces under the VEA, or members under the *Military Rehabilitation and Compensation Act 2004* (the MRCA).

#### Factors that must be related to service

5. Subject to clause 7, at least one of the factors set out in clause 6 must be related to the relevant service rendered by the person.

#### **Factors**

- 6. The factor that must exist before it can be said that, on the balance of probabilities, **erectile dysfunction** or **death from erectile dysfunction** is connected with the circumstances of a person's relevant service is:
  - (a) having a clinically significant psychiatric disorder from the specified list at the time of the clinical onset of erectile dysfunction; or
  - (b) smoking at least 20 pack-years of cigarettes, or the equivalent thereof in other tobacco products, before the clinical onset of erectile dysfunction; or
  - (c) the presence of hypertension at the time of the clinical onset of erectile dysfunction; or
  - (d) being obese at the time of the clinical onset of erectile dysfunction; or
  - (e) an inability to undertake any physical activity greater than three METs for at least the five years before the clinical onset of erectile dysfunction; or
  - (f) having a specified medical condition at the time of the clinical onset of erectile dysfunction; or
  - (g) having received a cumulative equivalent dose of at least 1.0 sievert of ionising radiation to the lower abdomen, pelvis, penis or perineal region within the ten years before the clinical onset of erectile dysfunction; or
  - (h) undergoing a course of therapeutic radiation for cancer, where the lower abdomen, pelvis, penis or perineal region was in the field of radiation, within the ten years before the clinical onset of erectile dysfunction; or
  - (i) having a specified endocrinological disorder at the time of the clinical onset of erectile dysfunction; or
  - (j) experiencing blunt or penetrating trauma to the external genitals, perineum or pelvis, including surgical trauma, within the three months before the clinical onset of erectile dysfunction; or
  - (k) having surgery to the prostate, excluding biopsy, within the three months before the clinical onset of erectile dysfunction; or
  - (l) experiencing a traumatic injury, including surgery, that results in acute and permanent neurological sequelae involving the brain, spinal cord, thoracolumbar nerve roots, cauda equina or the somatic or autonomic

- nerve supply to the penis, within the three months before the clinical onset of erectile dysfunction; or
- (m) having a specified neurological disorder at the time of the clinical onset of erectile dysfunction; or
- (n) having chronic renal disease requiring renal transplantation or dialysis at the time of the clinical onset of erectile dysfunction; or
- (o) having a renal transplantation before the clinical onset of erectile dysfunction; or
- (p) being treated with a drug or a drug from a class of drugs from the specified list at the time of the clinical onset of erectile dysfunction; or
- (q) having ischaemic priapism for a continuous period of at least the four hours before the clinical onset of erectile dysfunction; or
- (r) having Peyronie's disease before the clinical onset of erectile dysfunction; or
- (s) having a condition from the specified list which causes lower urinary tract symptoms, for the six months before the clinical onset of erectile dysfunction; or
- (t) having a clinically significant psychiatric disorder from the specified list at the time of the clinical worsening of erectile dysfunction; or
- (u) smoking at least 20 pack-years of cigarettes, or the equivalent thereof in other tobacco products, before the clinical worsening of erectile dysfunction; or
- (v) the presence of hypertension at the time of the clinical worsening of erectile dysfunction; or
- (w) being obese at the time of the clinical worsening of erectile dysfunction; or
- (x) an inability to undertake any physical activity greater than three METs for at least the five years before the clinical worsening of erectile dysfunction; or
- (y) having a specified medical condition at the time of the clinical worsening of erectile dysfunction; or
- (z) having received a cumulative equivalent dose of at least 1.0 sievert of ionising radiation to the lower abdomen, pelvis, penis or perineal region within the ten years before the clinical worsening of erectile dysfunction; or
- (aa) undergoing a course of therapeutic radiation for cancer, where the lower abdomen, pelvis, penis or perineal region was in the field of radiation, within the ten years before the clinical worsening of erectile dysfunction; or
- (bb) having a specified endocrinological disorder at the time of the clinical worsening of erectile dysfunction; or

- (cc) experiencing blunt or penetrating trauma to the external genitals, perineum or pelvis, including surgical trauma, within the three months before the clinical worsening of erectile dysfunction; or
- (dd) having surgery to the prostate, excluding biopsy, within the three months before the clinical worsening of erectile dysfunction; or
- (ee) experiencing a traumatic injury, including surgery, that results in acute and permanent neurological sequelae involving the brain, spinal cord, thoracolumbar nerve roots, cauda equina or the somatic or autonomic nerve supply to the penis, within the three months before the clinical worsening of erectile dysfunction; or
- (ff) having a specified neurological disorder at the time of the clinical worsening of erectile dysfunction; or
- (gg) having chronic renal disease requiring renal transplantation or dialysis at the time of the clinical worsening of erectile dysfunction; or
- (hh) having a renal transplantation before the clinical worsening of erectile dysfunction; or
- (ii) being treated with a drug or a drug from a class of drugs from the specified list at the time of the clinical worsening of erectile dysfunction; or
- (jj) having ischaemic priapism for a continuous period of at least the four hours before the clinical worsening of erectile dysfunction; or
- (kk) having Peyronie's disease before the clinical worsening of erectile dysfunction; or
- (ll) having a condition from the specified list which causes lower urinary tract symptoms, for the six months before the clinical worsening of erectile dysfunction; or
- (mm) inability to obtain appropriate clinical management for erectile dysfunction.

#### Factors that apply only to material contribution or aggravation

7. Paragraphs **6(t)** to **6(mm)** 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 not arising out of) the person's relevant service.

#### **Inclusion of Statements of Principles**

8. In this Statement of Principles if a relevant factor applies and that factor includes an injury or disease in respect of which there is a Statement of Principles then the factors in that last mentioned Statement of Principles apply in accordance with the terms of that Statement of Principles as in force from time to time.

#### Other definitions

- **9.** For the purposes of this Statement of Principles:
  - "a clinically significant psychiatric disorder from the specified list" means one of the following conditions, which is of sufficient severity to warrant ongoing management, which may involve regular visits (for example, at least monthly) to a psychiatrist, counsellor or general practitioner:
  - (a) alcohol dependence;
  - (b) major depressive episode or mixed episode of bipolar disorder; or
  - (c) depressive disorder;

### "a condition from the specified list which causes lower urinary tract symptoms" means:

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

#### "a drug or a drug from a class of drugs from the specified list" means:

- (a) antiandrogens, including finasteride, dutasteride and cyproterone acetate;
- (b) anticholinergics, including atropine, scopolamine and benztropine mesylate;
- (c) antidepressants, including tricyclic antidepressants, monoamine oxidase inhibitors and selective serotonin reuptake inhibitors;
- (d) antiemetics, including prochlorperazine, metoclopramide and domperidone;
- (e) antiepileptics, including barbiturates, carbamazepine, phenytoin and sodium valproate;
- (f) antihypertensive agents, including beta-blockers, central acting sympatholytics, angiotensin converting enzyme inhibitors and calcium channel blockers, but excluding alpha-blockers;
- (g) antipsychotics, including phenothiazines, butyrophenones, risperidone and clozapine;
- (h) cytotoxic agents, including alkylating agents, antimetabolites, vinca alkaloids, cisplatin, etoposide and bleomycin;
- (i) digoxin;
- (j) diuretics, including loop diuretics, thiazides and spironolactone;
- (k) histamine H<sub>2</sub>-receptor antagonists, including cimetidine and ranitidine;
- (l) lipid lowering drugs, including statins and fibrates;
- (m) lithium;
- (n) narcotics;
- (o) oral ketoconazole;
- (p) steroid or sex hormones, including oestrogen, progesterone, corticosteroids, anabolic steroids and testosterone; or
- (q) tranquillizers, including benzodiazepines;

- "a specified endocrinological disorder" means a disorder of the endocrine system which can result in sexual dysfunction, and includes:
- (a) acromegaly;
- (b) Cushing's syndrome;
- (c) hyperprolactinaemia;
- (d) hyperthyroidism;
- (e) hypogonadism;
- (f) hypothyroidism;
- (g) panhypopituitarism;
- (h) pituitary gland adenoma;
- (i) pituitary or hypothalamic dysfunction; or
- (j) testicular hypofunction;

#### "a specified medical condition" means:

- (a) atherosclerotic peripheral vascular disease;
- (b) cirrhosis of the liver;
- (c) diabetes mellitus;
- (d) iron overload;
- (e) ischaemic heart disease;
- (f) malignant neoplasm of the reproductive organs;
- (g) non-aneurysmal aortic atherosclerotic disease;
- (h) sleep apnoea; or
- (i) systemic sclerosis;

#### "a specified neurological disorder" means:

- (a) a lesion of the temporal lobe;
- (b) cerebrovascular accident;
- (c) epilepsy;
- (d) Guillain-Barre syndrome;
- (e) multiple sclerosis;
- (f) multiple system atrophy;
- (g) Parkinson's disease or secondary parkinsonism:
- (h) peripheral autonomic neuropathy; or
- (i) compression, neoplasm, infection or inflammation of the brain, spinal cord, thoracolumbar nerve roots, cauda equina or the somatic or autonomic nerve supply to the penis;
- "acromegaly" means a chronic disease of adults resulting from hypersecretion of growth hormone after closure of the epiphyses;
- "being obese" means an increase in body weight by way of fat accumulation which results in a Body Mass Index (BMI) of thirty or greater.

The BMI =  $W/H^2$  and where:

W is the person's weight in kilograms; and

H is the person's height in metres;

"blunt or penetrating trauma" means an injury that results in pain and swelling or tenderness for at least forty-eight hours and which is of sufficient severity to warrant medical attention;

"cumulative equivalent dose" means the total dose of ionising radiation received by the particular organ or tissue. The formula used to calculate the cumulative equivalent dose allows doses from multiple types of ionising radiation to be combined, by accounting for their differing biological effect. The unit of equivalent dose is the sievert. For the purposes of this Statement of Principles, the calculation of cumulative equivalent dose excludes doses received from normal background radiation, but includes therapeutic radiation, diagnostic radiation, cosmic radiation at high altitude, radiation from occupation related sources and radiation from nuclear explosions or accidents;

"death from 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;

"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 or blood transfusions;

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

#### "malignant neoplasm of the reproductive organs" means:

- (a) malignant neoplasm of the penis or other male genital organs;
- (b) malignant neoplasm of the prostate; or
- (c) malignant neoplasm of the testis or paratesticular tissues;

"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;

"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 7300 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 means either cigarettes, pipe tobacco or cigars, smoked alone or in any combination;

"Peyronie's disease" means induration 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) 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;

"terminal event" means the proximate or ultimate cause of death and includes:

- (a) pneumonia;
- (b) respiratory failure;

- (c) cardiac arrest;
- (d) circulatory failure; or
- (e) cessation of brain function.

#### **Application**

**10.** This Instrument applies to all matters to which section 120B of the VEA or section 339 of the MRCA applies.

#### **Date of effect**

11. This Instrument takes effect from 3 July 2013.

Dated this twenty-first	day of	June	2013
The Common Seal of the	)		
Repatriation Medical Authority	)		
was affixed to this instrument	)		
in the presence of:	)		

PROFESSOR NICHOLAS SAUNDERS AO CHAIRPERSON