



Statement of Principles concerning

OSTEOPOROSIS

No. 98 of 2014

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 osteoporosis No. 98 of 2014.

Determination

2. The Repatriation Medical Authority under subsection **196B(2)** and **(8)** of the *Veterans' Entitlements Act 1986* (the VEA):
 - (a) revokes Instrument No. 29 of 2006 concerning osteoporosis; and
 - (b) determines in its place this Statement of Principles.

Kind of injury, disease or death

3. (a) This Statement of Principles is about **osteoporosis** and **death from osteoporosis**.
(b) For the purposes of this Statement of Principles, "**osteoporosis**" means a systemic disease characterised by low bone mass and microarchitectural deterioration of bone tissue, with a consequent increase in bone fragility and susceptibility to fracture. Osteoporosis is considered to be present when:
 - (i) bone mineral density is 2.5 standard deviations or more below the mean bone mineral density of young adult sex-matched controls; or

- (ii) there is radiological evidence of a minimal trauma fracture, together with radiological evidence of reduced bone density in the region of the fracture prior to or at the time of the fracture.
- (c) Osteoporosis attracts ICD-10-AM code M80, M81 or M82.
- (d) In the application of this Statement of Principles, the definition of "**osteoporosis**" is that given at paragraph 3(b) above.

Basis for determining the factors

- 4. The Repatriation Medical Authority is of the view that there is sound medical-scientific evidence that indicates that **osteoporosis** and **death from osteoporosis** 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 *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 as a minimum exist before it can be said that a reasonable hypothesis has been raised connecting **osteoporosis** or **death from osteoporosis** with the circumstances of a person's relevant service is:
 - (a) being a prisoner of war before the clinical onset of osteoporosis; or
 - (b) smoking at least ten pack-years of cigarettes, or the equivalent thereof in other tobacco products, before the clinical onset of osteoporosis, and where smoking has ceased, the clinical onset of osteoporosis has occurred within 20 years of cessation; or
 - (c) for males only, drinking at least 150 kilograms of alcohol within any ten year period within the 20 years before the clinical onset of osteoporosis; or
 - (d) for females only, drinking at least 75 kilograms of alcohol within any ten year period within the 20 years before the clinical onset of osteoporosis; or
 - (e) having chronic renal failure at the time of the clinical onset of osteoporosis; or
 - (f) being treated with a drug from the specified list before the clinical onset of osteoporosis, where:
 - (i) the drug cannot be ceased or substituted; or
 - (ii) osteoporosis persists beyond 12 months after cessation of the drug; or
 - (g) having a specified endocrine abnormality for a continuous period of at least one year within the ten years before the clinical onset of osteoporosis; or

- (h) having a specified autoimmune disorder for at least the one year before the clinical onset of osteoporosis; or
- (i) having a specified medical condition for at least the one year before the clinical onset of osteoporosis; or
- (j) having myeloma, non-Hodgkin's lymphoma, Hodgkin's lymphoma or systemic mastocytosis at the time of the clinical onset of osteoporosis; or
- (k) undergoing solid organ, stem cell or bone marrow transplantation before the clinical onset of osteoporosis; or
- (l) having a specified gastrointestinal disease for a continuous period of at least one year within the ten years before the clinical onset of osteoporosis; or
- (m) having anorexia nervosa before the clinical onset of osteoporosis; or
- (n) having depressive disorder or schizophrenia for at least the one year before the clinical onset of osteoporosis; or
- (o) being immobile for at least three months within the two years before the clinical onset of osteoporosis; or
- (p) having a BMI of less than 20 for a continuous period of at least one year within the ten years before the clinical onset of osteoporosis; or
- (q) losing ten percent or more of body weight in any consecutive three year period when aged 50 years or older, within the ten years before the clinical onset of osteoporosis; or
- (r) an inability to undertake any physical activity greater than three METs for at least the five years before the clinical onset of osteoporosis; or
- (s) having an altered dietary pattern resulting in a decrease in average daily calcium intake to 400 milligrams per day or less, for a period of at least two years before age 20 years, or for a period of at least seven years after age 20 years, or the equivalent combination thereof, before the clinical onset of osteoporosis; or
- (t) having vitamin D deficiency, with a serum 25(OH)D level of less than 50 nanomoles per litre, for a continuous period of at least one year within the ten years before the clinical onset of osteoporosis; or
- (u) consuming at least 7.5 milligrams per day of vitamin A over a period of at least two years within the ten years before the clinical onset of osteoporosis; or
- (v) having severe vitamin C deficiency within the ten years before the clinical onset of osteoporosis; or
- (w) being exposed to cadmium at levels which have resulted in:
 - (i) renal damage; or
 - (ii) a urinary cadmium level of at least 0.5 micrograms per gram creatinine for a period of at least five years,
before the clinical onset of osteoporosis; or

- (x) having iron overload at the time of the clinical onset of osteoporosis; or
- (y) for a minimal trauma fracture only, being pregnant within the six weeks before the clinical onset of osteoporosis; or
- (z) being a prisoner of war before the clinical worsening of osteoporosis; or
- (aa) smoking at least ten pack-years of cigarettes, or the equivalent thereof in other tobacco products, before the clinical worsening of osteoporosis, and where smoking has ceased, the clinical worsening of osteoporosis has occurred within 20 years of cessation; or
- (bb) for males only, drinking at least 150 kilograms of alcohol within any ten year period within the 20 years before the clinical worsening of osteoporosis; or
- (cc) for females only, drinking at least 75 kilograms of alcohol within any ten year period within the 20 years before the clinical worsening of osteoporosis; or
- (dd) having chronic renal failure at the time of the clinical worsening of osteoporosis; or
- (ee) being treated with a drug from the specified list before the clinical worsening of osteoporosis, where:
 - (i) the drug cannot be ceased or substituted; or
 - (ii) osteoporosis persists beyond 12 months after cessation of the drug; or
- (ff) having a specified endocrine abnormality for a continuous period of at least one year within the ten years before the clinical worsening of osteoporosis; or
- (gg) having a specified autoimmune disorder for at least the one year before the clinical worsening of osteoporosis; or
- (hh) having a specified medical condition for at least the one year before the clinical worsening of osteoporosis; or
 - (ii) having myeloma, non-Hodgkin's lymphoma, Hodgkin's lymphoma or systemic mastocytosis at the time of the clinical worsening of osteoporosis; or
 - (jj) undergoing solid organ, stem cell or bone marrow transplantation before the clinical worsening of osteoporosis; or
 - (kk) having a specified gastrointestinal disease for a continuous period of at least one year within the ten years before the clinical worsening of osteoporosis; or
 - (ll) having anorexia nervosa before the clinical worsening of osteoporosis; or
 - (mm) having depressive disorder or schizophrenia for at least the one year before the clinical worsening of osteoporosis; or

- (nn) being immobile for at least three months within the two years before the clinical worsening of osteoporosis; or
- (oo) having a BMI of less than 20 for a continuous period of at least one year within the ten years before the clinical worsening of osteoporosis; or
- (pp) losing ten percent or more of body weight in any consecutive three year period when aged 50 years or older, within the ten years before the clinical worsening of osteoporosis; or
- (qq) an inability to undertake any physical activity greater than three METs for at least the five years before the clinical worsening of osteoporosis; or
- (rr) having an altered dietary pattern resulting in a decrease in average daily calcium intake to 400 milligrams per day or less, for a period of at least two years before age 20 years, or for a period of at least seven years after age 20 years, or the equivalent combination thereof, before the clinical worsening of osteoporosis; or
- (ss) having vitamin D deficiency, with a serum 25(OH)D level of less than 50 nanomoles per litre, for a continuous period of at least one year within the ten years before the clinical worsening of osteoporosis; or
- (tt) consuming at least 7.5 milligrams per day of vitamin A over a period of at least two years within the ten years before the clinical worsening of osteoporosis; or
- (uu) having severe vitamin C deficiency within the ten years before the clinical worsening of osteoporosis; or
- (vv) being exposed to cadmium at levels which have resulted in:
 - (i) renal damage; or
 - (ii) a urinary cadmium level of at least 0.5 micrograms per gram creatinine for a period of at least five years, before the clinical worsening of osteoporosis; or
- (ww) having iron overload at the time of the clinical worsening of osteoporosis; or
- (xx) for a minimal trauma fracture only, being pregnant within the six weeks before the clinical worsening of osteoporosis; or
- (yy) inability to obtain appropriate clinical management for osteoporosis.

Factors that apply only to material contribution or aggravation

7. Paragraphs **6(z) to 6(yy)** apply only to material contribution to, or aggravation of, osteoporosis where the person's osteoporosis 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 drug from the specified list" means any of the drugs (including where those drugs are contained in preparations) listed in the following Table of Drugs, in the specified combinations of administration, dose level and duration of treatment;

Drug or Class of Drugs	Mode *	Dose	Minimum Duration of Treatment
prednisolone or pharmacologically equivalent glucocorticoid	IV, IM, O	≥ 0.5 grams over 6 months	6 months
		≥ 3 grams	NS
beclomethasone, budesonide, fluticasone or other inhaled corticosteroids	inhalation	≥ 750 µg /day on average	24 months
		≥ 3 grams	NS
corticotrophins	NS	at least weekly	6 months
GnRH analogues without adequate add back therapy	NS	NS	6 months
thyroxine or liothyronine#	O	suppressive dose	12 months
chemotherapy for cancer	not topical	NS	3 months
tamoxifen†	O	NS	60 months
aromatase inhibitors	O	NS	12 months
antiandrogen therapy ‡	NS	NS	12 months
medroxyprogesterone acetate, without any oestrogen supplementation †	O, IM	NS	12 months
unfractionated heparin	IV, SC	≥ 15,000 units/day	3 months
low molecular weight heparin	IV, SC	NS	12 months
warfarin	O	NS	12 months
anticonvulsants	O	NS	24 months
lithium	O	NS	24 months
aluminium	O, parenteral	daily or most days a week	12 months
anti-HIV therapy	O	NS	12 months
loop diuretics	O	NS	24 months
thiazolidinediones	O		12 months

* Abbreviations: IV = intravenous; IM = intramuscular; SC = subcutaneous; O = oral; NS = not specified; GnRH = Gonadotrophin Releasing Hormone; mg = milligrams; µg = micrograms.

† In premenopausal women only. ‡ In males only. # In postmenopausal women only.

"add back therapy" means treatment with agents that prevent bone loss.

"suppressive dose" means treatment with thyroxine (or equivalent) which results in a TSH level below the normal range in the assay, or which results in a suppressed response to thyrotrophin test, or where the measured daily dose of thyroxine (or equivalent) is greater than 200 µg.

"a minimal trauma fracture" means a fracture that results from mechanical forces that would not ordinarily result in a fracture;

"a specified autoimmune disorder" means:

- (a) ankylosing spondylitis;
- (b) dermatomyositis;
- (c) pernicious anaemia;
- (d) psoriatic arthritis;
- (e) rheumatoid arthritis;
- (f) Sjogren's syndrome;
- (g) systemic lupus erythematosis; or
- (h) systemic sclerosis;

"a specified endocrine abnormality" means:

- (a) Cushing's syndrome;
- (b) goitre, where it has resulted in hyperthyroidism;
- (c) Graves' disease;
- (d) hyperprolactinaemia;
- (e) hyperthyroidism;
- (f) hypogonadism (including menopause);
- (g) primary hyperparathyroidism;
- (h) thyrotoxicosis; or
- (i) type 1 diabetes mellitus;

"a specified gastrointestinal disease" means:

- (a) bacterial overgrowth syndrome;
- (b) cirrhosis of the liver;
- (c) coeliac disease;
- (d) inflammatory bowel disease;
- (e) pancreatic insufficiency; or
- (f) total or partial gastrectomy;

"a specified medical condition" means:

- (a) chronic obstructive pulmonary disease;
- (b) human immunodeficiency virus infection;
- (c) multiple sclerosis; or
- (d) Parkinson's disease;

"alcohol" is measured by the alcohol consumption calculations utilising the Australian Standard of ten grams of alcohol per standard alcoholic drink;

"anorexia nervosa" means a mental disorder that meets the following diagnostic criteria (derived from DSM-5):

- A. Restriction of energy intake relative to requirements, leading to a significantly low body weight in the context of age, sex, developmental trajectory, and physical health. Significantly low weight is defined as a weight that is less than minimally normal or, for children and adolescents, less than that minimally expected; and

- B. Intense fear of gaining weight or of becoming fat, or persistent behaviour that interferes with weight gain, even though at a significantly low weight; and
- C. Disturbance in the way in which one's body weight or shape is experienced, undue influence of body weight or shape on self-evaluation, or persistent lack of recognition of the seriousness of the current low body weight;

"being immobile" means having gross diminution or near complete absence of movement of the body, such as would occur as a result of paralysis or strict bed rest;

"BMI" means body mass index and is calculated as follows:

$$\text{BMI} = \text{W}/\text{H}^2 \text{ where:}$$

W is the person's weight in kilograms; and

H is the person's height in metres;

"chronic renal failure" means having a glomerular filtration rate of less than 60 mL/min/1.73 m² for a period of at least three months, or the presence of irreversible kidney damage;

"death from osteoporosis" in relation to a person includes death from a terminal event or condition that was contributed to by the person's osteoporosis;

"DSM-5" means the American Psychiatric Association: *Diagnostic and Statistical Manual of Mental Disorders*, Fifth Edition. Arlington, VA, American Psychiatric Association, 2013;

"equivalent combination" means a calculation where one year of exposure before age 20 years is equivalent to 3.5 years of exposure after age 20 years;

"ICD-10-AM code" means a number assigned to a particular kind of injury or disease in The International Statistical Classification of Diseases and Related Health Problems, 10th Revision, Australian Modification (ICD-10-AM), Eighth Edition, effective date of 1 July 2013, copyrighted by the Independent Hospital Pricing Authority, and having ISBN 978-1-74128-213-9;

"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;

"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;

"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 mean 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;

"severe vitamin C deficiency" means symptoms of scurvy or a serum ascorbic acid level of less than 2.5 milligrams per litre;

"systemic mastocytosis" means a mast cell hyperplasia that is generally detected in the bone marrow, skin, gastrointestinal mucosa, liver or spleen;

"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 120A of the VEA or section 338 of the MRCA applies.

Date of effect

11. This Instrument takes effect from 17 November 2014.

Dated this **seventeenth** day of **October** 2014

The Common Seal of the)
Repatriation Medical Authority)
was affixed at the direction of:)



PROFESSOR NICHOLAS SAUNDERS AO
CHAIRPERSON