

Statement of Principles
concerning

OSTEOPOROSIS

No. 29 of 2006

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. 29 of 2006.

Determination

2. The Repatriation Medical Authority under subsection **196B(2)** and **(8)** of the *Veterans' Entitlements Act 1986* (the VEA):
 - (a) revokes Instrument No. 67 of 2002 as amended by Instrument No. 25 of 2004; 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 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 codes 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 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 clinical onset of osteoporosis; or
- (f) being treated with a drug from the specified list before the clinical onset of osteoporosis;
- (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 at the time of the clinical onset of osteoporosis; or
- (i) having multiple myeloma, lymphoma or systemic mastocytosis at the time of the clinical onset of osteoporosis; or
- (j) undergoing solid organ or bone marrow transplantation before the clinical onset of osteoporosis; or
- (k) having a specified gastrointestinal disease for a continuous period of at least the one year before the clinical onset of osteoporosis; or
- (l) having anorexia nervosa before the clinical onset of osteoporosis; or
- (m) being immobile for a continuous period of at least 60 days within the one year before the clinical onset of osteoporosis; or
- (n) having an altered dietary pattern resulting in a decrease in average daily calcium intake to 400 mg/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
- (o) having a BMI of less than 20 for a continuous period of at least four years within the ten years before the clinical onset of osteoporosis; or
- (p) an inability to undertake any physical activity greater than three METs for a continuous period of at least five years within the ten years before the clinical onset of osteoporosis; or
- (q) having acquired vitamin D deficiency for at least one year within the ten years before the clinical onset of osteoporosis; or

- (r) consuming more than 7.5 grams per day of Vitamin A over a period of at least two years within the ten years before the clinical onset of osteoporosis; or
- (s) having a severe vitamin C deficiency within the ten years before the clinical onset of osteoporosis; or
- (t) being exposed to cadmium at levels sufficient to cause renal damage before the clinical onset of osteoporosis; or
- (u) having iron overload at the time of clinical onset of osteoporosis; or
- (v) being a prisoner of war before the clinical worsening of osteoporosis; or
- (w) 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 has occurred within 20 years of cessation; or
- (x) 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
- (y) 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
- (z) having chronic renal failure at the time of clinical worsening of osteoporosis; or
- (za) being treated with a drug from the specified list before the clinical worsening of osteoporosis;
- (zb) 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
- (zc) having a specified autoimmune disorder at the time of the clinical worsening of osteoporosis; or
- (zd) having multiple myeloma, lymphoma or systemic mastocytosis at the time of the clinical worsening of osteoporosis; or

- (ze) undergoing solid organ or bone marrow transplantation before the clinical worsening of osteoporosis; or
- (zf) having a specified gastrointestinal disease for a continuous period of at least the one year before the clinical worsening of osteoporosis; or
- (zg) having anorexia nervosa before the clinical worsening of osteoporosis; or
- (zh) being immobile for a continuous period of at least 60 days within the one year before the clinical worsening of osteoporosis; or
- (zi) having an altered dietary pattern resulting in a decrease in average daily calcium intake to 400 mg/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
- (zj) having a BMI of less than 20 for a continuous period of at least four years within the 10 years before the clinical worsening of osteoporosis; or
- (zk) an inability to undertake any physical activity greater than three METs for a continuous period of at least five years within the ten years before the clinical worsening of osteoporosis; or
- (zl) having acquired vitamin D deficiency for at least one year within the ten years before the clinical worsening of osteoporosis; or
- (zm) consuming more than 7.5 grams per day of Vitamin A over a period of at least two years within the ten years before the clinical worsening of osteoporosis; or
- (zn) having a severe vitamin C deficiency within the ten years before the clinical worsening of osteoporosis; or
- (zo) being exposed to cadmium at levels sufficient to cause renal damage before the clinical worsening of osteoporosis; or
- (zp) having iron overload at the time of clinical worsening of osteoporosis; or

(zq) inability to obtain appropriate clinical management for osteoporosis.

Factors that apply only to material contribution or aggravation

7. Paragraphs 6(v) to 6(zq) 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, duration of treatment, and temporality (time relationship between the administration of the drug and the onset of the disease). Where a specified drug has been taken for more than two years before age 20 years in the specified combinations of administration, dose level and duration of treatment, then no time limit between the administration of the drug and the onset of the disease applies.

Table of Drugs

Drug or Group of Drugs	Mode *	Dose	Minimum Duration of Treatment	Temporality [number of years before the clinical onset or clinical worsening]
prednisolone or pharmacologic equivalent glucocorticoid	IV, IM, O, ocular	≥ 0.5 grams over 6 months	6 months	within the 5 years
		≥ 3 grams	NS	within the 10 years
		≥ 10 grams	NS	NS
beclomethasone, budesonide, fluticasone or other inhaled corticosteroids	Inhal.	≥ 750 µg /day on average	24 months	within the 5 years
		≥ 3 grams	NS	within the 10 years
corticotrophins	NS	at least weekly	6 months	within the 5 years
GnRH analogues without adequate add back therapy	NS	NS	6 months	within the 5 years

Drug or Group of Drugs	Mode *	Dose	Minimum Duration of Treatment	Temporality [number of years before the clinical onset or clinical worsening]
Thyroxine or Liothyronine#	O	suppressive dose	12 months	within the 5 years
Chemotherapy for cancer	Not topical	NS	3 months	NS
Tamoxifen†	O	NS	60 months	within the 10 years
Aromatase inhibitors	O	NS	12 months	NS
Antiandrogen therapy ‡	NS	NS	12 months	NS
Medroxyprogesterone acetate, without any oestrogen supplementation †	O, IM	NS	12 months	within the 5 years
Methotrexate [∞]	O	≥ 10 mg/week	6 months	within the 5 years
		≥ 0.6 grams	NS	
Unfractionated heparin	IV, SC	≥ 15,000 units/day	3 months	within the 5 years
Low molecular weight heparin	IV, SC	NS	12 months	within the 5 years
Oral anticoagulant	O	NS	12 months	within the 5 years
Anticonvulsants	O	NS	24 months	within the 10 years
Lithium	O	NS	24 months	within the 10 years
Aluminium	O, parenteral	Daily or most days a week	12 months	within the 5 years
Anti-HIV therapy	O	NS	12 months	within the 5 years

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

† In premenopausal women only. ‡ In males only. # In postmenopausal women only.
∞ Osteoporosis of the tibia 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 severe vitamin C deficiency” means symptoms of scurvy or a serum ascorbic acid level of less than 2.5 mg/L;

“a specified autoimmune disorder” means:

- (a) ankylosing spondylitis; or
- (b) pernicious anaemia; or
- (c) psoriatic arthritis; or
- (d) rheumatoid arthritis; or
- (e) systemic lupus erythematosus; or
- (f) systemic sclerosis;

“a specified endocrine abnormality” means:

- (a) Cushing’s syndrome; or
- (b) hyperparathyroidism; or
- (c) hyperprolactinaemia; or
- (d) hypogonadism; or
- (e) thyrotoxicosis; or
- (f) Type 1 diabetes mellitus;

“a specified gastrointestinal disease” means:

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

“acquired vitamin D deficiency” means having a serum 25(OH)D₃ level of less than 50 nmol/L and the deficiency is not due to hereditary causes;

“alcohol” is measured by the alcohol consumption calculations utilising the Australian Standard of 10 grams of alcohol per standard alcoholic drink;

“anorexia nervosa” means a mental disorder characterised by refusal to maintain a normal minimal body weight, intense fear of becoming obese that is undiminished by weight loss, disturbance of body image resulting in a feeling of being fat even when extremely emaciated, and amenorrhoea (in females);

“BMI” means body mass index and is calculated as follows:

The BMI = W/H^2 where:

W is the person’s weight in kilograms and

H is the person’s height in metres;

“chronic renal failure” means a glomerular filtration rate of permanently less than 60 ml/minute;

“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;

“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), Fourth Edition, effective date of 1 July 2004, copyrighted by the National Centre for Classification in Health, Sydney, NSW, and having ISBN 1 86487 594 1;

“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 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 twenty 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 7300 cigarettes, or 7.3 kg of smoking tobacco by weight. Tobacco products means either 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) warlike service under the MRCA; or
- (e) non-warlike service under the MRCA;

“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 28 June 2006.

Dated this *nineteenth* day of *June* 2006

The Common Seal of the)
Repatriation Medical Authority)
was affixed to this instrument)
in the presence of:)

KEN DONALD
CHAIRPERSON