

## Statement of Principles concerning

# No. 89 of 2011

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 diabetes mellitus No. 89 of 2011.

#### **Determination**

- 2. The Repatriation Medical Authority under subsection 196B(2) and (8) of the *Veterans' Entitlements Act 1986* (the VEA):
  - (a) revokes Instrument No. 11 of 2004, as amended by Instrument No. 9 of 2008, concerning diabetes mellitus; and
  - (b) determines in their place this Statement of Principles.

#### Kind of injury, disease or death

- 3. (a) This Statement of Principles is about diabetes mellitus and death from diabetes mellitus.
  - (b) For the purposes of this Statement of Principles, "diabetes mellitus" means a metabolic disorder characterised by hyperglycaemia. This disorder is diagnosed by:
    - (i) a fasting plasma glucose concentration of at least 7.0 millimoles per litre; or
    - (ii) a venous plasma glucose concentration of at least 11.1 millimoles per litre two hours after ingestion of 75 grams of glucose; or

- (iii) an HbA1c level of at least 6.5%.
- The diagnosis of type 2 diabetes mellitus requires two positive laboratory blood tests on separate days, unless the plasma glucose is unequivocally elevated in the presence of acute metabolic decompensation or obvious symptoms.
- (c) Diabetes mellitus attracts ICD-10-AM code E10, E11, E12, E13 or E14.
- (d) In the application of this Statement of Principles, the definition of "diabetes mellitus" 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 **diabetes mellitus** and **death from diabetes mellitus** 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 **diabetes mellitus** or **death from diabetes mellitus** with the circumstances of a person's relevant service is:
  - (a) for type 1 diabetes mellitus only,
    - (i) being infected with a Coxsackie B virus within the three years before the clinical onset of diabetes mellitus; or
    - (ii) being treated with interferon alpha within the six months before the clinical onset of diabetes mellitus; or
  - (b) for type 2 diabetes mellitus only,
    - (i) being overweight for a period of at least five years before the clinical onset of diabetes mellitus; or
    - (ii) an inability to undertake any physical activity greater than three METs for at least the five years before the clinical onset of diabetes mellitus; or
    - (iii) smoking at least ten pack-years of cigarettes or the equivalent thereof in other tobacco products before the clinical onset of diabetes mellitus, and where smoking has ceased, the clinical onset has occurred within ten years of cessation; or
    - (iv) being in an atmosphere with a visible tobacco smoke haze in an enclosed space for at least 10 000 hours before the clinical onset

- of diabetes mellitus, where the last exposure to that atmosphere occurred within the five years before the clinical onset of diabetes mellitus; or
- (v) having cirrhosis of the liver at the time of clinical onset of diabetes mellitus; or
- (vi) having glucocorticoid therapy as specified, before the clinical onset of diabetes mellitus, and where the glucocorticoid therapy as specified has ceased or decreased, the last dose of the therapy was received within the one month before the clinical onset of diabetes mellitus; or
- (vii) inhaling, ingesting or having cutaneous contact with a chemical agent contaminated by 2,3,7,8-tetrachlorodibenzo-para-dioxin (TCDD), for a cumulative period of at least 500 hours, within a consecutive period of ten years before the clinical onset of diabetes mellitus, where the first exposure occurred at least five years before the clinical onset of diabetes mellitus, and where that exposure has ceased, the clinical onset of diabetes mellitus occurred within 25 years of cessation; or
- (viii) having hepatitis C virus infection before the clinical onset of diabetes mellitus; or
- (ix) undergoing bilateral orchiectomy before the clinical onset of diabetes mellitus; or
- (x) being exposed to arsenic as specified before the clinical onset of diabetes mellitus; or
- (xi) being infected with human immunodeficiency virus before the clinical onset of diabetes mellitus; or
- (xii) having depressive disorder, bipolar disorder or schizophrenia at the time of the clinical onset of diabetes mellitus; or
- (xiii) being pregnant at the time of the clinical onset of diabetes mellitus; or
- (c) having a specified pathological condition involving the pancreas before the clinical onset of diabetes mellitus; or
- (d) undergoing surgery to the pancreas before the clinical onset of diabetes mellitus; or
- (e) having a specified endocrine disorder before the clinical onset of diabetes mellitus; or
- (f) 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 diabetes mellitus; or
- (g) ingesting *N*-3-pyridyl methyl-*N*'-p-nitrophenyl urea (Vacor) within the one month before the clinical onset of diabetes mellitus; or
- (h) undergoing solid organ or bone marrow transplantation before the clinical onset of diabetes mellitus; or

- (i) having haemolytic uraemic syndrome before the clinical onset of diabetes mellitus; or
- (j) for type 2 diabetes mellitus only,
  - (i) being overweight for a period of at least five years before the clinical worsening of diabetes mellitus; or
  - (ii) an inability to undertake any physical activity greater than three METs for at least the five years before the clinical worsening of diabetes mellitus; or
  - (iii) smoking at least ten pack-years of cigarettes or the equivalent thereof in other tobacco products before the clinical worsening of diabetes mellitus, and where smoking has ceased, the clinical worsening has occurred within ten years of cessation; or
  - (iv) being in an atmosphere with a visible tobacco smoke haze in an enclosed space for at least 10 000 hours before the clinical worsening of diabetes mellitus, where the last exposure to that atmosphere occurred within the five years before the clinical worsening of diabetes mellitus; or
  - (v) having cirrhosis of the liver at the time of clinical worsening of diabetes mellitus; or
  - (vi) having glucocorticoid therapy as specified, before the clinical worsening of diabetes mellitus, and where the glucocorticoid therapy as specified has ceased or decreased, the last dose of the therapy was received within the one month before the clinical worsening of diabetes mellitus; or
  - (vii) inhaling, ingesting or having cutaneous contact with a chemical agent contaminated by 2,3,7,8-tetrachlorodibenzo-para-dioxin (TCDD), for a cumulative period of at least 500 hours, within a consecutive period of ten years, before the clinical worsening of diabetes mellitus, where the first exposure occurred at least five years before the clinical worsening of diabetes mellitus, and where that exposure has ceased, the clinical worsening of diabetes mellitus occurred within 25 years of cessation; or
  - (viii) having hepatitis C virus infection before the clinical worsening of diabetes mellitus; or
  - (ix) undergoing bilateral orchiectomy before the clinical worsening of diabetes mellitus; or
  - (x) being exposed to arsenic as specified before the clinical worsening of diabetes mellitus; or
  - (xi) being infected with human immunodeficiency virus before the clinical worsening of diabetes mellitus; or
  - (xii) having depressive disorder, bipolar disorder or schizophrenia at the time of the clinical worsening of diabetes mellitus; or

- (xiii) being pregnant at the time of the clinical worsening of diabetes mellitus; or
- (k) having a specified pathological condition involving the pancreas before the clinical worsening of diabetes mellitus; or
- (l) undergoing surgery to the pancreas before the clinical worsening of diabetes mellitus; or
- (m) having a specified endocrine disorder before the clinical worsening of diabetes mellitus; or
- (n) 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 diabetes mellitus; or
- (o) ingesting *N*-3-pyridyl methyl-*N*'-p-nitrophenyl urea (Vacor) within the one month before the clinical worsening of diabetes mellitus; or
- (p) undergoing solid organ or bone marrow transplantation before the clinical worsening of diabetes mellitus; or
- (q) having haemolytic uraemic syndrome before the clinical worsening of diabetes mellitus; or
- (r) inability to obtain appropriate clinical management for diabetes mellitus.

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

7. Paragraphs **6(j)** to **6(r)** apply only to material contribution to, or aggravation of, diabetes mellitus where the person's diabetes mellitus 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 specified list 2" means:

- (a) amprenavir;
- (b) atazanavir;
- (c) darunavir;
- (d) fosamprenavir;
- (e) indinavir;
- (f) itraconazole;
- (g) ketoconazole;
- (h) lopinavir;

- (i) nelfinavir;
- (j) ritonavir;
- (k) saquinavir; or
- (1) tipranavir;

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

- (a) beta-blockers;
- (b) chlorpromazine;
- (c) clozapine;
- (d) fluphenazine;
- (e) gonadotrophin-releasing hormone (GnRH) agonists;
- (f) haloperidol;
- (g) mirtazapine;
- (h) nicotinic acid for the treatment of dyslipidaemia;
- (i) olanzapine;
- (j) pentamidine;
- (k) protease inhibitors;
- (1) quetiapine;
- (m) risperidone;
- (n) selective serotonin reuptake inhibitors;
- (o) statins;
- (p) stavudine;
- (q) streptozotocin;
- (r) thiazide diuretics;
- (s) thioridazine;
- (t) tricyclic antidepressants; or
- (u) zidovudine;

#### "a high or very high potency topical glucocorticoid" means:

- (a) betamethasone dipropionate 0.05%;
- (b) betamethasone valerate 0.1%;
- (c) clobetasol proprionate 0.05%;
- (d) diflucortolone valerate 0.1%;
- (e) fluocinolone acetonide 0.025%; or
- (f) another topical glucocorticoid of equivalent potency;

#### "a specified endocrine disorder" means:

- (a) acromegaly;
- (b) Cushing's syndrome;
- (c) glucagonoma;
- (d) hyperthyroidism;
- (e) phaeochromocytoma;
- (f) primary hyperaldosteronism; or
- (g) somatostatinoma;

#### "a specified pathological condition involving the pancreas" means:

- (a) acute pancreatitis;
- (b) chronic pancreatitis;
- (c) cystic fibrosis;
- (d) haemochromatosis; or
- (e) malignant neoplasm of the pancreas;

#### "being exposed to arsenic as specified" means:

- (a) consuming drinking water with an average arsenic concentration of at least 50 micrograms per litre for a cumulative period of at least ten years;
- (b) consuming drinking water resulting in a cumulative total arsenic exposure equivalent to having consumed drinking water containing at least 50 micrograms per litre for at least ten years; or
- (c) having clinical evidence of chronic arsenic toxicity;

"being infected with a Coxsackie B virus" means having laboratory evidence of a Coxsackie B virus infection;

"being overweight" means an increase in body weight by way of fat accumulation which results in at least one of the following:

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

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

W is the person's weight in kilograms and

H is the person's height in metres;

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

"equivalent glucocorticoid therapy" means a glucocorticoid in the following table, at the doses specified in the table, or a therapeutically equivalent dose of another glucocorticoid:

Glucocorticoid	Minimum cumulative dose (milligrams)	Minimum average rate (milligrams/day)
Cortisone	1875	62.5
Prednisone	375	12.5
Prednisolone	375	12.5
Methylprednisolone	300	10
Triamcinolone	300	10
Paramethasone	150	5
Betamethasone	60	2
Dexamethasone	50	1.67

#### "equivalent inhaled glucocorticoid" means:

- (a) 8000 micrograms of triamcinolone;
- (b) 1600 micrograms of budesonide;
- (c) 1000 micrograms of fluticasone; or
- (d) a therapeutically equivalent dose of another inhaled glucocorticoid;

"haemolytic uraemic syndrome" means a clinical syndrome characterised by renal failure, microangiopathic haemolytic anaemia and thrombocytopaenia;

#### "having glucocorticoid therapy as specified" means:

- (a) taking:
  - (i) hydrocortisone, orally, by injection, or per rectum,
    - (A) to a cumulative dose of at least 1500 milligrams, and
    - (B) at a minimum dose rate averaging 50 milligrams per day, or
  - (ii) equivalent glucocorticoid therapy, orally, by injection, or per rectum; or
- (b) inhaling at least 1600 micrograms of beclomethasone, or equivalent inhaled glucocorticoid, daily, for at least six months; or
- (c) using an ocular or intranasal glucocorticoid at above the recommended maximum therapeutic dosage level, daily, for at least six months; or
- (d) applying a high or very high potency topical glucocorticoid to at least 20% of total skin surface area, daily, for at least six months; or
- (e) using a glucocorticoid concurrently with a drug from specified list 2, daily, for at least 30 days;

"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), Seventh Edition, effective date of 1 July 2010, copyrighted by the National Centre for Classification in Health, Sydney, NSW, and having ISBN 978 1 74210 154 5;

### "inhaling, ingesting or having cutaneous contact with a chemical agent contaminated by 2,3,7,8-tetrachlorodibenzo-para-dioxin (TCDD)" means:

- (a) decanting or spraying;
- (b) cleaning or maintaining equipment used to apply;
- (c) being sprayed with;
- (d) handling or sawing timber treated with;
- (e) being in an environment shrouded in dust from timber treated with; or
- (f) using cutting oils contaminated with one of the following chemicals:
  - (i) 2,4,5-trichlorophenoxyacetic acid;
  - (ii) 2,4,5-trichlorophenoxypropionic acid;
  - (iii) 2,4,5-trichlorophenol;
  - (iv) 2-(2,4,5-trichlorophenoxy)-ethyl 2,2-dichloropropionate;

- (v) o,o-dimethyl-o-(2,4,5-trichlorophenyl)-phosphorothioate;
- (vi) pentachlorophenol;
- (vii) 2,3,4,6-tetrachlorophenol;
- (viii) 2,4,6-trichlorophenol;
- (ix) 1,3,4-trichloro-2-(4-nitrophenoxy)-benzene;
- (x) 2,4-dichloro-1-(4-nitrophenoxy)-benzene; or
- (xi) 2,4-dichloro-1-(3-methoxy-4-nitrophenoxy)-benzene;

"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 kilograms 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;

"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;

"type 1 diabetes mellitus" means a form of diabetes mellitus caused by complete or near-total insulin deficiency and requiring daily administration of insulin;

"type 2 diabetes mellitus" means a form of diabetes mellitus caused by variable degrees of insulin resistance and impaired insulin secretion.

#### **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**

in the presence of:

11.	This In	nstrument	takes	effect	from	13	July	2011.

Dated this **first** day of **July** 2011

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

KEN DONALD CHAIRPERSON